

ORACLE®

CLINTRIAL™

Multisite

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Overview

Clintrial™ 4 software (hereafter referred to as Clintrial software) is a comprehensive clinical research system for the collection, management, and review of clinical trials data. Clintrial software is designed for use by companies that must both:

- Collect clinical data to meet regulatory requirements for conducting clinical trials.
- Analyze data that is collected during those clinical trials.

Clintrial software enables companies to unify all of their clinical data collection and management, regardless of source or phase of development (pre- or post-market).

About this book

This book is written for all Clintrial software users. It explains Clintrial software concepts and describes the tasks you can perform with Clintrial software. Other chapters cover product installation, and setup of the Sample Studies.

About the Clintrial software documentation

The Clintrial software documentation includes books that contain conceptual information. The Clintrial software Help contains procedures for the tasks that you perform with the Clintrial software.

The Clintrial software documentation assumes that you know how to perform basic tasks on your computer.

What are the Clintrial software books?


The Clintrial 4.7 documentation includes the documents in the following table. All documentation is available from the Phase Forward Download Center.

Title:	Content:
<i>Release Notes</i>	The <i>Release Notes</i> document describes enhancements introduced and problems fixed in the current release, upgrade considerations, release history, and other late-breaking information.
<i>Known Issues</i>	<p>The <i>Known Issues</i> document provides detailed information about the known issues in this release, along with workarounds, if available.</p> <p>Note: The most current list of known issues is available on the Phase Forward Extranet.</p> <p>To sign in to the Extranet, go to https://extranet.phaseforward.com and click Customer Login. Enter your email address and password, and navigate to the Known Issues section. Select a product, and then enter your search criteria.</p>
<i>Getting Started</i>	<p>The <i>Getting Started</i> guide:</p> <ul style="list-style-type: none">• Provides a summary of each Clintrial module, a description of the relationships between modules, and descriptions of key concepts.• Describes how to install, upgrade, and de-install the Clintrial software.• Describes how to configure the Clintrial application.• Provides information and procedures for customizing the Windows Registry.• Explains how to use the Medika Sample Studies.
<i>Admin and Design</i>	<p>The <i>Admin and Design</i> document describes how to use:</p> <ul style="list-style-type: none">• The Admin module to work with user accounts, access rights, parameters, and system administration tools.• The Design module to set up and maintain Clintrial application objects, such as protocols, panels, and study books.
<i>Secure Configuration Guide</i>	The <i>Secure Configuration Guide</i> provides an overview of the security features provided with the Clintrial application including details about the general principles of application security, as well as how to install, configure, and use the Clintrial application securely.

Title:	Content:
<i>Reference Guide</i>	<p>The <i>Reference Guide</i> provides:</p> <ul style="list-style-type: none"> • Definitions of the Oracle database tables that store Clintrial metadata and clinical data. • Descriptions of the use of PL/SQL for Clintrial-specific procedures. • Explanations of data types and naming conventions. • Information on using SQL, setting up custom menus, and running batch jobs. • A glossary of terms.
<i>Manage, Classify, and Lab Loader</i>	<p>The <i>Manage, Classify, and Lab Loader</i> document describes how to use:</p> <ul style="list-style-type: none"> • The Manage module to perform data management tasks such as coding (including integration with Central Coding), global modification, validation, auditing, and batch loading of clinical data. • The Classify module to track, review and solve for values that fail automatic coding; to audit the contents of a coding thesaurus protocol; and to build and test effective thesaurus algorithms. • The Lab Loader module to batch load laboratory data and to set up Lab Loader objects.
<i>Enter, Resolve, and Retrieve</i>	<p>The <i>Enter, Resolve, and Retrieve</i> document describes how to use:</p> <ul style="list-style-type: none"> • The Enter module to enroll subjects, enter and edit data, verify data, and work with reports. • The Resolve module to identify, track, and report data discrepancies, as well as how to customize the Resolve module, including writing rules that reference data items. • The Retrieve module to extract clinical data from the database and work with query results.
<i>Multisite</i>	<p>The <i>Multisite</i> document describes:</p> <ul style="list-style-type: none"> • How to distribute codelists and protocols. • How to set up a replication environment. • How other Clintrial modules work differently in a Multisite environment.
<i>Quick Reference Card for Enter</i>	<p>The <i>Quick Reference for Enter</i> lists Enter module menu commands and shortcut keys.</p>

Conventions

The following conventions are used in the Clintrial software books:

Convention:	Description:
Italics	Italics are used to indicate the following: <ul style="list-style-type: none">• New terms• Titles of books• Variable names in code examples or file names
Ctrl + c	Key combinations where you press the first key and hold it down while you press the second key. For example, to copy selected text to the clipboard, you press the Ctrl key and hold it down while pressing the c key.
bold	Menu names, command names, dialog box buttons, and key names appear in bold type. Additionally, the text you enter in fields during procedures appears in bold type.
COMMENT IS NULL	Examples of programming code (such as PL/SQL) or SQL commands are emphasized with a different font.
	This caution symbol advises users that failure to take or avoid a specified action could result in significant data problems.

Medika Sample Studies

The Clintrial software provides three sample studies that you can optionally install and use as a learning aid.

For information about installing and using the sample study, see the *Clintrial Getting Started* guide, Chapter 7.

Clintrial 4.7 compatibility with other Oracle Health Sciences products

The *Products Compatibility Matrix*, which identifies Clintrial compatibility with other Oracle Health Sciences products, can be downloaded from <https://extranet.phaseforward.com>.

To sign in, click **Customer Login**. Enter your email address and password, and navigate to the **Bulletins** section.

If you need assistance

If you are an Oracle customer with a maintenance agreement, you can contact the Global Support Center for assistance with product issues.

Your maintenance agreement indicates the type of support you are eligible to receive and describes how to contact Oracle. Additionally, the Oracle website lists the toll-free support number for your product, location, and support level:

<http://www.oracle.com/support/>

In the event that our toll-free telephone service is interrupted, please use either of the following methods to contact the Global Support Center:

- email
saasclinicalsupport_ww@oracle.com
- telephone

In the US: 1-800-633-0925

Outside of the US: +44 (0) 207 131 2801

Oracle also provides assistance with User Management, Site Assessment, and Provisioning. Please refer to your Master Services Agreement and individual Statement of Work to determine if you are eligible to use these services.

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Overview

This chapter introduces the basic concepts you need to use the Clintrial software. For installation information, see *Getting Started*.

The information in this chapter is generally conceptual. Procedures for most of these topics appear in the Clintrial software Basics Help that you can access through the Help menu on any Clintrial software module. A brief overview on how to use Clintrial software Help appears in "Using Help" on page 23.

To access the Clintrial software and its Help topics, you must start a Clintrial software module. Instructions for starting a Clintrial software module appear in this chapter as well as in the Clintrial software Basics Help.

Clintrial software modules

The Clintrial software consists of a set of integrated modules that can be installed as needed. This modular approach enables you to describe, collect, and manage clinical data according to the needs of your company's studies.

The Clintrial software core modules

The Clintrial software includes the core modules Admin, Design, Enter, Manage, and Retrieve.

About the Admin module

Use the Admin module to perform the system administration tasks. You can:

- Create user accounts and usergroup accounts.
- Manage passwords.
- Set up and manage access rights for users, usergroups, and protocols for all Clintrial software modules.
- Set system parameters.
- Monitor database space.
- Produce auditing reports for users and security.
- Produce reports about system activities.

About the Design module

Use the Design module to design and create the Clintrial database and the study books that you need to enter clinical data. You can:

- Design the clinical database to model your clinical protocol and meet your needs for storing and retrieving data.
- Create online representations of your paper CRFs for data-entry, verification, and editing.
- Create and manage your metadata standards.
- Produce reports about metadata.
- Import/export protocols.

About the Enter module

Use the Enter module to enter clinical data in the database interactively. You can:

- Add subjects to a study.
- Enter clinical data interactively.
- Verify clinical data.
- Edit clinical data.
- Add flags and notes to clinical data.
- Produce reports about clinical data.
- View scanned pages of your paper CRFs.
- Manually create and edit discrepancies, if the Resolve extended module is installed.

About the Manage module

Use the Manage module to perform data management tasks. You can:

- Batch load and apply data-entry checks to clinical data.
- Code clinical data using a coding thesaurus.
- Validate and merge clinical data in the database.
- Make global changes to or delete clinical data.
- Edit records using an Error Log.
- Track the auditing of data.
- Produce reports about metadata objects.

About the Retrieve module

Use the Retrieve module to access and extract clinical data from the database.

You can:

- Create queries using:
 - Query By Form.
 - Query By Panel.
 - Ad Hoc Query.
 - Query By SQL.
- Save query specifications in a query library.
- Save query results to a variety of formats, such as SAS or spreadsheet files.

The Clintrial software extended modules

In addition to the Clintrial software core modules, your company may have purchased one or more of the following Clintrial software extended modules: Classify, Lab Loader, Multisite, and Resolve.

About the Classify module

Use the Classify extended module to work with thesaurus protocols and automatic coding. You can:

- Build and test complex coding algorithms.
- Find, track, and review solutions for values that fail automatic coding.
- Examine the contents of a coding thesaurus protocol, and compare different coding thesaurus protocols.
- Audit the contents of a coding thesaurus protocol.

About the Lab Loader module

Use the Lab Loader extended module to load laboratory data into Clintrial protocols. You can:

- Extend the batch loading capabilities provided in the Manage module.
- Build and maintain a set of lab normal ranges.
- Process loaded lab data.
- Batch load lab data to a source protocol.
- Perform preparatory work on lab data prior to transfer to a clinical data protocol.
- Transfer lab data into a clinical data destination protocol.

About the Multisite module

Use the Multisite extended module to perform interdatabase instance operations. You can:

- Distribute protocols and codelists to multiple sites.
- Replicate clinical and account data between multiple sites.
- Copy functions and base tables.
- Use protocols and codelists in a global environment.
- Share tables and PL/SQL functions across multiple sites.

About the Resolve module

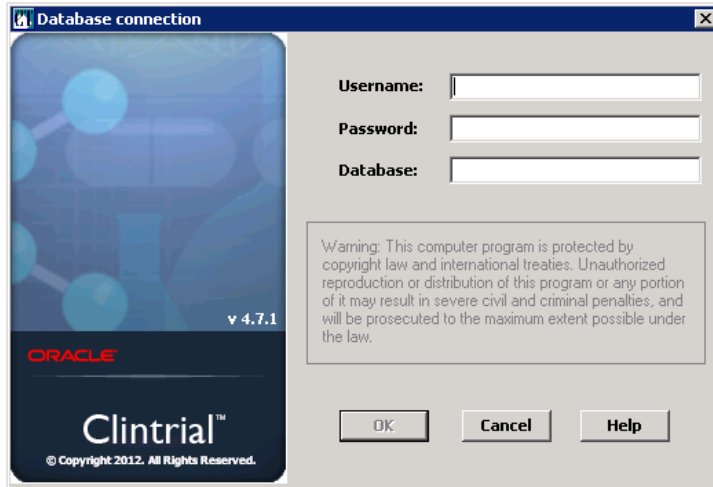
Use the Resolve extended module to manage discrepancy and resolution capabilities that support the work you perform in other Clintrial software modules. You can:

- Identify, track, and resolve potential or actual discrepancies in clinical data (inconsistent or missing data).
- Check for discrepancies automatically or by manual inspection.
- Record investigation and resolution information.

Starting a module

To start a module, from the Windows **Start** menu, select **Programs**. Select **Oracle Health Sciences**, the Clintrial program group, then the module.

When you start a module, the Database Connection dialog box opens:



Starting a module for the first time

The first time you start a Clintrial software module, the fields in the Database Connection dialog box are empty. You must specify the following:

- Your user name
- Your password
- The Oracle Net Service Name for the database you will be using

If you do not know your user name or password, or the database service name that you should use, see your Clintrial software administrator.

Starting a module other than the first time

The next time you start a Clintrial software module, the user name and database service name that you last used to start a Clintrial software module on your computer are displayed as defaults in the Database Connection dialog box.

Using a Clintrial software module

The basic tasks necessary to use a Clintrial software module are:

- Using the Switchboard
- Setting the protocol
- Switching databases
- Re-ordering columns in list windows
- Changing your password
- Exiting the module

How to use the Switchboard

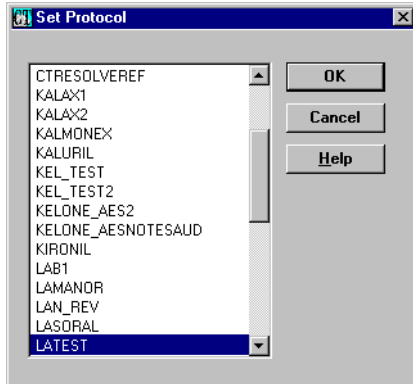
You can start any of the installed Clintrial software modules from the Switchboard **Run** menu. When you start the Switchboard, you provide a user name, password, and database service name. Each time that you start a different Clintrial software module from Switchboard, the Clintrial software uses the database connection information that you initially provided when you started Switchboard. More complete instructions appear in the Clintrial software Basics Help.

Note: Although you can always start the installed Clintrial software modules from the Switchboard, menu commands in the modules are available only if you have the appropriate access rights.

How to set a protocol

A *Clintrial software protocol* is a logical container that organizes the objects and clinical data for a clinical study.

When you first connect to the database, the Set Protocol dialog box opens:



Select the protocol in which you want to work. If you do not know the protocol in which you should work, see your Clintrial software administrator.

Note: The next time you start a Clintrial software module, the Clintrial software automatically selects the protocol that your user account most recently selected.

How to switch databases

To switch from the current database to another database without exiting the Clintrial software, close any open windows, and from the **File** menu, select **Connect**. More complete instructions appear in the Clintrial software Basics Help.

How to re-order columns in list windows

For windows that display list grid views, such as lists of logs in Manage or lists of Discrepancies in Resolve, you may use the mouse to drag columns to new positions to tailor the view to your needs. For example, you can drag and drop the most significant columns to the left portion of the open window, or place two related columns side-by-side in order to ease comparison of the data.

How to change your password

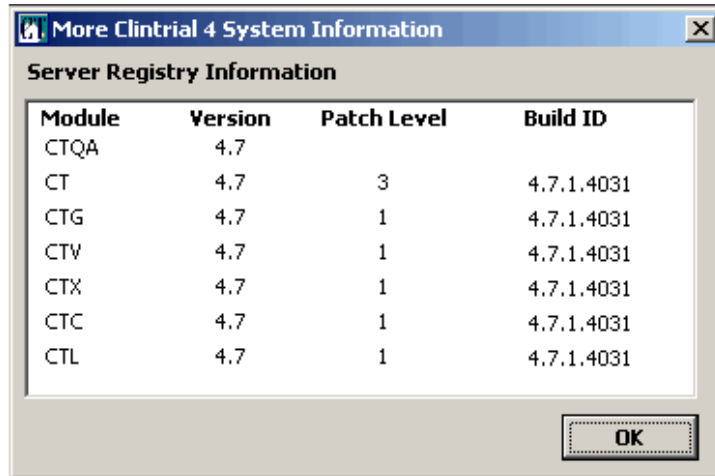
To modify the password for your user account, from the **File** menu, select **Password**. More complete instructions appear in the Clintrial software Basics Help.

How to access the Server Registry Information

You can access the Server Registry Information report from any of the Clintrial software modules.

To open the report:

1. From the **Help** menu, select **About**.
2. Click **More**. The Server Registry Information opens, for example:



How to exit a module

To exit a module, from the **File** menu, select **Exit**. When you exit the application, the main window of the module closes and the Clintrial software disconnects you from the database. More complete instructions appear in the Clintrial software Basics Help.

Using Help

Each Clintrial software module is delivered with Help. Help includes:

- Context-sensitive Help for windows and dialog boxes
- Procedural instructions for tasks
- Brief overviews of concepts

- Descriptions of menus and options
- A glossary of Clintrial software terms

A Clintrial software Help file is installed automatically for each module that you install. In addition, the Help files that are not module-specific are always installed on your computer.

Below is an example of the screen that appears when you choose **Help: About** when you are in the Clintrial Admin module:




How to search for information

To search for information in the Help:

1. From the **Help** menu, select **Help Topics**. The Help Topics dialog box opens.
2. To find a topic in the Help:
 - Click the **Contents** tab to view topics by category.
 - Click the **Index** tab to view a list of index entries.
 - Click the **Find** tab to search for specific words in the Help.

How to get help on windows and dialog boxes

To get help on an open window or dialog box, do one of the following:

- Press **F1**.
- On the toolbar, click .
- Click **Help**.

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Introduction to Multisite

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Overview

Multisite is the extended module that you use to perform the following interdatabase instance operations:

- Distribution
- Replication
- Sending tables and PL/SQL functions from one site to other sites, as described in Chapter 6

What is distribution?

Distribution is the movement and management of metadata objects among multiple sites. Using Multisite, you copy or distribute metadata objects from one site to one or more other sites, as well as control and track revisions of those objects across sites.

You can distribute two types of objects that you create in Design:

- Protocols, including all objects contained within protocols
- Codelists

You can use distribution in Multisite whether or not you use replication.

For more information about distribution, see Chapter 4.

What is replication?

Replication is the movement of data in a protocol or account among multiple sites. There are two types of replication:

- Protocol replication
- Account replication

What is protocol replication?

Protocol replication is the movement of data in a protocol among multiple sites, allowing users at different sites to work with data in a single protocol. Data entered at different sites moves, or replicates, to other sites that are participating in replication for that protocol. To participate in protocol replication, a site must also participate in distribution for that protocol.

Note: In order to avoid possible problems, Multisite Replication has been disabled for both EDC and hybrid protocols. If Multisite Replication is installed, and either type of protocol is selected, all Replication menu options will be disabled in Multisite. If an existing protocol is put into Replication, and then a synchronization with an InForm protocol is attempted through CIS, the synchronization will abort and this error message will be displayed in the CIS event log:

CIS Database ERROR ORA-20784: Protocol <Name> is in Replication. Cannot initialize.

What is account replication?

Account replication is the movement of data in accounts other than protocols among multiple sites. Account replication allows users at different sites to enter and use shared account data. You can set up replication environments for the following accounts:

- CTS account, for flags and notes



Caution: The CTS account must be in replication at all sites at which protocol replication takes place.

- CTCLASSIFY account
- REVIEWADMINGLOBAL account

Note: These accounts are created at each site by the server installation, not by distribution.

For more information on replication, see Chapter 5.

Conventions

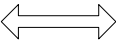
In all figures showing Multisite environments in this guide, the following conventions are used:

Symbol:



Description:

A one-directional, solid line indicates the distribution of an object from one site to another site.

Symbol:	Description:
	A two-directional, clear line indicates replication of clinical data between a Replication Master site and a Replication Subordinate site.

Multisite environments

A *Multisite environment* is a set of sites that are linked and participate in distribution, or distribution and replication.

What is a replication environment?

A *replication environment* is a set of sites within the Multisite environment that participate in replication for a specific protocol or account.

There is one replication environment for a protocol or account in replication. A single site can participate in multiple replication environments.

What is a site?

A *site* is an Oracle database instance that is used as a Clintrial software database instance in a Multisite environment.

Sites can exist on different servers that are connected by a network. Multiple sites can also exist on a single server.

Types of sites

There are five types of sites in a Multisite environment:

- Distribution Master site
- Distribution Subordinate site
- Multisite Master site
- Replication Master site
- Replication Subordinate site

For information about defining sites and configuring the Multisite environment, see Chapter 3.

What is a Distribution Master site?

A *Distribution Master site* is the site that initially creates and distributes a codelist or protocol. You distribute a codelist or protocol from the Distribution Master site to one or more Distribution Subordinate sites.

The Distribution Master site is the only site that can modify a codelist or protocol that it has distributed.

What is a Distribution Subordinate site?

A *Distribution Subordinate site* is a site that accepts a distributed codelist or protocol. There can be multiple Distribution Subordinate sites for each codelist or protocol in distribution.

What is the Multisite Master site?

The *Multisite Master site* is the site at which you register all sites that participate in replication.

The Multisite Master site can also be a Replication Master site or a Replication Subordinate site in any given replication environment.

There is only one Multisite Master site in a Multisite environment.

What is a Replication Master site?

A *Replication Master site* is the site in the replication environment that sets up replication for a specific protocol or account, and where trusted data for that protocol or account is stored. For information about trusted data, see page 108.

What is a Replication Subordinate site?

A *Replication Subordinate site* is a site in the replication environment that collects data for a specific protocol or account and replicates that data to the Replication Master site.

Sites of multiple types

A single site can function as several different types of sites. For example, a site can be a Distribution Subordinate site and a Replication Master site for one protocol. For other examples of Multisite environments, see Appendix B: .

Multisite access rights and access levels

There are two Multisite non-protocol access rights:

- Distribute
- Replicate

Each of these access rights can have an access level of:

- None
- Read
- Full

For more information, see *Admin and Design* or Chapter 7 of this book, or your Clintrial software administrator.

Multisite user interface

This section provides an overview of the following Multisite user interface elements:

- Browsers
- Menus
- Toolbar buttons

For more information about the Multisite user interface, see the Multisite Help.

Browsers

A *browser* is a window that lists certain objects, such as accounts or sites. You open browsers by selecting commands from the **Objects** menu, which is described on page 40.

To perform tasks in Multisite, you select an object in a browser, then select a menu command or click a toolbar button.

The following browsers are available in Multisite:

- Site Browser
- Protocol Browser
- Codelist Browser
- Other Clintrial Accounts browser
- Accept Functions browser

Site Browser

The Site Browser shows all the sites that are known by the site to which you are connected. Sites become known when they are registered for distribution or replication, as described on Chapter 3.

Note: Oracle recommends (but does not require) that the Global Name, the Clintrial Site Name and the Site Service Name be identical to the database instance name.

The database instance name, set during the creation of the database, may be viewed by using this command in SQL Plus:

```
SQL>SELECT name FROM v$database
```

The Global Name (**Global Name** in the Multisite Site browser) is defined during Clintrial core server installation, and is derived from the instance global name. The instance global name may be viewed by using this command in SQL Plus:

```
SQL>SELECT global_name FROM sys.global_name;
```

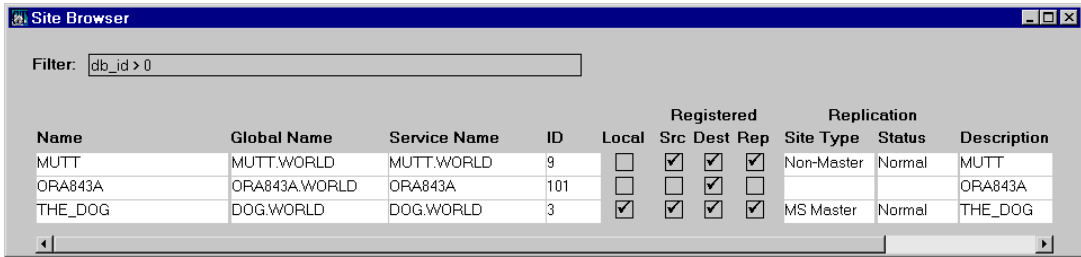
The Clintrial Site Name (**Site** in the Multisite Site browser) is defined during Clintrial Core Server installation, and may be viewed by using this command in SQL Plus:

```
SQL>SELECT name FROM cts.database WHERE TYPE = 1
```

The Clintrial Site Service Name (**Service Name** in the Multisite Site browser) is defined during Clintrial Multisite Distribution installation, and captured in CTINST.LOG. It may be viewed by using this command in SQL Plus:

```
SQL>SELECT SQLNET FROM cts.database WHERE TYPE = 1
```

The following figure shows the Site Browser:



The following table lists and describes the columns in the Site Browser:

Column:	Description:
Name	The name of the site specified during the core server installation.
Global Name	The Oracle Global Name of the site.
Service Name	The Service Name of the site.
ID	The database ID of the site, which is entered during the core server installation.
Local	If checked, indicates that the site is the site to which you are currently logged in.
Src	For the current site, if checked, indicates that the site has registered at least one other site for distribution. For other sites, if checked, indicates that the site has registered the current site for distribution.
Dest	If checked, indicates that the site has been registered for distribution from at least one other site.
Rep	If checked, indicates that the site has been registered for replication at the Multisite Master site.
Site Type	Indicates whether the site is the Multisite Master site, or a Non-Multisite Master site.

Column:	Description:
Status	Indicates the status of the site. Possible values are: <ul style="list-style-type: none"> <i>Blank</i>, if the site has never been registered for replication. <i>Normal</i>, if the site is registered for replication. <i>Dropped</i>, if the site has been deregistered for replication.
Description	A description of the site. This description can be modified using Admin. For more information, see <i>Admin and Design</i> .

Note: When you install the Clintrial core server software, you enter a database ID for the database instance. Normally, this database ID appears in the Site Browser in Multisite in the ID column. However, if you have initialized the replication site, but the site is not yet registered for replication at the Multisite Master site, that site cannot retrieve the value for the Multisite Master site database ID. Therefore, at such a site, the value for the Multisite Master site database ID is always -1. For information about initializing sites for replication, see page 60.

Protocol Browser

The Protocol Browser shows all the protocols at the current site.

The following figure shows the Protocol Browser:

Protocol Name	Distribution			Acceptance		Replication		Status	Errors	Change
	Closed	Dest Sites	Source Site	Status	Revision	Master Site				
ART_THES	<input checked="" type="checkbox"/>	1	MUTT	Accepted	1.1					
ART_THESAURUS	<input checked="" type="checkbox"/>	2				THE_DOG	Normal	0	0	
CT42_MEDIKA	<input checked="" type="checkbox"/>	2				THE_DOG	Normal	0	0	
DDPROTO	<input type="checkbox"/>									
DRUG_THES	<input checked="" type="checkbox"/>	1	MUTT	Accepted	1.1					
DRUG_THESAURUS	<input checked="" type="checkbox"/>	2								

The following table lists and describes the columns in the Protocol Browser:

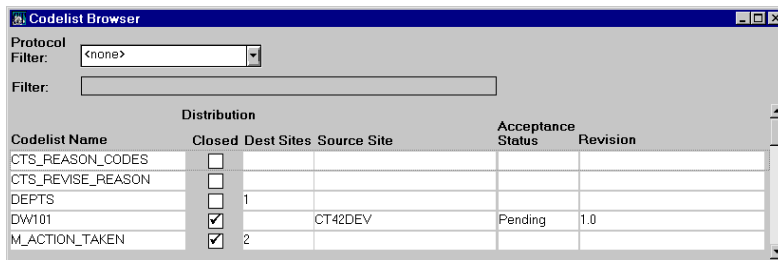
Column:	Description:
Protocol Name	The name of the protocol stored at the site.

Column:	Description:
Closed	If checked, indicates that the protocol is closed for revision. At a Distribution Subordinate site for a protocol, Closed is always checked.
Dest Sites	The number of sites to which the protocol has been distributed from the current site.
Source Site	If the current site is a Distribution Subordinate site, the name of the site from which the protocol was distributed.
Acceptance Status	If the current site is a Distribution Subordinate site, an indication of whether revisions of the protocol are waiting to be accepted. For information about the possible Acceptance statuses, see page 83.
Revision	If the current site is a Distribution Subordinate site, the current revision of the protocol.
Master Site	If the protocol has been registered for replication, the name of the Replication Master site for the protocol.
Status	The status of replication for the protocol. For information about the possible replication statuses, see page 126.
Errors	The current number of replication errors for the protocol.
Changes	The number of records changed in the protocol since replication last occurred.

Codelist Browser

The Codelist Browser shows all the codelists at the current site.

The following figure shows the Codelist Browser:



You can use the Protocol Filter drop-down list to display only those codelists associated with items in the selected protocol.



Caution: If you select a protocol in the Protocol Filter drop-down list, the list of codelists displayed in the Codelist Browser may not include all the codelists that need to be at each site with the protocol. If an item in the protocol is associated with a subset codelist, the base codelist is displayed in the Codelist Browser. However, if that base codelist is a subset codelist of another base codelist, that base codelist is not displayed.

The following table lists and describes the columns in the Codelist Browser:

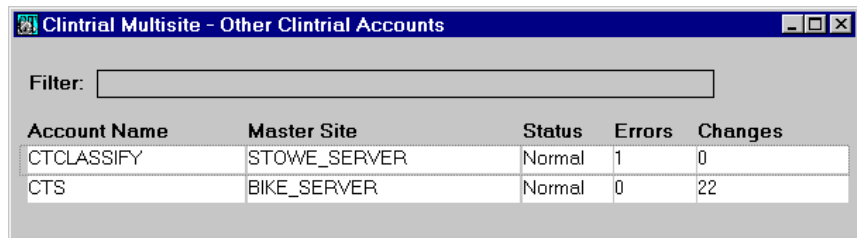
Column:	Description:
Codelist Name	The name of the codelist stored at the site.
Closed	If checked, indicates that the codelist is closed for revision. At a Distribution Subordinate site for a codelist, Closed is always checked.
Dest Sites	The number of sites to which the codelist has been distributed from the current site.
Source Site	If the current site is a Distribution Subordinate site, the name of the site from which the codelist was distributed.
Acceptance Status	If the current site is a Distribution Subordinate site, an indication of whether revisions of the codelist are waiting to be accepted. For information about the possible Acceptance statuses, see page 83.
Revision	If the current site is a Distribution Subordinate site, the current revision of the codelist.

Other Clintrial Accounts browser

The Other Clintrial Accounts browser shows the accounts other than protocols that can be replicated. These accounts include the following:

- The CTS account, which contains definitions of flags and notes.
- The CTCLASSIFY account, which is used by Classify. This account only appears if Classify is installed at the site. For more information on Classify in a Multisite environment, see Chapter 12.
- The REVIEWADMINGLOBAL account, which contains data for using Integrated Review™ in a Multisite environment. For more information, see the Integrated Review documentation.

The following figure shows the Other Clintrial Accounts browser:

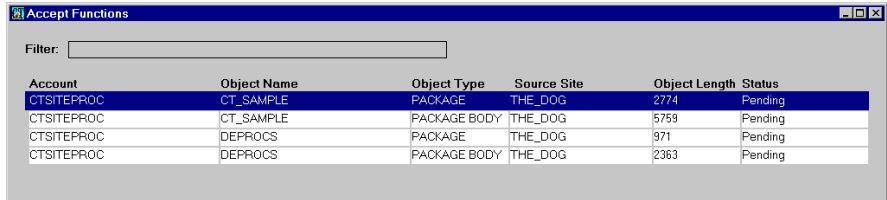


The following table lists and describes the columns in the Other Clintrial Accounts browser:

Column:	Description:
Account Name	The name of the account.
Master Site	If the account has been registered for replication, the name of the Replication Master site for the account.
Status	The status of replication for the account. For information about the possible replication statuses, see page 126.
Errors	The current number of replication errors for the account.
Changes	The number of records changed in the account since replication last occurred.

Accept Functions browser

The Accept Functions browser shows the functions that have been sent to the current site, but that have not yet been accepted. The following figure shows the Accept Functions browser:



Account	Object Name	Object Type	Source Site	Object Length	Status
CTSITPROC	CT_SAMPLE	PACKAGE	THE_DOG	2774	Pending
CTSITPROC	CT_SAMPLE	PACKAGE BODY	THE_DOG	5759	Pending
CTSITPROC	DEPROCS	PACKAGE	THE_DOG	971	Pending
CTSITPROC	DEPROCS	PACKAGE BODY	THE_DOG	2363	Pending

The following table lists and describes the columns in the Accept Functions browser:

Column:	Description:
Account	The name of the account that contains the object.
Object Name	The name of the object.
Object Type	The type of the object. Possible values are: <ul style="list-style-type: none"> • Function • Procedure • Package • Package Body
Source Site	The name of the site that sent the object to the current site.
Object Length	The length of the object.
Status	The status of the sent function. Possible values are: <ul style="list-style-type: none"> • <i>Pending</i> – The function has been sent to the current site, but has not yet been accepted. • <i>Accepted</i> – The function has been accepted at the current site. • <i>Error</i> – The function was accepted at the current site, but there were compilation errors.

Menus

You use the following menus to complete tasks in Multisite:

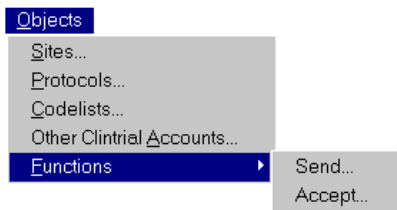
- Objects menu
- Sites menu
- Distribution menu
- Replication menu
- Reports menu
- Distribution/Replication (pop-up) menu
- Errors (Distribution) menu
- Errors (Replication) menu
- History menu

Note: Other menus in the Clintrial software include the File menu, the Edit menu, the View menu, the Tools menu, the Custom menu, the Window menu, and the Help menu. These menus are not specific to Multisite and therefore are not discussed in this section. You can find more information about these menus and their commands in the Multisite Help.

Objects menu

Use the Objects menu to open the different browsers.

The following figure shows the Objects menu:



The following table describes the commands in the Objects menu:

Command:	Use to:	See:
Sites	Open the Site Browser.	Page 33
Protocols	Open the Protocol Browser.	Page 35
Codelists	Open the Codelist Browser.	Page 36

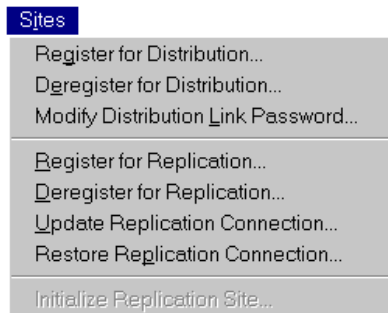
Command:	Use to:	See:
Other Clintrial Accounts	Open the Other Clintrial Accounts browser.	Page 38
Functions >> Send	Open the Send Functions dialog box.	Page 139
Functions >> Accept	Open the Accept Functions browser.	Page 39 and Page 140

Sites menu

Use the Sites menu to set up sites in the Multisite environment.

Note: The Sites menu only appears when the Site Browser is the active window.

The following figure shows the Sites menu:



The following table describes the commands in the Sites menu:

Command:	Use to:	See:
Register for Distribution	Register a site so the current site can distribute objects to it.	Page 54
Deregister for Distribution	Deregister a site so the current site can no longer distribute objects to it.	Page 54

Command:	Use to:	See:
Modify Distribution Link Password	Change the password used by the current site for the link between the current site and a site that it has registered for distribution.	Page 56
Register for Replication	Register the site for replication at the Multisite Master site.	Page 61
Deregister for Replication	Deregister the site for replication at the Multisite Master site.	Page 62
Update Replication Connection	Update the replication connection from other sites that connect to a site where the proxy account password has changed.	Page 63
Restore Replication Connection	Restore the replication connection at one site when the proxy account passwords have changed at two connected sites.	Page 63
Initialize Replication Site	Indicate to the current site which site is the Multisite Master site, and to create a proxy account at the current site for the Multisite Master site.	Page 60

Distribution menu

Use the Distribution menu to perform codelist and protocol distribution, clinical data backloading, and copying of base tables from one site to another.

Note: The Distribution menu only appears when the Protocol Browser or Codelist Browser is the active window.

The following figure shows the Distribution menu:



The following table describes the commands in the Distribution menu:

Command:	Use to:	See:
Distribute	Distribute a codelist or protocol from the current site.	Page 77
Open for Revision	Make a distributed codelist or protocol modifiable at the Distribution Master site.	Page 84
Close for Revision	Close the codelist or protocol to further modifications, and assign a new revision number at the Distribution Master site.	Page 85
Compare Revisions	Compare the current codelist or protocol to the last snapshot of the object at the Distribution Master site.	Page 86
Backload Data	Copy clinical data in a protocol from a Destination site for testing purposes at the Source site. (Available only when the Protocol Browser is the active window.)	Page 86
Cancel Changes	Cancel the changes made to a codelist or protocol since the object was last opened for revision at the Distribution Master site.	Page 88

Command:	Use to:	See:
Detach Destination	Remove a Destination site from the distribution of a codelist or protocol at the Source site.	Page 96
Accept Revision	Accept the latest revision of a codelist or protocol at the Destination site.	Page 82
Detach from Source	Remove a Destination site from the distribution of a codelist or protocol at the Destination site at the Destination site.	Page 96
Copy Base Tables	Copy base tables from the current site to a Destination site.	Page 141
Show Release History	View the Release History.	Page 91
Show Revision Comparison	View the Revision Comparison or the Comparison Details.	Page 93
Review Distribution Errors	View information about errors that occurred during the acceptance of a codelist or protocol.	Page 90
Show Details	View read-only information about a codelist or protocol in distribution, or view Comparison Details.	Page 89 and page 94

Replication menu

Use the Replication menu to set up and perform replication.

The Replication menu is only available when the Replication server software is installed at the current site. For more information, see *Getting Started*.

Note: The Replication menu only appears when the Protocol Browser or the Other Clintrial Accounts browser is the active window.

The following figure shows the Replication menu:



Note: If the Replication menu is selected when the Other Clintrial Accounts browser is open, some commands on the Replication menu are different than those shown in the previous example. Account is used instead of Protocol.

The following table describes the commands in the Replication menu:

Command:	Use to:	See:
Register Protocol	Indicate to the Multisite Master site that you want the current site to be the Replication Master site for a selected protocol or account.	Page 113
or		
Register Account		

Command:	Use to:	See:
Deregister Protocol	Remove the protocol or account from replication.	Page 114
or		
Deregister Account		
Request Participation	Indicate to the Replication Master site that you want the current site to be a Replication Subordinate site for a specific protocol or account.	Page 115
Invite Site	Accept a site's request to be a Replication Subordinate site for the protocol or account.	Page 116
Uninvite Site	Remove a site from the replication environment.	Page 118
Schedule Replication	Select the time and frequency that data replicates between the Replication Master site and a Replication Subordinate site.	Page 119
Stop Replication	Cancel a scheduled replication from one site to another site in the replication environment.	Page 119
Fetch Changes	Make new or modified data in a specific protocol or account replicate immediately from any site in the replication environment to the current site.	Page 120
Send Changes	Make data in a specific protocol or account replicate immediately from the current site to another site in the replication environment.	Page 120
Transfer Ownership	Move ownership, that is, the ability to modify data, from one site to another in a replication environment.	Page 121
Set Replication Restrictions	Limit which subjects or records in a protocol or account are replicated from the Replication Master site to each site in the replication environment.	Page 122

Command:	Use to:	See:
Show Replication Restrictions	Show replication restrictions at the Replication Master site.	Page 132
Halt Protocol or Halt Account	Stop replication activity for a protocol or account, and synchronize all data in that protocol or account, at all sites in the replication environment.	Page 123
Resume Protocol or Resume Account	Resume replication for a halted protocol or account according to the replication schedule.	Page 124
Force Ownership Transfer	Move ownership from a Replication Subordinate site to the Replication Master site, while logged in to the Replication Master site.	Page 121
Show Status	View read-only information about a protocol or account in replication.	Page 128
Review Replication Errors	Review information about errors that occurred during the replication of data in a protocol or account.	Page 132
Review Replication History	Review information about the replication of data in a protocol or account.	Page 129
Modify Protocol Password or Modify Account Replication Information	Fix the link between the Replication Master site and the Replication Subordinate site by modifying the protocol or account password.	Page 125
Delete Non- Local Record	Delete unowned records from an uninvited site.	Page 125

Reports menu

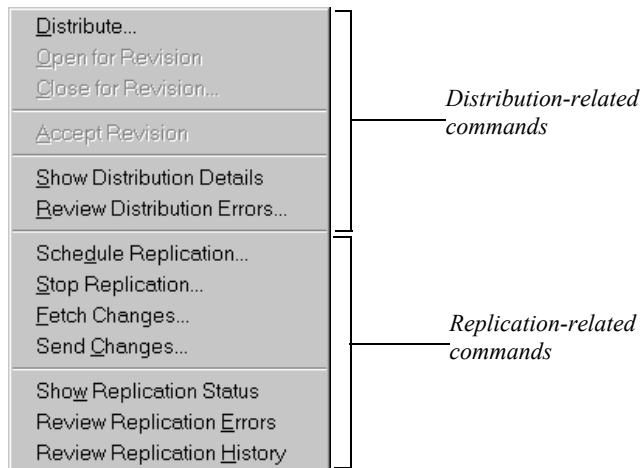
You can view the Replication Environment Report, which displays the names of all replicating protocols and replicating accounts in a Multisite system, and their master site.

To run this report, log in to the Multisite Master site and from the **Reports** menu, select **Replication Environment**.

Distribution/Replication menu

If you have both distribution and replication access rights, and you right-click when the Protocol Browser is the active window, the menu that appears is a combination of the Distribution menu and the Replication menu. Some, but not all, commands from the Distribution menu and Replication menu are included in the Distribution/Replication menu.

The following figure shows the Distribution/Replication menu:



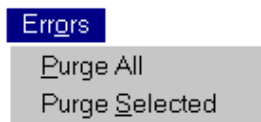
For information about Distribution-related commands, see page 42. For information about Replication-related commands, see page 44.

Errors menu (Distribution)

Use this Errors menu to work with distribution errors.

Note: The Errors menu for distribution errors only appears when the Distribution Errors window is the active window.

The following figure shows the Errors menu for distribution errors:



The following table describes the commands in the Errors menu. For more information on working with distribution errors, see page 90.

Command:	Use to:
Purge All	Delete all the errors from the Distribution Errors window.
Purge Selected	Delete the selected errors from the Distribution Errors or Replication Errors window.

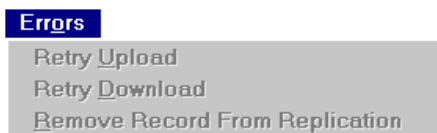
Errors menu (Replication)

Use this Errors menu to work with replication errors.

Replication errors, whether they occurred during uploading or downloading, are recorded at the Replication Subordinate site that participated in the replication, because the data stored at the Replication Master site is presumed to be correct.

Note: The Errors menu for replication errors only appears when the Replication Errors window is the active window.

The following figure shows the Errors menu for replication errors:



The following table describes the commands in the Errors menu. For more information on working with replication errors, see page 132.

Command:	Use to:
Retry Upload	Retry replication from the Replication Subordinate site to the Replication Master site for the selected Upload error(s).

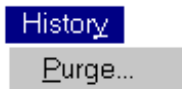
Command:	Use to:
Retry Download	Retry replication from the Replication Master site to the Replication Subordinate site for the selected Download error(s).
Remove Record From Replication	Remove the record from replication.

History menu

Use the History menu to purge rows in the Replication History window.

Note: The History menu only appears when the Replication History window is the active window.

The following figure shows the History menu:



Use the Purge command to delete rows from the Replication History window with a date prior to the date you enter. For more information about the Replication History window, see page 129.

Toolbar buttons

You can use the toolbar buttons to perform some tasks in Multisite.

Note: There are corresponding menu commands for all toolbar buttons.

You can move the Multisite toolbar by clicking on the toolbar, holding the mouse button down, and dragging the toolbar to the preferred location.

To show or hide the toolbar button, from the **Window** menu, select **Toolbar**.

You can also modify the toolbar's location and appearance by right-clicking, and selecting a command from the pop-up menu.

For information about specific toolbar buttons, place the pointer over the toolbar button and read the tip that is displayed, and the MicroHelp in the status bar at the bottom of the window.

3

Setting Up a Multisite Environment

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- Deregistering sites for replication 62
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Overview

You set up the Multisite environment by setting up distribution sites and replication sites. The different processes for setting up distribution sites and replication sites are described in this chapter.

Setting up distribution sites

This section describes the following tasks that you perform to set up distribution sites:

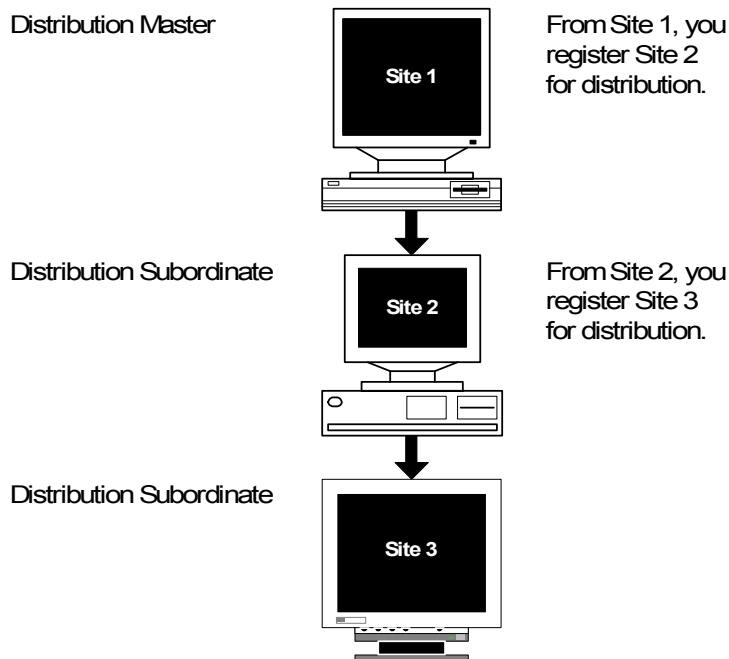
- Registering sites for distribution
- Deregistering sites for distribution
- Modifying distribution passwords

Registering sites for distribution

Before you can distribute a codelist or protocol, or copy a function or base table, you must register the Destination site for distribution. When you register a Destination site for distribution, you create a database link between the CTSRM account at the current site, which is the Source site, and the CTSRM account at the Destination site. For information about the CTSRM account, see the *Reference Guide*.

For example, if you want Site 1 to distribute Protocol A to Site 2, you must first register Site 2 for distribution from Site 1. If you then want Site 2 to distribute Protocol A to Site 3, you must first register Site 3 for distribution from Site 2. If you register Site 3 for distribution from Site 1, this would not enable you to distribute or copy objects from Site 2 to Site 3.

The following figure shows the registration tasks required to set up distribution from Site 1 to Site 2, and then set up distribution from Site 2 to Site 3:



Caution: A site that is to be a Replication Master site for a protocol must register all Replication Subordinate sites for distribution. Registering a site for replication, which is described on page 61, does not register the site for distribution.

For information about Source sites and Destination sites, see page 74.

Deregistering sites for distribution

You can also deregister a Destination site. When you deregister a Destination site, you remove the database link from the CTSRM account at the Source site to the CTSRM account at the Destination site, and you can no longer distribute or copy objects to that site from the current site.



Caution: You must detach all protocols and codelists in distribution at a site before you can deregister the site for distribution. For information about detaching protocols and codelists, see page 95.

Modifying distribution passwords

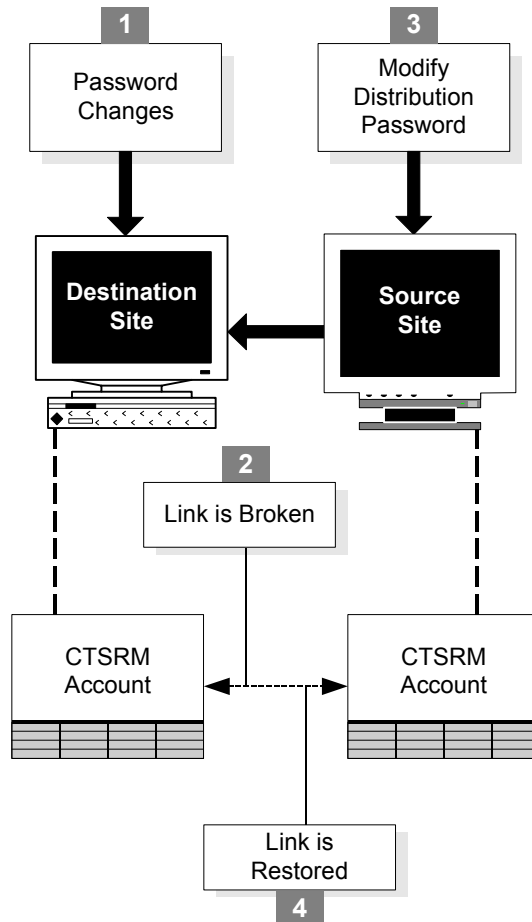
When you register a site for distribution, the CTSRM accounts at the two sites become connected. A *distribution password* provides security for this connection.

When you register a Destination site for distribution, you enter the CTSRM password for that site. The password you enter becomes the distribution password for the connection between the CTSRM accounts at the two sites.

If the CTSRM password at the Destination site changes after you registered that site for distribution, you must modify the distribution password at the Source site to match the CTSRM password at the Destination site.

For information about Source sites and Destination sites, see page 74.

The following figure shows what happens when you modify a distribution password:



Setting up replication sites

This section describes the tasks that you perform to set up replication sites.

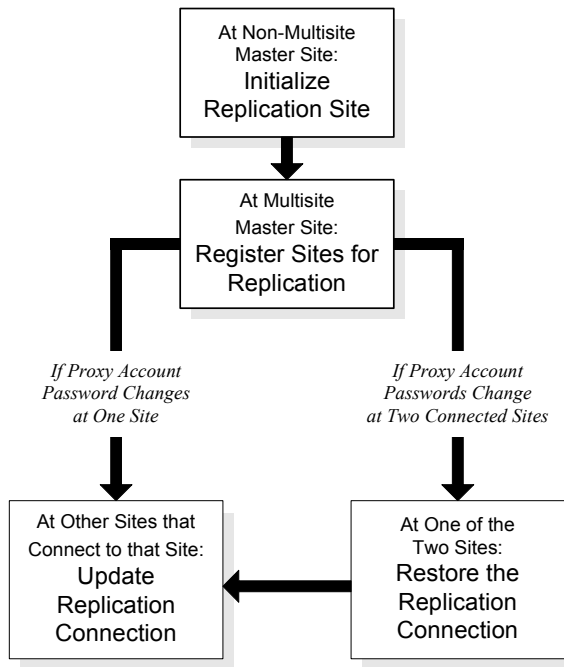
The following table lists the tasks that you perform to set up sites for replication and the type of site at which you perform the task:

Task:	Site:	See:
Initializing replication sites	Any non-Multisite Master site	Page 60

Task:	Site:	See:
Registering sites for replication	Multisite Master site	Page 61
Updating the replication connection	Any site that is registered for replication	Page 63
Restoring the replication connection	Any site that is registered for replication	Page 63

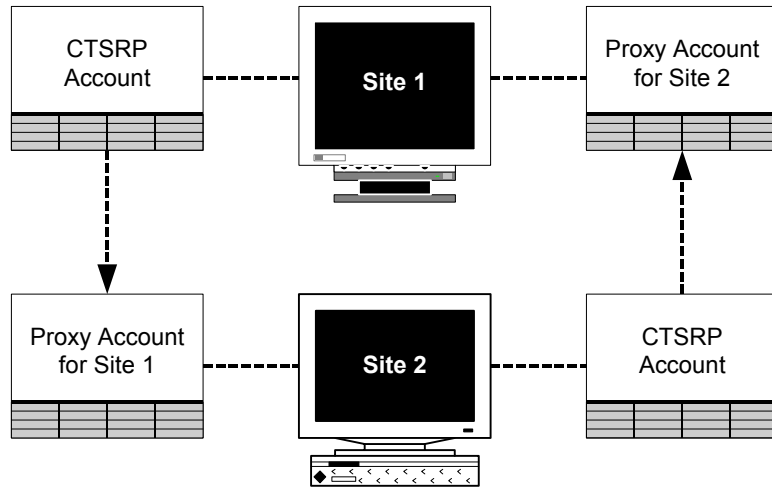
Workflow

The following figure shows a workflow for setting up replication sites:



What is a proxy account?

A *proxy account* is an account at one site that allows another site to connect to and perform operations at that site. Proxy accounts enable sites to connect to each other in the Multisite environment, as shown in the following figure:



For information about the CTSRP account, see the *Reference Guide*.

Each site in a Multisite environment on which replication is installed must be represented by a proxy account at other sites. Specifically, proxy accounts are used as follows:

- Each site that is initialized for replication has a proxy account for the Multisite Master site.
- The Multisite Master site has a proxy account for each site that is registered for replication.
- A Replication Master site has a proxy account for each of its Replication Subordinate sites, and each of those Replication Subordinate sites has a proxy account for the Replication Master site. For more information on setting up replication environments, see page 111.



Caution: When proxy account passwords change, sites participating in replication can no longer communicate. To correct this situation, you must either update or restore the replication connection, as described on page 63.

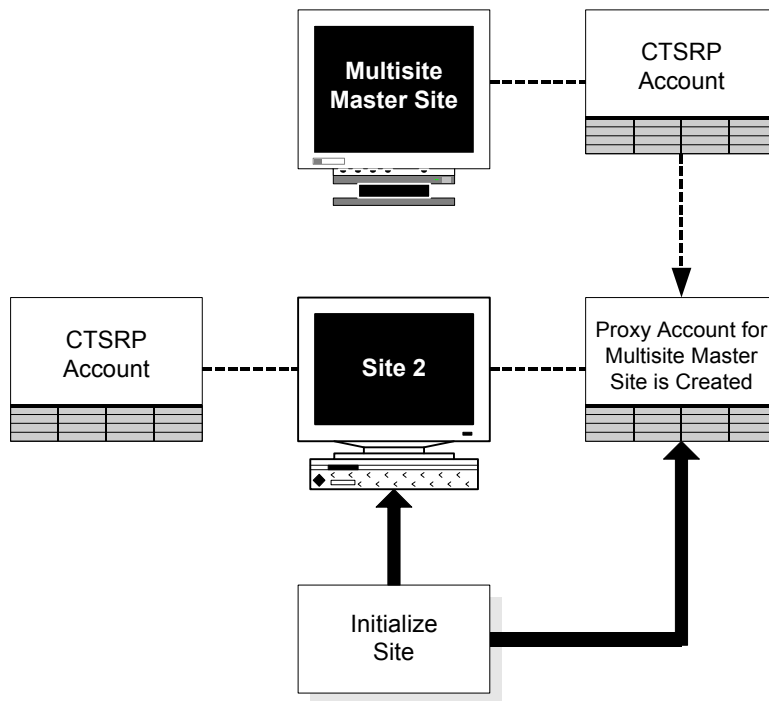
Initializing a replication site

From each non-Multisite Master site in a Multisite environment, you must initialize the site to indicate to the current site which site is the Multisite Master site. When you initialize the site, you create a proxy account at the current site for the Multisite Master site.



Caution: You must initialize a site for replication before you can register that site for replication.

The following figure shows what happens when you initialize a site for replication:



Note: When you install the Clintrial core server software, you enter a database ID for the database instance. Normally, this database ID appears in the Site Browser in Multisite in the ID column. However, if you have initialized the replication site, but the site is not yet registered for replication at the Multisite Master site, that site cannot retrieve the database ID for the Multisite Master site. Therefore, at such a site, the database ID for the Multisite Master site ID is always -1.

Registering a site for replication

Before a site can participate in a replication environment, you must register the site for replication at the Multisite Master site. By registering a site for replication, you create a proxy account at the Multisite Master site for the site that you are registering.



Caution: Before you can register a site for replication, you must initialize that site for replication.

When registering a site for replication, you:

- Enter a Site Global Database Name.
- Enter a Site Service Name.
- Indicate whether the site is a Remote Site.

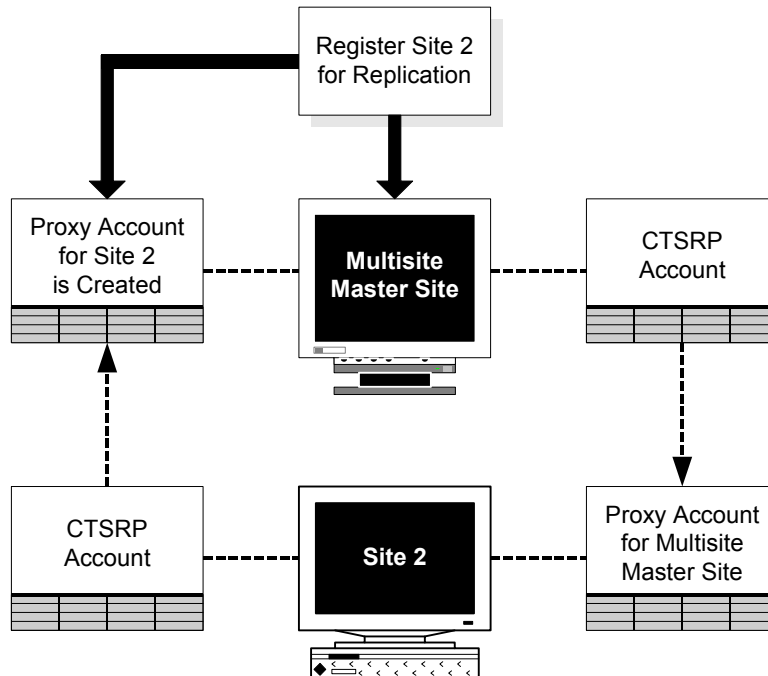
Note: Oracle recommends (but does not require) that the Site Global Database Name and the Site Service Name be identical to the Clintrial Site Name, which is defined during Clintrial Core Server installation, and captured in CTINST.LOG. The Clintrial Site Name may be viewed by using this command in SQL Plus:

```
SQL>SELECT name FROM cts.database WHERE TYPE = 1
```

Name	Defined/Retrieved	Notes
Clintrial Site Name	Defined during CT installation, captured in CTINST.LOG. Can be viewed in the following item: SQL>Select name from cts.database	Recommended to make this the same as the instance name (select name from v\$database).
Global Name	Derived from the name of the instance and the domain name. Captured in the following item: SQL>Select db_name from cts.database	This is NOT the same as SYS.GLOBAL_NAME and will not be automatically updated if SYS.GLOBAL_NAME is updated.

Name	Defined/Retrieved	Notes
Service Name	Defined during the installation of Multisite Distribution, captured in CTCINST.LOG. Can be viewed as follows: SQL>select SQLNET from cts.database	n/a

The following figure shows what happens when you register a site for replication:



Deregistering sites for replication

You can also deregister a site for replication. When you deregister a site for replication, that site can no longer participate in a replication environment. You deregister sites for replication from the Multisite Master site.

If you later want a site that you have deregistered for replication to participate in replication, you must initialize the replication site, as described on page 60.



Caution: You must deregister all protocols and accounts in replication at a site and uninvite the site from all replication environments before you can deregister the site for replication. For information about deregistering protocols and accounts, see page 114. For information about uninviting sites, see page 118.

Updating and restoring the replication connection

Updating the replication connection is the process of generating a new password for a site's proxy account at the site where the password changed.

Restoring the replication connection is the process of reverting the proxy account's password to the previous password at the site where the password changed.

For example, if the password for Site 2's proxy account changes at Site 1, you must connect to Site 1 and either update or restore the replication connection:

- If you update the replication connection, a new password is generated for Site 2's proxy account at Site 1, and this new password is communicated to Site 2 through Site 1's proxy account.
- If you restore the replication connection, the password for Site 2's proxy account reverts to the previous password, restoring the connection from Site 2 to Site 1.

A second example is when the password for Site 2's proxy account changes at Site 1, and the password for Site 1's proxy account changes at Site 2. In this situation:

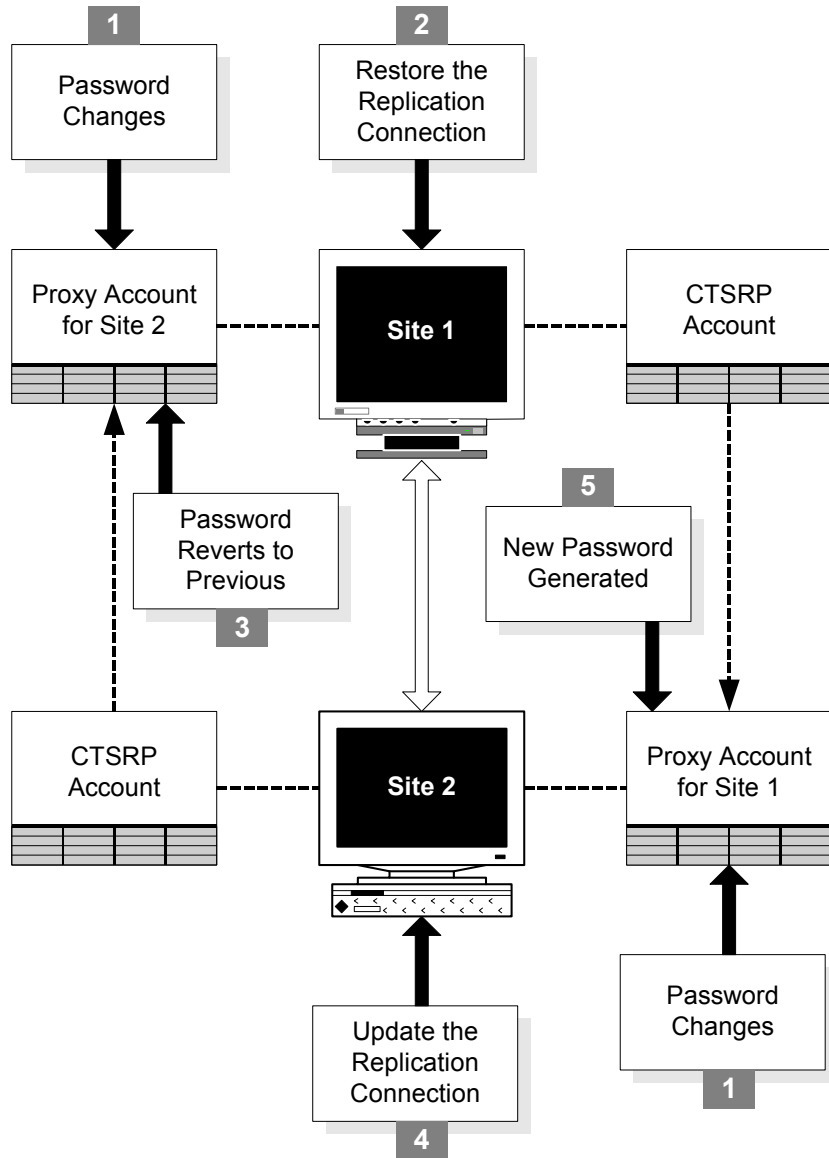
- You must connect to one of the sites and restore the replication connection.



Caution: You cannot update a replication connection in this situation because updating the replication connection requires that the password for one of the proxy accounts at the two sites has not changed.

- After restoring the replication connection at one of the sites, you must connect to the other site, and then either update or restore the replication connection to the site where you previously restored the replication connection.

The following figure shows this second example, where at Site 2 you update the replication connection. You could also restore the replication connection at Step 4. In this case, at Step 5, the password for Site 1's proxy account would revert to the previous password.



If the proxy account password has changed at two sites, you must restore the replication connection from one site before you can update the replication connection from the other site. For information about restoring the replication connection, see the next section.



Caution: When you restore the replication connection to a site, the Clintrial software reverts the password to its previous version for the proxy account at that site, overwriting the existing password. Therefore, if you create a password profile for the proxy account, you must not set the `PASSWORD_REUSE_TIME` parameter. For more information about setting password profiles for accounts, see your Oracle documentation.

Using Multisite with CIS

The Clintrial Multisite module allows the user to distribute Clintrial software metadata in the form of a protocol from one database instance to another. The basis for this distribution is to have metadata changes controlled by a Master protocol and subsequently applied to a Subordinate protocol. The Master protocol will only allow metadata changes once it has been set to an open state, and can only be distributed once it is set to a closed state. Only metadata changes that were applied during the open state will result in metadata changes to the Subordinate.

Clintrial software protocols can be created from InForm software via the Clintrial Integrated Solution (CIS). Amendments to the metadata of this protocol can be done via the Clintrial Master protocol or via InForm software through CIS software to the Master protocol (in an open state). Both methods can then be applied to the Subordinate protocol via distribution.

This method can then be used to facilitate the management of study changes within a test environment. Once tested and approved, metadata can be distributed into the production environment.

To allow this method to function the protocol has to be 'prepared'.

Preparing the protocol

The connection between the InForm and Clintrial server is maintained via a synchronization connection. A synchronization connection can be made to an existing Clintrial protocol, or can create the protocol based on the metadata submitted by InForm software.

A synchronization cannot be made to a protocol that was previously created by another synchronization connection. From the architecture, it is clear to see that this is a requirement of the connection that is made within the production environment. Although the Subordinate protocol was created by the Master protocol, (and therefore by Clintrial software), it will contain all the objects that were originally created by a synchronization connection. Any new synchronization connection to the Subordinate protocol will fail, as it will contain objects that the connection does not expect to find. Because of this, the protocol must be prepared prior to the architecture being deployed.

The preparation of the base protocol only needs to be performed once. Following preparation and deployment, the Multisite environment can be used successfully.

Preparation steps:

1. Create a synchronization connection containing the full trial metadata (only) to the Clintrial environment from the InForm machine within the test environment.
2. Once completed, a Clintrial protocol will be created.
3. From the Clintrial Design module, de-install both tables and data dictionary for the following tables:
 - INF_SITE
 - INF_USER
4. Delete the above panels.
5. Connect via SQL to the Clintrial protocol schema and drop all tables whose names begin with INF_.
6. Export the protocol metadata.
7. Import the protocol metadata providing a new protocol name.

Distribution of the prepared protocol

Once the protocol has been prepared and imported, you can begin to complete the configuration that is required to give you a distributed environment.

The prepared protocol was created via a synchronization connection, but now does not contain any InForm software related object. The protocol is now ready to be distributed and receive synchronization requests.

Using the Clintrial Design module, distribute the protocol from the Master to the Subordinate. Ensure that the Master protocol remains closed until synchronization has been completed.

Synchronization

Distribution has now provided two target protocols, one for use within the test environment and one for use within the production environment. Any synchronization connections created during the protocol preparation phase can be removed from CIS (in release 4.0 SP3 and above only) and InForm software.

Create a synchronization connection from the test environment to the Master protocol, and another synchronization connection from the production environment to the Subordinate protocol. All InForm software required objects are created at this stage.

Further metadata changes

Once the distributed environment is created, further metadata changes may be required.

Executed from the Test InForm machine:

1. Place the Master Clintrial Protocol in the 'Open for revision' state.
2. Insert all metadata XML onto the InForm trial within the test environment.
3. Synchronize the metadata changes over to the Clintrial Master protocol.
4. Place the Master Clintrial Protocol in the 'Closed for revision' state.
5. Distribute the new metadata changes to the Subordinate protocol.
6. Insert all metadata XML onto the InForm trial within the production environment.
7. Synchronize the metadata changes over to the Clintrial Subordinate protocol.

Executed from the Master Clintrial protocol:

1. Place the Master Clintrial Protocol in the 'Open for revision' state.
2. Make the required metadata changes via the Clintrial Design module.
3. Distribute the new metadata changes to the Subordinate protocol.

There should be no occasions where metadata changes for a Clintrial protocol are initiated by the production InForm machine.

4 *Distribution*

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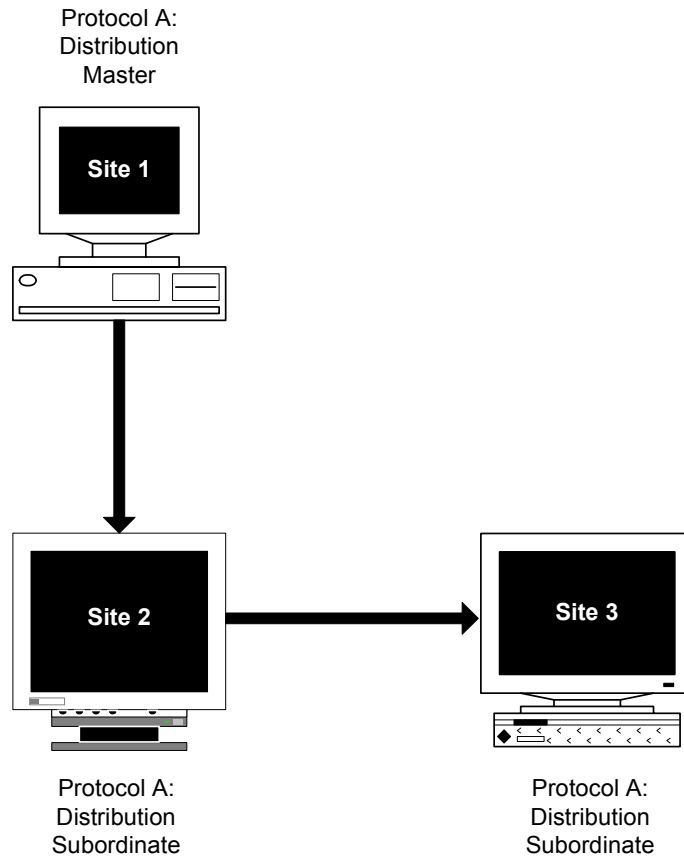
Overview

Distribution is the movement and management of metadata objects among multiple sites. Using Multisite, you copy, or distribute, metadata objects from one site to one or more other sites, as well as control and track revisions of those objects across sites.

You can distribute two types of objects that you create in Design:

- Protocols, including all objects contained within protocols
- Codelists

The following figure shows an example of distribution in a Multisite environment:





Caution: It is not possible to accept a new Multisite distribution if certain batch jobs are running on an instance. The Error message

"There are active Clintrial jobs on the server. The requested operation and Clintrial jobs cannot run at the same time. Continue?"

appears when certain jobs are running.

This problem may occur during several Clintrial software activities such as Multisite distribution, merge, validation, and screening. When this occurs, the problem may be that privileges are being granted to protocols, but execute privileges cannot be granted when the package is being executed.

To find out which jobs are running, execute the following SELECT statement:

```
SELECT job_id, job_type, protocol FROM cts.job_log WHERE  
overall_status='RUNNING';
```

If the jobs are Multisite related, you can halt the jobs from Multisite module (For information about halting a job, see the on-line help or later in this *Multisite* manual).

To remove any running jobs, you can use the `ctx_cjobs.sql` script. If there are any running jobs to remove, Clintrial software creates the `restore_ctx_jobs.sql` script. After completing the activity that was blocked by the running job, you can restore the job by running `restore_ctx_jobs.sql`.

Distribution and protocol replication

Although you can use distribution in Multisite without using protocol replication, you cannot use protocol replication without using distribution. To create a protocol replication environment, you must distribute the protocol from the Replication Master site to all Replication Subordinate sites.

For more information on replication, see Chapter 5.

Working with functions and base tables

Multisite also enables you to send functions and base tables from one site to another site. However, modifications made to functions and tables that you copy to other sites are neither controlled nor tracked as they are for protocols and codelists.

For more information on working with functions and base tables, see Chapter 6.

Distribution sites

There are two characteristics of sites that participate in the distribution of codelists and protocols:

- The site's type
- The site's role

Types of sites

Two types of sites participate in the distribution of a codelist or protocol:

- A Distribution Master site
- One or more Distribution Subordinate sites

For information about registering and setting up sites, see Chapter 3.

What is a Distribution Master site?

A *Distribution Master site* is the site that initially creates and distributes a codelist or protocol. You distribute a codelist or protocol from the Distribution Master site to one or more Distribution Subordinate sites.

The Distribution Master site is the only site that can modify a codelist or protocol that it has distributed.



Caution: Because canceling changes when revising a protocol in distribution can result in data loss, the Distribution Master site should not be part of a replication environment for the protocol. Only Distribution Subordinate sites should be part of a replication environment for a protocol. For information about canceling changes, see page 88. For information about replication environments, see page 102.

What is a Distribution Subordinate site?

A *Distribution Subordinate site* is a site that accepts a distributed codelist or protocol. There can be multiple Distribution Subordinate sites for each codelist or protocol in distribution.

After accepting the distributed codelist or protocol at the Distribution Subordinate site, you can:

- Create other objects at the site by copying the distributed codelist or objects in the distributed protocol.

- Attach distributed codelists to items.
- Use a distributed protocol to collect clinical data.
- Distribute the codelist or protocol to one or more other Distribution Subordinate sites.

You cannot modify a distributed codelist or protocol at a Distribution Subordinate site unless you detach the site from the Distribution Master site. For information about detaching sites, see page 95.

Furthermore, a Distribution Subordinate site has the role of a Destination site. It may also have the role of a Source site. For more information about roles of Distribution Subordinate sites, see page 74.

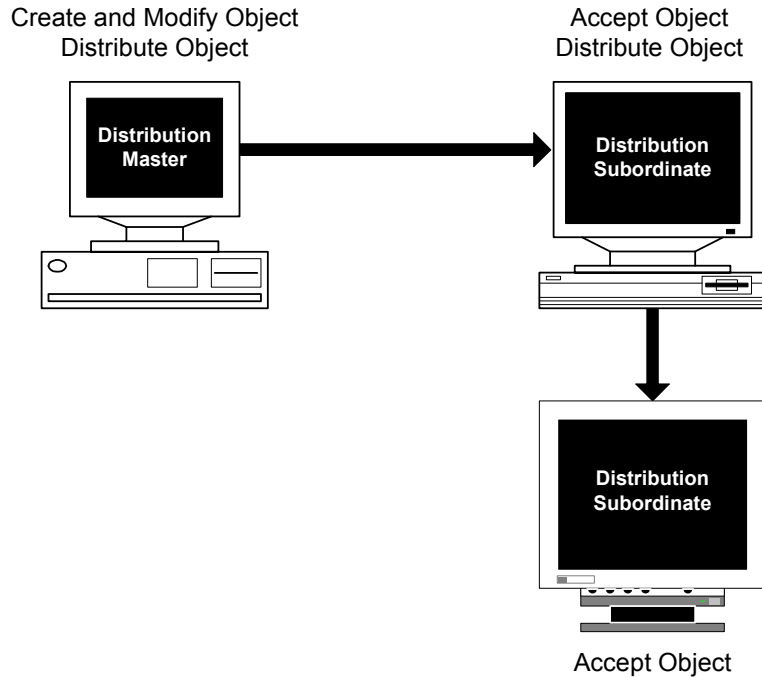
Sites of multiple types

A single site can function as multiple types of sites for different objects. For example, a site can be both the Distribution Master site for a protocol, and the Distribution Subordinate site for a codelist. A site can also be a Distribution Subordinate site and a Replication Master site for one protocol.

For other examples of Multisite environments, see Appendix B: .

Example of types of sites in distribution

The following figure shows the relationship between a Distribution Master site and Distribution Subordinate sites, and the basic tasks that you can perform at each site:



Roles of sites

A site that participates in the distribution of protocols and codelists can have one or both of the following roles:

- Source site
- Destination site

What is a Source site?

A *Source site* is a site that distributes a codelist or protocol. A Distribution Master site is always a Source site. A Distribution Subordinate site is a Source site if it distributes a codelist or protocol to another Distribution Subordinate site.

What is a Destination site?

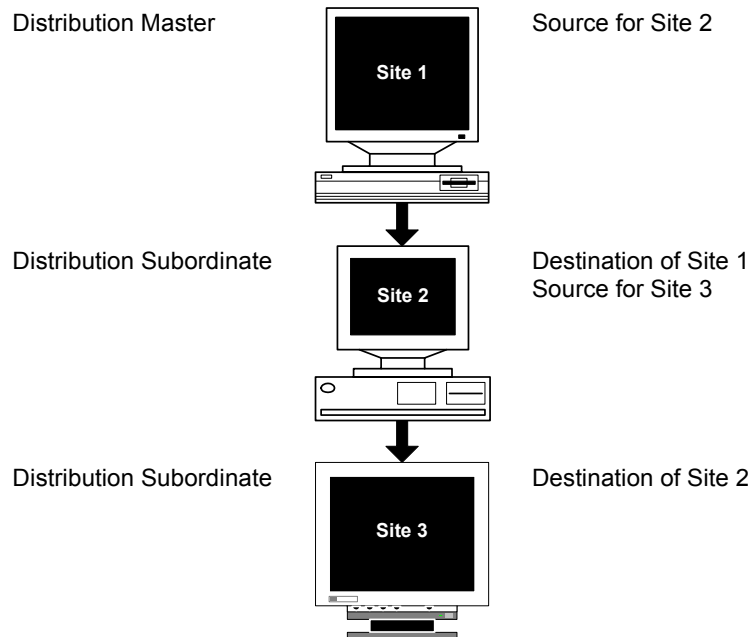
A *Destination site* is a site that accepts a distributed codelist or protocol. A Distribution Subordinate site is always a Destination site, whether the codelist or protocol is distributed to it from the Distribution Master site or from another Distribution Subordinate site.

A Distribution Master site for a codelist or protocol is never a Destination site for that same object.

Sites with multiple roles

A Distribution Subordinate site can be both a Source site and a Destination site for a single codelist or protocol.

The following figure shows the different roles of three sites that participate in the distribution of a protocol:



Working with codelists and protocols in distribution

This section describes how you use Multisite to distribute codelists and protocols.

The following table lists the tasks involved in codelist and protocol distribution, the type of site at which you perform the task, the role of the site, and where to find more information on the task:

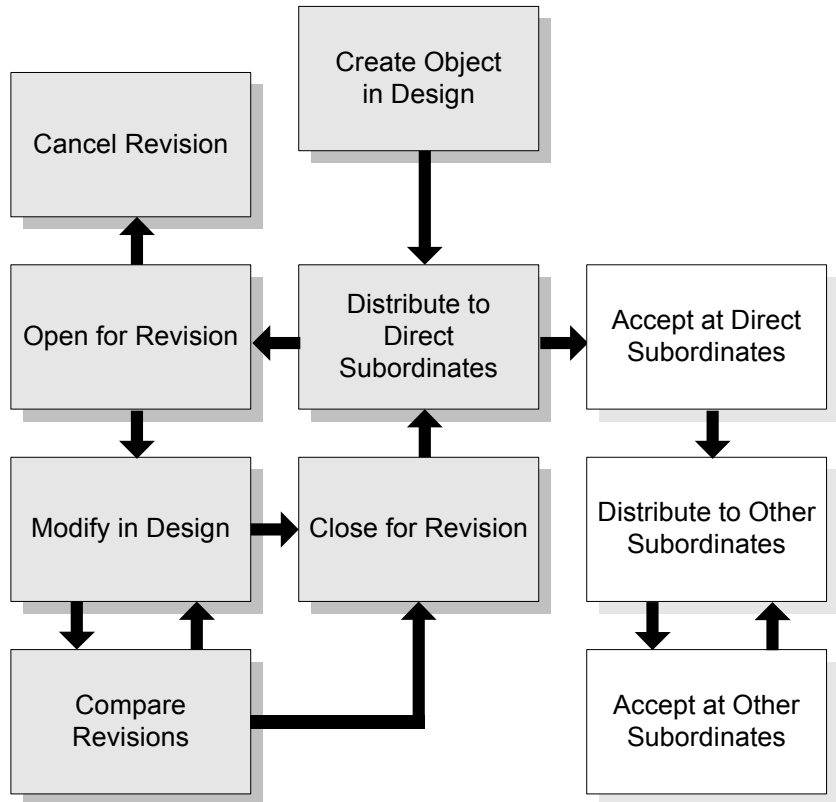
Task:	Type of site:	Role of site:	See:
Distributing a codelist or protocol for the first time	Distribution Master site	Source site	page 77
Distributing a codelist or protocol	Distribution Master site or Distribution Subordinate site	Source site or Destination site	page 77
Accepting a codelist or protocol	Distribution Subordinate site	Destination site	Page 82
Opening a codelist or protocol for revision	Distribution Master site	Source site	Page 84
Closing a codelist or protocol for revision	Distribution Master site	Source site	Page 85
Comparing revisions	Distribution Master site	Source site	Page 86
Backloading data	Distribution Master site or Distribution Subordinate site	Source site	Page 86
Canceling changes made to a codelist or protocol	Distribution Master site	Source site	Page 88

Sample distribution workflow

The following figure shows a distribution workflow for a protocol. You complete tasks in the shaded boxes at the Distribution Master site. You complete tasks in the clear boxes at Distribution Subordinate sites. Not all distribution-related tasks in the previous table are included in this workflow.

Note: This workflow can also apply to a codelist in distribution.

Direct Subordinates refers to sites that are Destination sites of the Distribution Master site. Other Subordinates refers to sites that are Destination sites of a Distribution Subordinate site.



Distributing a codelist or protocol

You distribute a codelist or protocol when you want to:

- Distribute the codelist or protocol for the first time.
- Distribute a revision of the codelist or protocol.
- Distribute a codelist or protocol from a Distribution Subordinate site to another Distribution Subordinate site.

Note: When you distribute a protocol for which clinical data tables are installed, the clinical data tables are not distributed to Distribution Subordinate sites. After accepting the protocol for the first time, you must compile rules and derivations, and install database tables for the panels in the protocol at each Distribution Subordinate site. When accepting revisions, you only have to compile rules and derivations and install database tables for newly created panels. For information about compiling rules and derivations or installing panels, see the *Design* section of *Admin and Design*.

Locking and distribution

In a Multisite environment, a protocol lock is not distributed. You must use Design to lock a distributed protocol at each site. A locked protocol cannot accept distributed metadata changes. You must unlock the protocol at each site before it can accept the changes.

After distributing an object, you must accept the object. For information about accepting objects, see page 82.

Distributing a protocol in a replication environment

When preparing a replication environment, you must distribute a protocol directly from a Replication Master site to each Replication Subordinate site.



Caution: If you distribute a protocol to a Distribution Subordinate site from a site that is not the Replication Master site for that protocol, the Distribution Subordinate site cannot participate in replication for the protocol.

Distributing multiple objects at the same time

You can select multiple codelists or multiple protocols to distribute at the same time. When you select multiple codelists or multiple protocols, in the Distribute Codelists dialog box or the Distribute Protocols dialog box, you must indicate whether you want to distribute the codelists or protocols to all the sites with the Distribution Status of Distribution Pending, or to a set of selected sites.



Caution: If you distribute the codelists or protocols to all sites with the Distribution Status of Distribution Pending, the codelists or protocols are not distributed to sites with a Distribution Status of Not in Distribution. Therefore, selecting this option is only useful when sending out revisions of previously distributed objects.

If you are distributing the codelists or protocols for the first time, you are prompted to enter the revision information for each codelist or protocol.

Distributing a codelist or protocol for the first time

When you distribute a codelist or protocol for the first time:

- The site from which you distribute the object becomes the Distribution Master site for the codelist or protocol.
- All sites to which you distribute the object become Distribution Subordinate sites.
- You can distribute the object from the Distribution Master site to additional Distribution Subordinate sites at any time.



Caution: Because canceling changes when revising a protocol in distribution can result in data loss, the Distribution Master site should not be part of a replication environment for the protocol. Only Distribution Subordinate sites should be part of a replication environment for a protocol. For information about replication environments, see Chapter 5.

When you distribute a codelist or protocol for the first time, you:

- Enter a Revision number, which can be any numeric value or character.
- Optionally, enter a Description of the revision.
- Select one or more Destination sites.
Only sites that you have registered for distribution are listed. For information about registering sites for distribution, see page 54.
Because this is the first time you are distributing the object, all the listed sites have a status of Not in Distribution. For information about Distribution Statuses, see page 81.

The sites to which you distribute the object become Distribution Subordinate sites automatically for the codelist or protocol.

Distributing a revision of a codelist or protocol

You distribute a revision of a codelist or protocol after you have:

1. Opened the object for revision, as described on page 84.
2. Modified the object using Design.
3. Closed the object for revision, as described on page 85.

You then distribute the revision of the codelist or protocol to all those Distribution Subordinate sites that you select to have a revision of the object.



Caution: When you distribute a revision of a codelist or protocol, you must distribute the revised object to all of the existing Destination sites before you can open the codelist or protocol for another revision. For information about opening a codelist or protocol for revision, see page 84.

When you distribute a revision of a codelist or protocol, you select one or more Destination sites. You do not enter a Revision Number or Description, because you entered this information when you closed the revision.

You can select any Destination sites with a status of Not in Distribution or Distribution Pending. For information about Distribution Statuses, see page 81.

After distributing a revision of a codelist or protocol, you must accept the revision at each Destination site, as described on page 82.

Distributing a protocol using Central Coding

When you distribute a protocol from the Distribution Master site to Distribution Subordinate sites, Central Coding information will be the same. This includes the coding Dictionary information, as well as the value of the CC_HOST parameter.

Note: All Subordinates and the Master of the protocol must use the same Central Coding server.

In order to accept the protocol distribution at a subordinate site, the dictionary definition must already exist there. If not, you will get an Accept error. However, the Clintrial software does not check whether the Targets, Associated Items and Type are consistent with the existing definition.

Distributing a codelist or protocol from a Distribution Subordinate site

When you distribute a codelist or protocol from a Distribution Subordinate site, that site becomes a Source site in relation to the sites to which you are distributing the object.

You distribute a codelist or protocol from a Distribution Subordinate site after you have accepted the object at that site.

When you distribute a codelist or protocol from a Distribution Subordinate site, you select one or more Destination sites. You do not enter a Revision Number or Description, because you entered this information at the Distribution Master site.

You can select any Destination sites with a status of Not in Distribution or Distribution Pending. For information about Distribution Statuses, see the next section.

After distributing a codelist or protocol from a Distribution Subordinate site, you must accept the object at each Destination site, as described on page 82.

Distribution Statuses

The following table lists and describes the possible Distribution Statuses:

Distribution Status:	Description:
Not in Distribution	<p>The selected codelist or protocol has not been distributed to the site. You can distribute the object to a site with this status.</p> <p>Note: If an object of the same name has been distributed to the site from a different Source site, the site's Distribution Status for the selected codelist or protocol is Not in Distribution. You cannot distribute an object to a site in these circumstances.</p>
Distribution Pending	<p>The selected codelist or protocol has been previously distributed to the site. However, the revision of the object at the Source site is more current than the revision of the object last sent to the Destination site. You can distribute the latest revision of the object to a site with this Distribution Status.</p>
Up to Date	<p>The most current revision of the codelist or protocol has been distributed to the site. You do not need to distribute the object again, and you cannot select a site with this Distribution Status.</p>

Note: The Distribution Status does not reflect the Acceptance Status of the codelist or protocol at the Destination site. For example, a protocol can have a Distribution Status of Up to Date, but not be accepted at the Destination site. For information about Acceptance Statuses, see page 83.

After distributing a codelist or protocol

After you distribute a codelist or protocol:

- The Distribution Status for the Destination site changes to Up to Date.

- You must accept the codelist or protocol at each Destination site, as described in the next section.
- You cannot modify the codelist or protocol at a Distribution Subordinate site. You can only modify the codelist or protocol at the Distribution Master site if you open the object for revision. For information about opening objects for revision, see page 84.

Accepting a codelist or protocol

You accept a codelist or protocol at the sites to which you distributed the object, that is, at the Destination sites. Accepting a codelist or protocol stores the object at the Destination site.

Accepting codelists

If a codelist of the same name already exists at a Destination site when you try to accept a distributed codelist:

- If the code type and value type of the two codelists are the same, you are prompted to indicate whether you want the distributed codelist to overwrite the existing codelist.
- If the code type or value type of the codelists is different, and the codelist is not referenced by clinical data, you are prompted to indicate whether you want the distributed codelist to overwrite the existing codelist. If the codelist is referenced by clinical data, you cannot overwrite the existing codelist.

If you choose not to overwrite the codelist, the Acceptance Status of the distributed codelist remains Pending at the Destination site.

Accepting subset codelists

You cannot accept a subset codelist unless the base codelist already exists at the site. If you try to accept a subset codelist before the base codelist exists at the site, a distribution error is recorded, and the Acceptance Status becomes Error. When the base codelist exists at the site, you can accept the subset codelist. For information about distribution errors, see page 90.

Accepting protocols

You must accept a protocol at a site before that site can become part of a replication environment for that protocol and participate in replication. If you are accepting a revision of a protocol that is in replication, the Replication Status of the protocol must be Halted. For information about replication, see Chapter 5.

You cannot accept the initial distribution of a protocol at a Destination site at which a different protocol with the same name already exists.

When you accept a protocol at a Destination site for the first time, you must select a Data Space and Index Space for the protocol. For information about Data Space and Index Space for protocols, see *Admin and Design*.

Note: When you accept a protocol for the first time, you must compile rules and derivations, and install database tables for panels in the protocol. When accepting revisions, you only have to compile rules and derivations and install database tables for newly created panels. For information about compiling rules and derivations or installing panels, see *Admin and Design*.

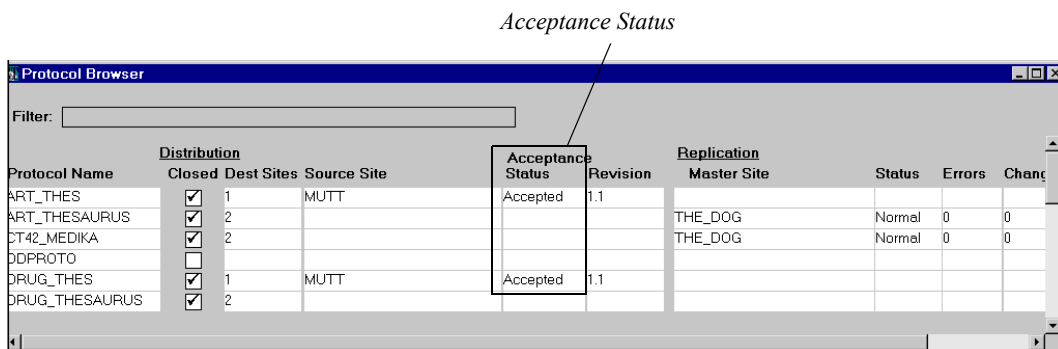
Accepting multiple objects

You can select multiple codelists or multiple protocols to accept at the same time.

When you accept multiple protocols for the first time, you are prompted to select the Data Space and Index Space for each protocol.

Acceptance Status

The Acceptance Status of a codelist or protocol appears in the object's browser, as shown in the following figure:



The following table lists and describes the possible Acceptance Statuses:

Acceptance Status:	Description:
Pending	The most recently distributed revision of the codelist or protocol has not been accepted at this Destination site.
Accepted	The most recently distributed revision of the codelist or protocol has been accepted at this Destination site.
Error	Acceptance of the most recently distributed revision of the codelist or protocol has been attempted at this Destination site, with one or more errors.
(blank)	The codelist or protocol is at its Distribution Master site, or is not in distribution.

After accepting a codelist or protocol

After you accept a codelist or protocol:

- At the Destination site, the Acceptance Status of the object changes to Accepted.
- The latest distributed revision of the object is stored at the Destination site.
- You cannot modify the object at the Destination site, unless you detach the site from the Source site. For information about detaching a site from its Source site, see page 95.
- If you plan to use the protocol at the Destination site to collect clinical data, either at this site alone or as part of a replication environment, you must compile rules and derivations and install database tables for the panels in the protocol. For information about compiling rules and derivations or installing panels, see *Admin and Design*. For information about replication environments, see Chapter 5.

Opening a codelist or protocol for revision

You open a codelist or protocol for revision at the Distribution Master site for the object. When you open a codelist or protocol for revision, a snapshot is taken of the object.

A *snapshot* is information about the codelist or protocol metadata that is captured at the time that you open the object for revision. The snapshot is used when:

- You compare revisions of codelists or protocols. When you compare revisions, Multisite generates information describing the differences between the snapshot and the revised object. For information about comparing revisions, see page 93.
- You cancel changes. When you cancel changes, the codelist or protocol uses the snapshot to revert the object back to its state when you opened it for revision. For information about canceling changes, see page 88.



Caution: You can only open an object for revision if you have distributed the latest revision of the object to all existing Destination sites, or if you have not distributed the object to any Destination sites since you last closed the object for revision.

After you open a codelist or protocol for revision, you can:

- Use Design to modify the object.
- Compare the modified version of the object to the previous released version. For information about comparing object versions, see page 93.
- Cancel the changes to the object at any time to revert the object back to its state when you opened it for revision. For information about canceling changes, see page 88.
- For protocols, backload data, as described on page 86.

When you have finished making revisions to the object, you must close the object for revision, as described in the next section, before you can release the revised object to the Destination sites.



Caution: If a protocol is in replication, and the Distribution Master site is in the replication environment (which is not recommended) you cannot open the protocol for revision unless you first halt the protocol. For information about halting a protocol, see page 123.

Closing a codelist or protocol for revision

You close a codelist or protocol for revision at the Distribution Master site for the object. You must close a codelist or protocol for revision before you can distribute a revised version of the object.

When you close an object for revision:

- You enter a Revision Number, which can be any numeric value or character that you have not previously used for a revision of the object.
- You can optionally enter a Description of the revision.

- A comparison is made automatically between the snapshot and the modified object.

After you close a codelist or protocol for revision:

- You cannot modify the object.
- You can view the comparison reports. For information about comparison reports, see page 93.
- You can backload data into the protocol for testing purposes. For information about backloading data, see “Backloading data” on this page.
- You can cancel the changes to the object. For information about canceling metadata changes, see page 88.
- You can distribute the revised version of the codelist or protocol. For information about distributing codelists and protocols, see page 77.

Comparing revisions of a codelist or protocol

As described in the previous section, when you close a codelist or protocol for revision, a comparison between the snapshot and the revised object is made automatically.

You can also compare the snapshot and the revised object interactively any time between opening and closing the object for revision.

When you compare revisions of an object, Multisite generates information describing all the differences between the snapshot and the revised version of the object. You can then view this information in the comparison reports. For information about comparison reports, see page 93.

Backloading data

Backloading data is the process of copying clinical data in a protocol at a Destination site into the protocol at the Source site for testing purposes. You backload data while logged in to the Source site. You can backload all the data in a protocol, or a subset of that clinical data. The Destination site that originally stores the clinical data that you backload may or may not be part of a replication environment. You can backload data from update tables or data tables at the Destination site.

A panel must be installed at the Source site before you can backload data.



Caution: You cannot backload data to a Source site that is part of the replication environment for the protocol. For information about replication environments, see page 102.

How you backload data

To backload data, you:

1. Select the Destination site from which you want to backload data.
2. Select the panel(s) into which to backload data.
3. Select the table (UPDATE or DATA) at the Destination site from which to backload data.
4. Optionally, create a SQL restriction to limit the data to backload.

Note: Only data that is screened, verified, or validated (that is, records with a status of 1 or 0) is backloaded to the Source site.

What happens when you backload data?

When you backload data:

- Any existing data in the UPDATE table for the selected panel(s) at the Source site is deleted.
- Data in the selected tables at the Destination site is copied to the UPDATE table for the selected panel(s) at the Source site.

Note: Only screened, verified, or validated data is copied from the Destination site.

- At the Source site, rows are inserted into the Enrollment panel's DATA table for all previously unenrolled subjects for which clinical data is copied.

After backloading data

After you backload data:

- You can test the protocol at the Source site with the clinical data.
- You can continue to revise the protocol metadata at the Distribution Master site, if the protocol is open for revision.
- You can close the protocol for revision, as described on page 85.

Canceling changes

At any point after opening a codelist or protocol for revision and before distributing the revised object, you can cancel the changes made to the object.



Caution: If the Distribution Master site is part of a replication environment for a protocol (which is not recommended), you cannot cancel changes to an object. For information about replication environments, see Chapter 5.

When you cancel the changes, the codelist or protocol reverts to the state it was in when the snapshot of the object was taken, that is, when you opened the object for revision.

You can cancel changes to a codelist or protocol only at the Distribution Master site for the object.



Caution: When you cancel changes to a protocol, clinical data is deleted from database tables when the panel that defined the database tables was:

- Added since the protocol was opened for revision.
- Any items in the panel were created since the protocol was opened for revision.
- Any items in the panel were widened since the protocol was opened for revision.

After you cancel changes to a codelist or protocol, you must open the object for revision again if you want to make further changes to it. For information about opening a codelist or protocol for revision, see page 84.

Tracking distribution

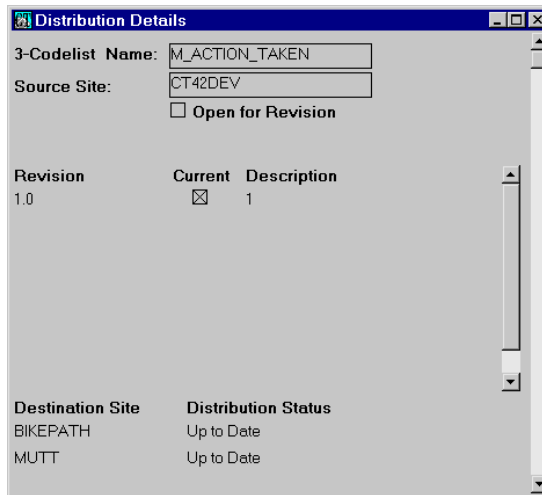
You can track codelists and protocols in distribution by:

- Showing details of the objects in distribution
- Reviewing distribution errors
- Viewing the Release History
- Viewing revision comparisons

Showing details of objects in distribution

When you show details of a codelist or protocol in distribution, you open a window that contains certain read-only information about the selected object.

The following figure shows the Distribution Details window for a codelist. The fields in this window are the same for both codelists and protocols.



The following table lists and describes the fields and columns in the Distribution Details window:

Field or column:	Description:
Protocol Name or Codelist Name	The name of the protocol or codelist at the current site.
Source Site	The site that distributed the object.
Open for Revision	If checked, the object is open for revision at the current site.
Revision	The Revision Number entered when the object was first distributed or closed for revision.
Current	If checked, the specified revision of the object is the one available for use at the current site.
Description	An optional description of the revision.

Field or column:	Description:
Destination Site	Sites to which the object was distributed from the current site.
Distribution Status	Indicates whether the latest revision of the object has been distributed to the Destination site.

Reviewing distribution errors

When you review distribution errors, you open a window that contains certain read-only information about the distribution errors that have occurred at the site at which you are working.

The following figure shows the Distribution Errors window for a protocol. The columns in this window are the same for both codelists and protocols.

Name	Version	Table Name	Error Date	Action	Remarks
MEDIKA_CTX	2	ITEM	01/18/1999 13:54:58	REJECT	Codelist UNITS not found for item DATA.UNITS
MEDIKA_CTX	2	ITEM	01/18/1999 13:54:58	REJECT	Codelist DOSAGE not found for item DATA.DOSAGE

The following table lists and describes the columns in the Distribution Errors window:

Column:	Description:
Name	The name of the codelist or protocol.
Version	The version of the object.
Table Name	The name of the table for which the error occurred.
Error Date	The date and time the error occurred.
Action	The action taken by Multisite. The possible values are: <ul style="list-style-type: none"> REPORT – The distribution was successful, but there may be problems. REJECT – The distribution failed.

Column:	Description:
Remarks	Detailed information about the error. For example, the name of a missing codelist that is associated with an item in a distributed protocol.

Purging the distribution errors

The Distribution Errors window contains a row for each distribution error for the selected protocol or codelist. You can purge all the errors, or selected errors, by using the **Error** menu.

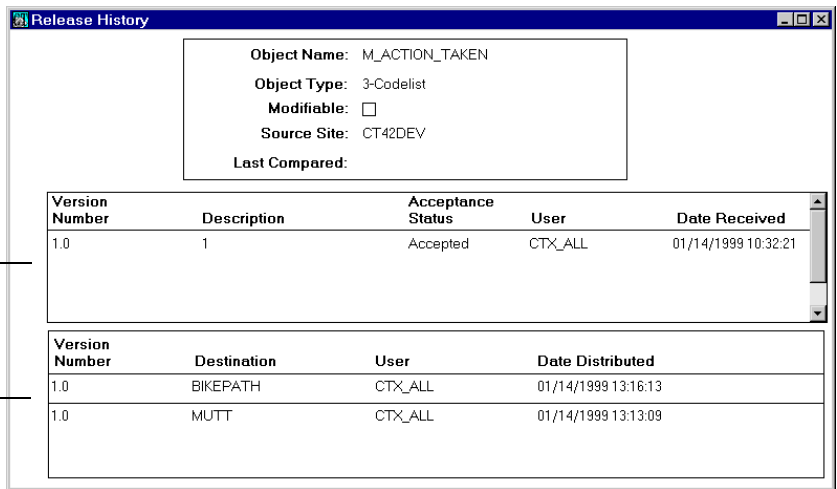
Viewing the Release History

When you view the Release History, you open a window that contains certain read-only information about the revisions of the selected codelist or protocol.

The following figure shows the Release History window for a codelist. The columns in this window are the same for both codelists and protocols.

Information about the acceptance of the object at the current site.

Information about the distribution of the object from the current site.



The following table lists and describes the columns in the Release History window:

Column:	Description:
Object Name	The name of the codelist or protocol for which the report gives a release history.
Object Type	The type of object for which the report gives a release history.
Modifiable	If checked, the current site is the Distribution Master site for the object and the object is open for revision.
Source Site	The site that distributed the object to the current site.
Last Compared	The date and time the object was last compared.
Version Number (one for each row of acceptance history)	The Version Number of the object.
Description (one for each row of acceptance history)	The description of the object.
Acceptance Status (one for each row of acceptance history)	The acceptance status of the object.
User (one for each row of acceptance history)	The user name of the user who accepted the object.
Date Received (one for each row of acceptance history)	The date the object was received from the distribution at the current site (not accepted).
Version Number (one for each row of distribution history)	The version number of the object.
Destination (one for each row of distribution history)	The sites to which the object was distributed.

Column:	Description:
User (one for each row of distribution history)	The user name of the user who distributed the object.
Date Distributed (one for each row of distribution history)	The date the object was distributed.

Viewing revision comparisons

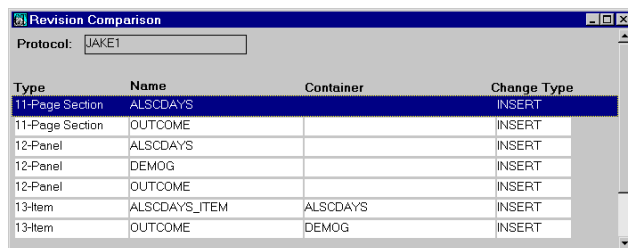
Two different windows provide information about the differences between versions of a codelist or protocol:

- Revision Comparison
- Comparison Details

Both comparison windows display the information generated when a comparison is made, either interactively or automatically, when you close an object for revision, between the current state of the object and the snapshot of the object.

The Revision Comparison Summary window

The following figure shows the Revision Comparison window:



The screenshot shows a window titled "Revision Comparison" with a text field for "Protocol: JAKE1". Below the text field is a table with the following data:

Type	Name	Container	Change Type
11-Page Section	ALSCDAYS		INSERT
11-Page Section	OUTCOME		INSERT
12-Panel	ALSCDAYS		INSERT
12-Panel	DEMOG		INSERT
12-Panel	OUTCOME		INSERT
13-Item	ALSCDAYS_ITEM	ALSCDAYS	INSERT
13-Item	OUTCOME	DEMOG	INSERT

The following table lists and describes the columns in the Revision Comparison window for protocols:

Column:	Description:
Type	The type of object that was updated, created, or deleted.

Column:	Description:
Name	The name of the object that was updated, created, or deleted.
Container	If the object is contained by another object, the name of the container.
Change Type	The type of change to the object. The possible values are: <ul style="list-style-type: none"> • UPDATE – The object was modified. • INSERT – The object was created. • DELETE – The object was deleted.

The following table lists and describes the columns in the Revision Comparison window for codelists:

Column:	Description:
Codelist	The name of the codelist that was modified.
Change Type	The type of change to the object. The possible values are: <ul style="list-style-type: none"> • UPDATE – The object was modified. • INSERT – The object was created. • DELETE – The object was deleted.

The Comparison Details window

To view the Comparison Details window:

1. Select a row in the Revision Comparison Summary window.
2. From the **Distribution** menu, select **Show Details**.
Details of the selected row appear in the Comparison Details window.
3. If required, select a row in the upper part of the window to display more information about the change.

The following figure shows the Comparison Details window for an item:

	INSERTION	NEW
Protocol:	MEDIKA_CTX	
Panel:	DATA	
Item Name:	UNITS	
SAS Name:	UNITS	
Required:	<input type="checkbox"/>	<input type="checkbox"/>
Derived:	<input type="checkbox"/>	<input type="checkbox"/>
Copy with Panel:	<input type="checkbox"/>	<input type="checkbox"/>
Context Type:	Non-context Item	
Data Type:		FIXED
Units:		
DB Format:	NUMBER(5)	
Min Value:		
Max Value:		
Codelist:	UNITS	

Note: The Comparison Details window varies depending on the type of object selected.

Detaching sites

Detaching a site is the process of removing a Destination site from the distribution of a codelist or protocol.

After you have detached a site:

- You cannot distribute revisions of the codelist or protocol to that site.
- The site can no longer participate in replication for the protocol.
- Users can modify or delete the codelist or protocol at that site.
- If you later decide that you want to distribute the protocol to that site, you must delete the protocol that was previously distributed, then distribute the protocol from the Source site as if for the first time.

If you want to delete a codelist or protocol from a site, you must first:

- Detach all Destination sites.
- Detach that site from its Source site.

There are two ways of detaching a site:

- Detaching a Destination site

- Detaching from the Source site

Detaching a Destination site

Detaching a Destination site is the process of removing a Destination site from the distribution of a codelist or protocol while working at the Source site.



Caution: You cannot detach a destination site for a protocol if that site is participating in replication for that protocol. You must first uninvite the site, as described on page 118.

To detach a Destination site:

1. Log in to the Source site.
2. In the Codelist Browser or Protocol Browser, select the object for which you want to detach a Destination site.
3. From the **Distribution** menu, select **Detach Destination**.
The Detach Protocol or Detach Codelist dialog box opens.
4. Select the site to detach from the Destination Site drop-down list and click **Detach**.

Detaching from the Source site

Detaching from the Source site is the process of removing a Destination site from the distribution of a codelist or protocol while working at the Destination site.



Caution: It is recommended that you only use the **Distribution** menu's **Detach from Source** command when you cannot access the Source site. When detaching an object from the Source site, you make the codelist or protocol modifiable at the Destination site. However, you do not change any Distribution information at the Source site. Therefore, if you want to modify or delete the codelist or protocol at the Source site, you must still log in to the Source site and detach the Destination site.

To detach from the Source site:

1. Log in to the Destination site.
2. In the Codelist Browser or Protocol Browser, select the object for which you want to detach the current site.
3. From the **Distribution** menu, select **Detach from Source**.
You are prompted to confirm the detachment.

4. Click **Yes** to detach from the Source site, or **No** to cancel the detachment.

5 *Replication*

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Overview

Replication is the movement of data in a protocol or account among multiple sites. There are two types of replication:

- Protocol replication
- Account replication

What is protocol replication?

Protocol replication is the movement of data in a protocol among multiple sites, allowing users at different sites to work with data in a single protocol. Data entered at different sites moves, or replicates, to other sites that are participating in replication for that protocol. To participate in protocol replication, a site must also participate in distribution for that protocol.

Although you can use distribution in Multisite without using protocol replication, you cannot use protocol replication without using distribution. For more information on distribution, see Chapter 4.



Caution: You cannot use protocol replication at a site unless the CTS account is in replication at that site.

Note: In order to avoid possible problems, Multisite Replication has been disabled for both EDC and hybrid protocols. If Multisite Replication is installed, and either type of protocol is selected, all Replication menu options will be disabled in Multisite. If an existing protocol is put into Replication, and then a synchronization with an InForm protocol is attempted through CIS, the synchronization will abort and an error message will be displayed.

What is account replication?

Account replication is the movement of data in accounts other than protocols among multiple sites. Account replication allows users at different sites to enter and use shared account data. You can set up replication environments for the following accounts:

- CTS account, which contains definitions of flags and notes



Caution: The CTS account must be in replication at all sites at which protocol replication takes place.

- CTCLASSIFY account

- REVIEWADMINGLOBAL account

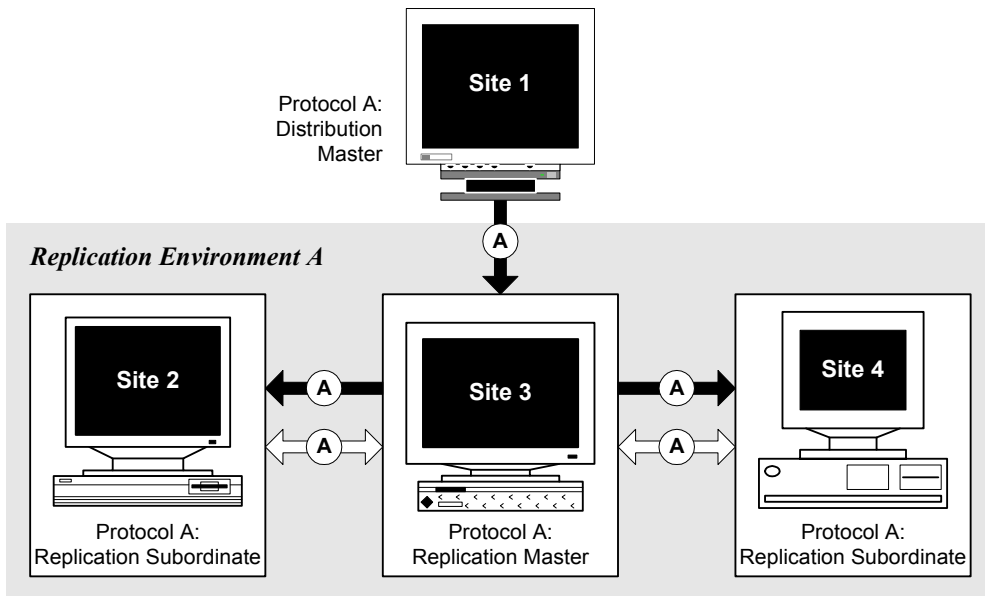
These accounts are created at each site by the server installation, not by distribution.

What is a replication environment?

A *replication environment* is a set of sites within the Multisite environment that participate in replication for a specific protocol or account.

There is one replication environment for each protocol or account in replication. A single site can participate in multiple replication environments for multiple protocols or accounts.

The following figure shows an example of a replication environment:



Sites in a replication environment

A replication environment for a single protocol or account consists of:

- The Multisite Master site
- A Replication Master site

- One or more Replication Subordinate sites, which may be Remote sites

The remainder of this section reviews the definitions of the sites in a replication environment. For information about registering and setting up sites, see Chapter 3.

What is the Multisite Master site?

The *Multisite Master site* is the site at which you register all sites that participate in replication. For more information about registering sites for replication, see page 61.

There is only one Multisite Master site in a Multisite environment.

The Multisite Master site can also be a Replication Master site or Replication Subordinate site in any given replication environment.

The Multisite Master site must be the Replication Master site for the CTS account.

What is a Replication Master site?

A *Replication Master site* is the site in the replication environment that sets up replication for a specific protocol or account, and where trusted data for that protocol or account is stored. For information about trusted data, see page 108.

A Replication Master site does not necessarily own all the data in the protocol or account. If data is entered at a Replication Subordinate site, then uploaded to the Replication Master site, the Replication Subordinate site still owns the data. In this case, the Replication Master site is the central repository for the data, but it cannot modify data that it does not own. For information about data ownership, see page 107.



Caution: Because some tasks that you perform when revising a protocol in distribution can result in data loss, the Distribution Master site should not be part of a replication environment for the protocol. Only Distribution Subordinate sites should be part of a replication environment for a protocol. For information about distribution, see Chapter 4.

The following table lists the tasks that you can perform at a Replication Master site:

Task:	See:
Accept the protocol distributed from a Distribution Master site or Distribution Subordinate site for the protocol.	Page 82
Register the protocol or account.	Page 113
Distribute the protocol to the Replication Subordinate sites.	Page 71
Invite Replication Subordinate sites into the replication environment.	Page 116
Receive uploaded data from all the Replication Subordinate sites in the replication environment.	Page 109
Schedule replication of data to all Replication Subordinate sites in the replication environment.	Page 119
Set replication restrictions for the replication of data to all Replication Subordinate sites in the replication environment.	Page 122
Transfer ownership of data from any site in the replication environment.	Page 121
Halt replication for a protocol or account.	Page 123
Resume replication for a protocol or account.	Page 124

What is a Replication Subordinate site?

A *Replication Subordinate site* is a site in the replication environment that collects data for a specific protocol or account and uploads that data to the Replication Master site.

A Replication Subordinate site has ownership of the data that it enters; however, this data is not trusted until it is successfully uploaded to the Replication Master site. For information about ownership and trusted data, see page 107.

The following table lists the tasks that you can perform at a Replication Subordinate site:

Task:	See:
Accept the protocol distributed from the Replication Master site.	Page 82
Request participation in a replication environment.	Page 115
Enter data for the protocol or account.	<i>Enter, Resolve, and Retrieve</i>
Schedule replication of data to the Replication Master site.	Page 119
Receive downloaded data from the Replication Master site that was entered at other sites in the replication environment.	Page 110
Transfer ownership of records owned at that site.	Page 121
Work with replication errors.	Page 132

What is a Remote site?

A *Remote site* is a site in a replication environment that is not always connected by a network to other sites in the replication environment. Remote sites are always Replication Subordinate sites. A Replication Master site cannot be a remote site.

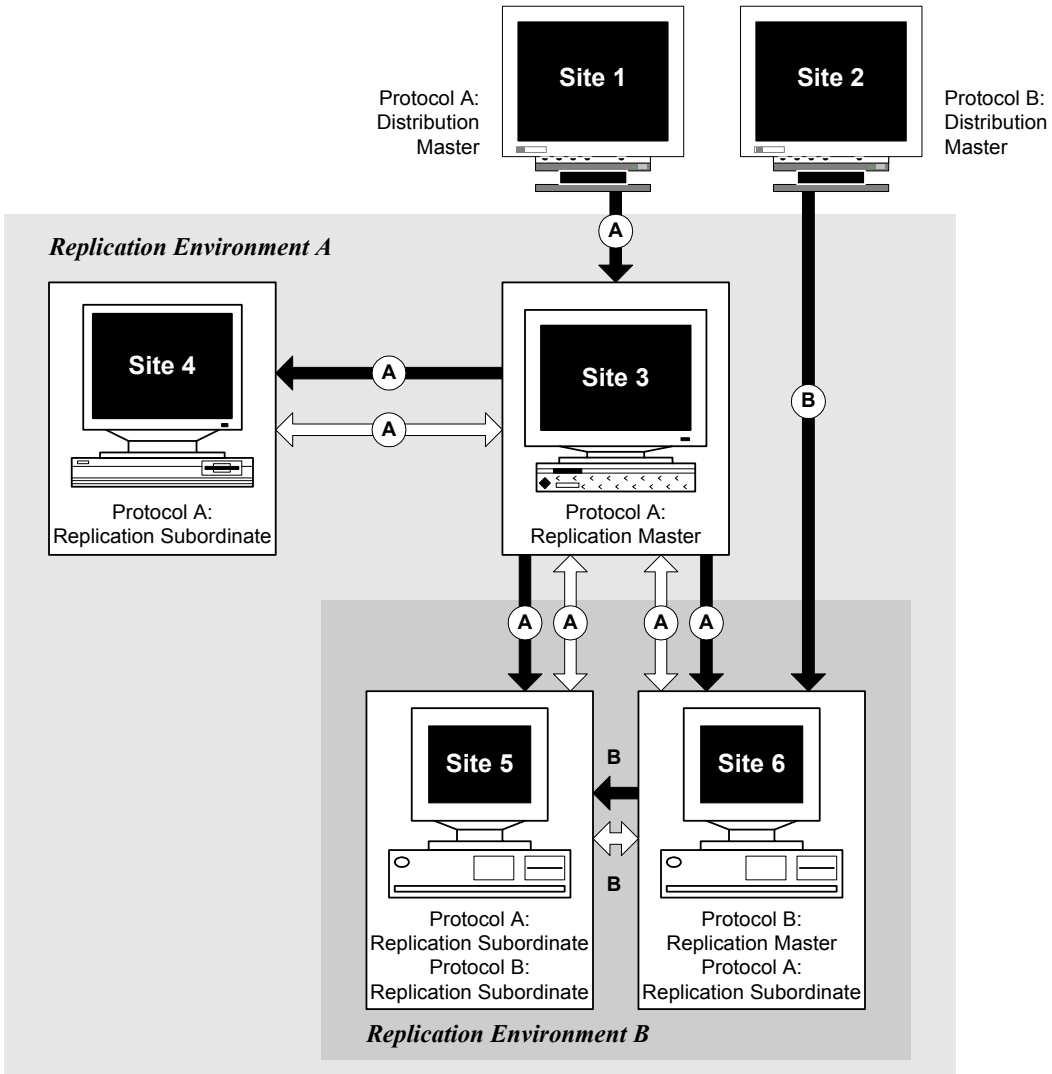
Remote sites replicate data when connected to the network by sending changes, as described on page 120.

Sites of multiple types

A single site can function as multiple types of sites in a Multisite environment. For example, a site can be both a Distribution Subordinate site and a Replication Master site for one protocol. A site can also be a Replication Master site for one protocol, and a Replication Subordinate site for another protocol.

For other examples of Multisite environments, see Appendix B: .

In the following figure, Site 6 is both a Replication Master site for Protocol B and a Replication Subordinate site for Protocol A:



Data in a replication environment

The following two concepts are essential to understanding data in a replication environment:

- Data ownership
- Trusted data

What is data ownership?

Data ownership is the ability of a site in a replication environment to modify or delete data.

You can transfer ownership of subjects, or records in an account, from one site to another site in a replication environment. For information about transferring ownership, see page 121.

Data ownership and protocol replication

In protocol replication, a site originally has ownership of all clinical data for subjects that are enrolled at that site. Only that site can enter or edit data for those subjects.

If the same subject is enrolled at two sites before replication takes place, an error is generated when the second site attempts to replicate data for that subject.

For Type 0 panels, a site has ownership of records entered at the site. All records in an observation must be owned at the same site.

If duplicate grouping items are entered at two sites before replication takes place, an error is generated when the second site attempts to replicate data for that grouping item.

Data ownership and account replication

In account replication, a site has ownership of data, in a table in that account, that is created at that site. For example, if you create a flag definition at Site 2, you can only modify that flag definition at Site 2.

When you set up a replication environment for the CTS account, which contains definitions for flags and notes, the Replication Master site, which is also the Multisite Master site, assumes ownership of the Clintrial software-supplied flag

and note definitions. After you set up the replication environment, you can modify or delete the Clintrial software-supplied flag and note definitions only at the Replication Master site for the CTS account.

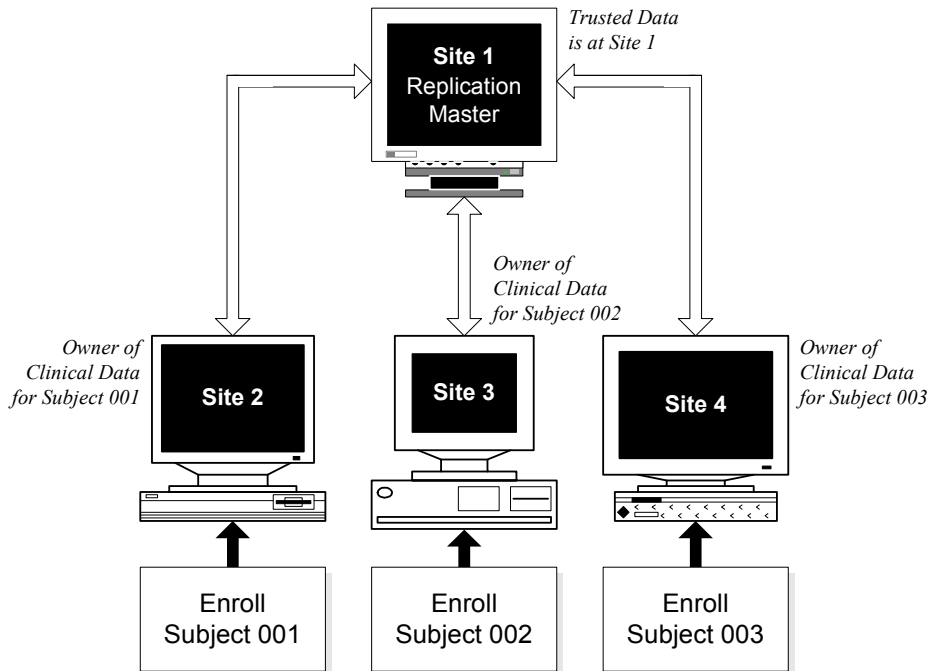
What is trusted data?

Trusted data is data that has been successfully uploaded from Replication Subordinate sites to the Replication Master site, and now resides at the Replication Master site. This data is considered to be *trusted* because the Replication Master site has the most complete and current set of data for the protocol or account of any site in the replication environment.

The Replication Master site does not necessarily have ownership of trusted data; ownership of data belongs to the site in the replication environment where it was entered, unless you transfer the ownership, as described on page 121.

How ownership and trusted data relate

The following figure shows the relationship between ownership and trusted data in a replication environment:



Movement of data in a replication environment

Data in a replication environment moves between sites in two ways:

- Data uploading
- Data downloading

What is data uploading?

Data uploading is the replication of data from a Replication Subordinate site, where the data was entered, to the Replication Master site.

After each Replication Subordinate site in the replication environment has uploaded data:

- The data is stored at both the Replication Subordinate site and the Replication Master site.
- Each Replication Subordinate site has ownership of data entered at that site, unless you transfer ownership of data as described on page 121.
- Data stored at the Replication Master site is considered to be trusted data.
- Data entry can continue at all sites in the replication environment.
- Replication Subordinate sites can continue to upload new or modified data.

What is data downloading?

Data downloading is the replication of data from the Replication Master site to the Replication Subordinate sites in the replication environment.

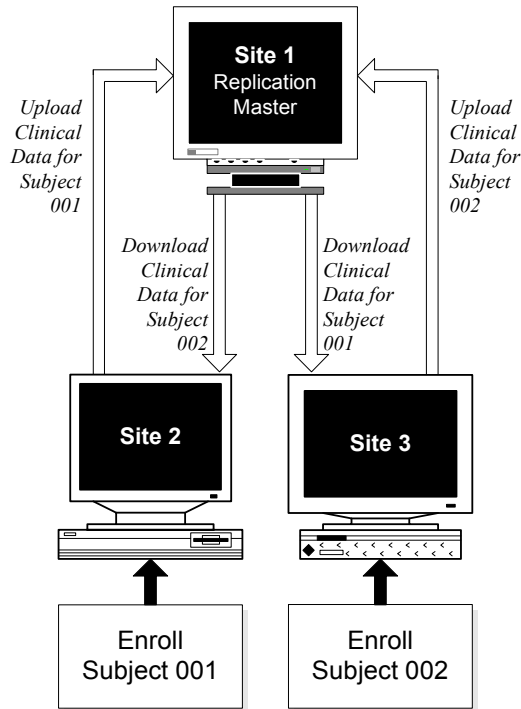
Note: Data is not downloaded to the Replication Subordinate site that entered and uploaded that data, because that site already has a copy of that data.

After data is downloaded from the Replication Master site to each Replication Subordinate site:

- Each Replication Subordinate site stores data entered in the replication environment that you select to have downloaded. However, only the data stored at the Replication Master site is considered to be trusted data.
- Each Replication Subordinate site has ownership of data entered at that site, unless you transfer ownership of data, as described on page 121.
- Each Replication Subordinate site can view data that was entered at other Replication Subordinate sites, if that data was downloaded from the Replication Master site, but it cannot modify this data.
- Data entry can continue at all sites in the replication environment.
- Replication Subordinate sites can continue to upload new or modified data.

Example of uploading and downloading

The following figure shows the uploading and downloading of clinical data for a protocol in a replication environment:



Setting up a replication environment

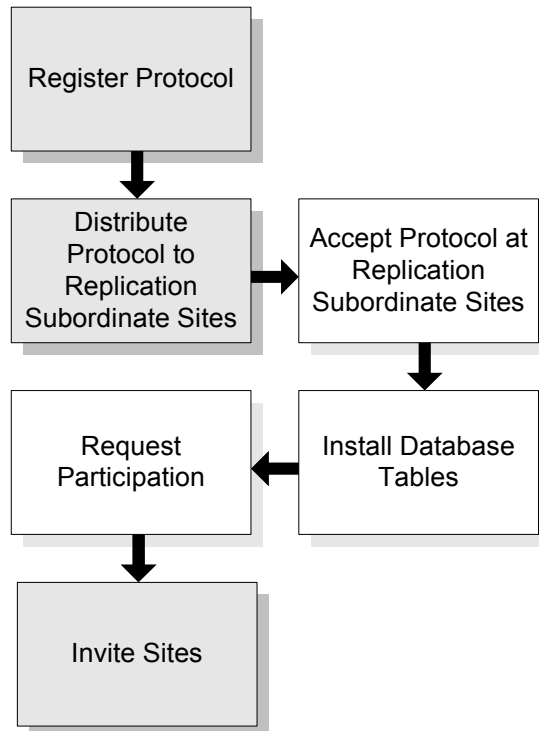
After you set up the Multisite environment, as described in Chapter 3, you set up one or more replication environments.

The following table lists the tasks, in order, that you perform to set up a replication environment, and where to find more information on these tasks:

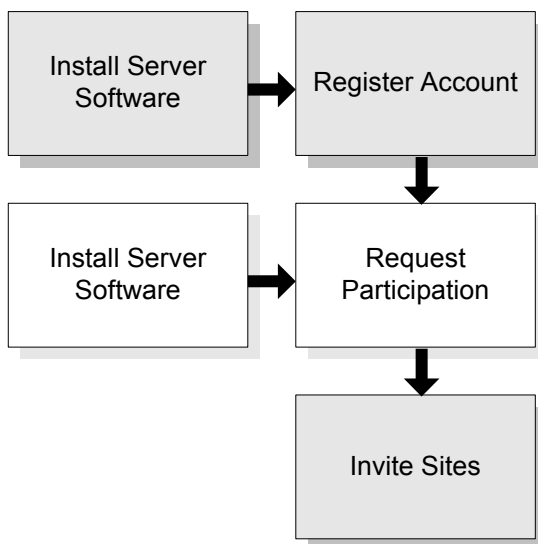
Step:	Task:	See:
1.	Register the protocol or account at the Replication Master site.	Page 113

Step:	Task:	See:
2.	For protocol replication, distribute the protocol from the Replication Master site to the Replication Subordinate sites.	Page 114 and Chapter 4
3.	For protocol replication, accept the protocol at Replication Subordinate sites.	Page 114 and Chapter 4
4.	For protocol replication, install database tables.	<i>Admin and Design</i>
5.	Request participation at each Replication Subordinate site.	Page 115
6.	Invite sites from the Replication Master site.	Page 116

The following figure shows the tasks you complete to prepare a protocol replication environment. You complete tasks in the shaded boxes at the Replication Master site. You complete tasks in the clear boxes at Replication Subordinate sites.



The following figure shows the tasks you complete to prepare an account replication environment. You complete tasks in the shaded boxes at the Replication Master site. You complete tasks in the clear boxes at Replication Subordinate sites.



Registering the protocol or account

Registering the protocol or registering the account is the process of indicating to the Multisite Master site that you want the current site to be the Replication Master site for a selected protocol or account. There can be only one Replication Master site for a protocol or account; therefore, you can only register the protocol or account at a single site.

Note: You can only register the CTS account at the Multisite Master site.



Caution: If the rollback segment at the Replication Master site is too small, registering a protocol may fail and generate an error message. If this occurs, you must increase the Initial and Next extents of the rollback segment. As a guideline, to register the MEDIKA_CLINICAL protocol, the Initial extent of the rollback segment should be at least 2 MB and the Next extent of the rollback segment should be at least 1 MB. For more information, see your Clintrial software administrator.

Before registering a protocol or account

Before you can register a protocol or account at the Replication Master site, the protocol or account must exist at that site. Accounts are created when the Clintrial server software is installed. Protocols must be distributed to and accepted at that site.

Before registering a protocol, you must install database tables for all panels at the site from which you are registering the protocol.



Caution: Because some tasks that you perform when revising a protocol in distribution can result in data loss, the Distribution Master site should not be part of a replication environment for the protocol. Only Distribution Subordinate sites should be part of a replication environment for a protocol. For information about distribution sites, see page 72.

For information about distributing protocols, see page 77.

Failures when registering a protocol or account

If registering a protocol or account fails, the Replication Status of the protocol or account remains Registering. If this occurs, after resolving the problem, you can try registering the protocol or account again without first having to deregister the protocol or account.

Deregistering a protocol or account

Deregistering a protocol or account removes the protocol or account from replication.



Caution: If you deregister the CTS account while protocols are in replication, you risk having an inconsistent set of flag definitions and note classes at different sites.

Distributing protocols in a replication environment

When preparing a protocol replication environment, you must ensure that:

- The Replication Master site is the site that distributes the protocol to all Replication Subordinate sites in the replication environment.
- Each Replication Subordinate site accepts the protocol.
- The revision of the protocol must be the same at all sites in the replication environment.

For information about distributing and accepting protocols, see Chapter 4.

Requesting participation

Requesting participation is the process of indicating to the Replication Master site that you want the current site to be a Replication Subordinate site.

Before requesting participation

Before you can request that a site participate in the replication environment as a Replication Subordinate site, you must:

- Register the protocol or account at the Replication Master site, as described on page 113.
- For protocol replication, distribute the protocol from the Replication Master site to the Replication Subordinate site, then accept the protocol at the Replication Subordinate site. For information about distributing and accepting protocols, see Chapter 4.
- At the Replication Subordinate site, use Design to install database tables for all panels.

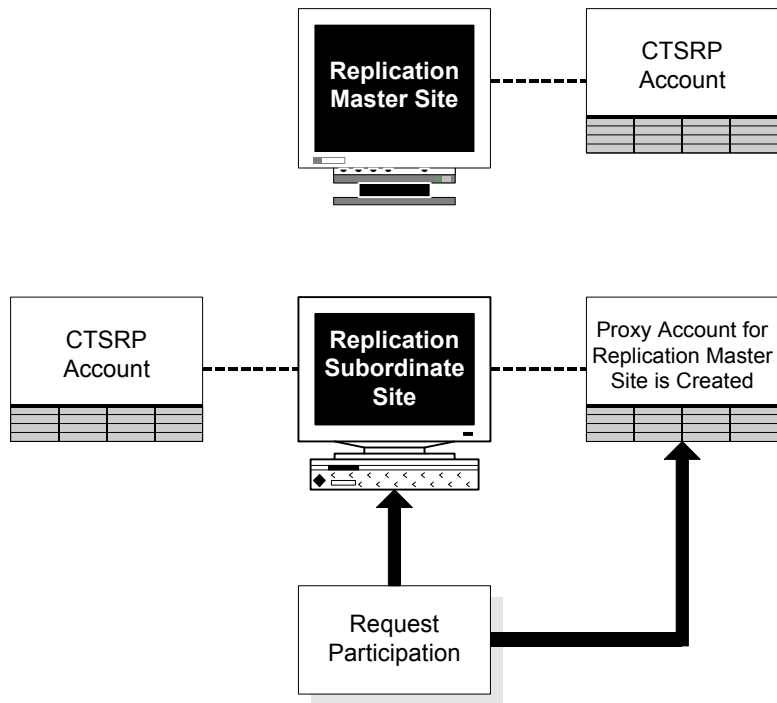


Caution: A site cannot participate in protocol replication unless the CTS account is in replication at that site.

What happens when you request participation?

When you request participation, a proxy account is created at the Replication Subordinate site for the Replication Master site, that is, the site where you registered the protocol or account.

The following figure shows what happens when you request participation:



Inviting sites

Inviting sites is the process of accepting a site's request to be a Replication Subordinate site for the protocol or account. You invite sites from the Replication Master site.

Before inviting sites

Before you can invite Replication Subordinate sites into a replication environment, you must:

- Register the protocol or account at the Replication Master site, as described on page 113.
- For protocol replication, distribute the protocol from the Replication Master site to the Replication Subordinate site, then accept the protocol at the Replication Subordinate site. For information about distributing and accepting protocols, see Chapter 4.

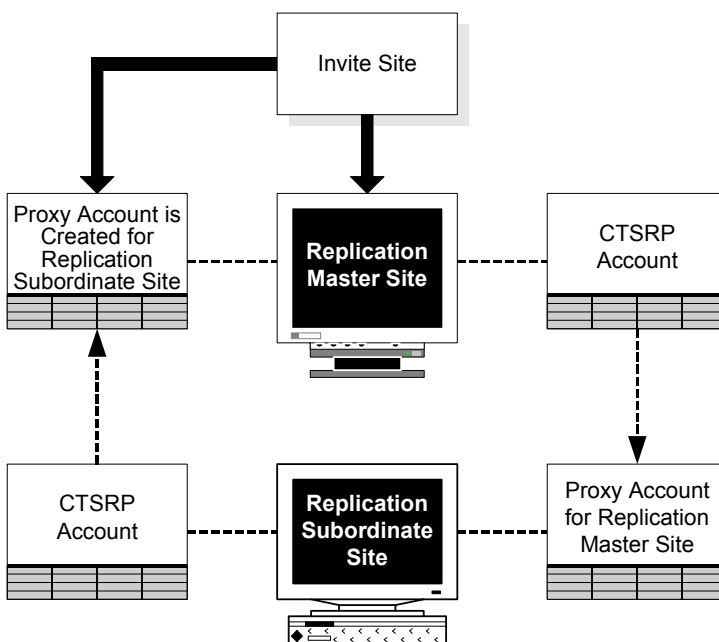
- Request participation from the Replication Subordinate site, as described on page 115.
- Ensure that the Replication Status at the Replication Master site for the protocol or account is Normal. For information about replication status, see page 126.

Before a site is invited into a replication environment for a protocol, data collection can begin at that site. Data stored at the site when that site is invited into the replication environment must be uploaded to the Replication Master site.

What happens when you invite a site?

When you invite a site, a proxy account is created for the Replication Subordinate site that you are inviting.

The following figure shows what happens when you invite a site:



Inviting a site as Read Only

If you check Read Only when inviting a site, users at the site will be able to view data in replication. However, users at the site will not be able to create, modify, or delete data in the protocol or account.

Uninviting sites

Uninviting a site is the process of removing a site from replication for a protocol or account.

When you uninvite a site, records owned by that site are deleted from other sites in the replication environment. However, the site you uninvite still contains records owned by other sites. You can delete these nonlocal records, as described on page 125.

Note: When you uninvite a site from replication for a protocol, deregistering the protocol from replication occurs as follows:

- If the protocol is distributed only to a single site, Multisite deregisters the protocol and the protocol is removed from the Replication Browser at the replication master site.
- If the protocol is distributed to multiple sites, Multisite does not deregister the protocol. You must deregister the protocol at the replication master site, at which time it is deleted from the Replication Browser.



Caution: Do not uninvite a site for the CTS account if the site is in a protocol replication environment, because flags and notes that are created or modified at another site may not become available at the site.

Working with replication

After you have prepared the replication environment, you begin working with replication of a protocol or account in that environment.

The following table describes the tasks that you perform to manage replication. You do not need to perform these tasks in any specific order.

Task:	See:
Scheduling replication	Page 119
Stopping replication	Page 119
Fetching changes	Page 120
Sending changes	Page 120
Transferring ownership	Page 121

Task:	See:
Setting replication restrictions	Page 122
Halting a protocol or account	Page 123
Resuming a protocol or account	Page 124
Modifying the protocol or account password	Page 125

Scheduling replication

Scheduling replication is the process of selecting the time and interval that data replicates between the Replication Master site and a Replication Subordinate site.

At each Replication Subordinate site, you schedule the uploading of new or modified data to the Replication Master site.

At the Replication Master site, you schedule the downloading of data from the Replication Master site to each Replication Subordinate site.

Note: When you install Multisite, the replication schedule for each account or protocol is set to every sixty seconds by default. You may want to modify this replication schedule.

You must schedule replication at each site in the replication environment.

Stopping replication

Stopping replication is the process of canceling a scheduled replication from one site to another site in the replication environment.

At each Replication Subordinate site, you can stop the uploading of new or modified data to the Replication Master site.

At the Replication Master site, you can stop the downloading of the data from the Replication Master site to each Replication Subordinate site.

Stopping replication, as opposed to halting the protocol or account, only cancels replication from the site from which you are working. For information about halting a protocol, see page 123.

After you stop replication, there is no scheduled replication to the site(s) that you indicated. To start replication, you must schedule replication. You can also send changes to one or more sites outside of scheduled replication, as described on page 120.

Fetching changes

Fetching changes is the process of making new or modified data in a specific protocol or account replicate immediately from a site in the replication environment to the current site.

If you are logged in to the Replication Master site, you can fetch changes from any Replication Subordinate site. If you are logged in to a Replication Subordinate site, you can fetch changes from the Replication Master site.

You can only fetch changes from another site if the Replication Status is Normal.



Caution: When you fetch changes, the replication schedule is modified at the site from which you are fetching changes. The same interval remains in effect, but the starting time changes to the time when you fetch changes. For example, if the replication interval is set to every hour, and you fetch changes at 3:15 P.M., replication from the site from which you are fetching changes will now occur at 15 minutes past every hour, regardless of the original starting time. For information about scheduling replication, see page 119.

Sending changes

Sending changes is the process of making new or modified data in a specific protocol or account replicate immediately to a site in the replication environment from the current site.

If you are logged in to the Replication Master site, you can send changes to any Replication Subordinate site. If you are logged in to a Replication Subordinate site, you can send changes to the Replication Master site.

You can only send changes to another site if the Replication Status is Normal.

Sending changes to another site in the replication environment does not affect the replication schedule.

Transferring ownership

Transferring ownership is the process of moving ownership, that is, the ability to modify data, from one site to another in a replication environment.

You can transfer ownership only of data is owned by the current site.

For more information on data ownership, see page 107.

Transferring ownership of data in a protocol

When you transfer ownership of data in a protocol from one site to another site:

- You can transfer ownership of all subjects, or data in Type 0 panels, owned at the site.
- You can select subjects for which to transfer ownership. Ownership of all clinical data associated with the selected subjects is transferred.
- For Type 0 panels, you can select primary key values for which to transfer ownership. When you transfer ownership of records grouped in an observation, you must transfer ownership of all the records in an observation. Ownership of all records with the selected primary key values is transferred.

Transferring ownership of data in accounts

When you transfer ownership of data in an account, you transfer ownership of all data in the account owned at a site. You cannot transfer a subset of account data owned at a site.



Caution: You cannot transfer ownership of data in the CTCLASSIFY account.

Forcing the transfer of ownership

From a Replication Master site, you can force the transfer of ownership of data from a Replication Subordinate site to the Replication Master site. Transferring ownership of data owned by a Replication Subordinate site while logged in to the Replication Master site is considered *forced* because you are manipulating data from a site (the Replication Master site) that does not own the data.

To force the transfer of ownership from a Replication Subordinate site, that site must not be currently connected to the network. (If the Replication Subordinate site is connected to the network, you must log in to that site and transfer ownership of data owned at that site.)

When you force the transfer of ownership, you must transfer ownership of all data in the protocol or account owned at the Replication Subordinate site. You cannot force the transfer of ownership of a subset of the data.



Caution: Perform a forced transfer only when there is no alternative. Whenever possible, you should log in to the site that owns the data for which you want to transfer ownership. If you perform a forced transfer, you can get inconsistent data at different sites, because data entry and editing can continue at the Replication Subordinate site until that site is connected to the network.

Ownership transfer for protocols which use Central Coding

If you transfer ownership of a subject from one site to another in a protocol which uses Oracle's Central Coding application, then the coding information will stay the same for all records and not be recoded.

If you transfer ownership of a subject, for which a coding request has been sent to Central Coding, but not yet coded and/or delivered back to Clintrial, then the information will be delivered to the **original** site. That site will not be able to update the information, since it is no longer the owner, and will send a response to Central Coding indicating that the Delivery was unsuccessful. You need to manually clear the WORKFLOW item, so that a new request can be sent from the new owner site.

Note: Oracle recommends that ownership transfer not be done for records pending delivery of coding information.

Note: One of the uses of ownership transfer was to transfer ownership to a central Clintrial coding server, and then transfer back after recoding. This is no longer necessary when using Central Coding.

If you set the AUTOCODE_RECODE_ALL to Yes for the protocol, all records owned by the site will be recoded. Central Coding will see a different "Client Name" and will recode all those requests.

Oracle does not recommend setting AUTOCODE_RECODE_ALL to Yes for protocols using Central Coding.

Setting replication restrictions

Setting replication restrictions is the process of limiting which records or subjects in a protocol are replicated from the Replication Master site to each Replication Subordinate site. Replication restrictions limit which unowned records or subjects a Replication Subordinate site can view.

At a minimum, a Replication Subordinate site always has access to records or subjects owned by that site. At a maximum, a Replication Subordinate site has view access to all records or subjects owned by all other sites in the replication environment.

You set replication restrictions from the Replication Master site for each Replication Subordinate site. When you set a replication restriction for a Replication Subordinate site, only those unowned records that meet the restriction are downloaded to that site.

Note: You cannot set replication restrictions accounts.

If you do not set replication restrictions, all records in a protocol are replicated. If you do set replication restrictions, only those records you select are replicated to the selected Replication Subordinate site.



Caution: Before you can set replication restrictions for a site, you must stop replication to that site. If you do not stop replication to the site, you get an error message when you try to set replication restrictions.

You can review all replication restrictions, as described on page 132.

Halting a protocol or account

Halting a protocol or halting an account is the process of stopping all activity for a protocol or account, and of synchronizing all data in that protocol or account, at all sites in the replication environment. You can only halt a protocol or account from the Replication Master site.

When you halt a protocol or account, no data entry or editing can take place for that protocol or account at any site in the replication environment.

Halting a protocol or account has a greater affect than stopping replication, which affects replication only for the site(s) that you select. For information about stopping replication, see page 119.



Caution: When you halt a protocol or account, the replication schedule is modified at all sites in the replication environment. The same interval remains in effect, but the starting time and date change to the time and date when you halt the protocol or account. For example, if the replication for a protocol is scheduled to occur from each site on the 15th of each month, and you halt the protocol on the 20th, the replication schedule changes to now occur on the 20th of each month. For information about scheduling replication, see page 119.

When you halt a protocol or account:



- The Replication Status changes from Normal, to Halting, to Halted.
Caution: If a replication error exists when you halt the protocol or account, the Replication Status remains at Halting until you resolve the error.
For information about Replication Status, see page 126.
- No actions can be taken on the protocol or account, including data-entry, at any site in the replication environment while data is being synchronized at all sites. Data synchronization includes the uploading of data from all Replication Subordinate sites, and then the downloading of data from the Replication Master site.
- The replication schedule does not change. When you resume replication for the protocol or account, the previous replication schedule remains in effect.

What is synchronization?

Synchronization is the process of ensuring that all new or modified data is uploaded to the Replication Master site and downloaded to each Replication Subordinate site before the protocol or account is halted.

Halting replication and Remote sites

If a Remote site is part of the replication environment, the halting process does not complete until the site is connected to the replication environment and the synchronization process is complete.

Resuming a protocol or account

Resuming a protocol or resuming an account is the process of changing the Replication Status of a protocol or account from Halted to Normal, so that replication can take place according to the most recent replication schedule.

When you resume a protocol or account, the Replication Status at the Replication Master site becomes Normal. The Replication Status at each Replication Subordinate site becomes Resuming, then Normal.

Note: If you halted replication to modify the protocol metadata, and you resume replication without accepting the updated protocol at a Replication Subordinate site, the Replication Status at that Replication Subordinate site remains Resuming, and you cannot enter data at that site.

Note: If you resume a protocol that has panels with uninstalled tables on a Replication Subordinate site, the Replication Status at the subordinate site will remain Resuming.



Caution: When you resume a protocol or account, the replication schedule is modified at the Replication Master site. The same interval remains in effect, but the starting time and date change to the time and date when you resume the protocol or account. For example, if the replication for a protocol is scheduled to occur from each site on the 15th of each month, and you resume the protocol on the 20th, the replication schedule at the Replication Master site changes to now occur on the 20th of each month. For information about scheduling replication, see page 119.

For information about Replication Status, see page 126.

Modifying the protocol or account password

Modifying the protocol or account password is the process of changing the password used to link a protocol or account at a Replication Subordinate site to the protocol or account at the Replication Master site. You modify a protocol or account password from the Replication Subordinate site.

If you modify the protocol or account password using Admin or SQL, and the protocol or account is in replication, you must modify the protocol or account password used in a replication environment.

Deleting nonlocal records

Deleting nonlocal records is the process of deleting an unowned record from the site. You can delete unowned records for an uninvited site. For information on uninviting sites, see page 118.

Locking and replication

You cannot:

- Lock a protocol in a Multisite environment if it is in replication. You must halt the replication before you can lock the protocol.
- Resume a protocol if it is locked. You must unlock the protocol before you resume it.

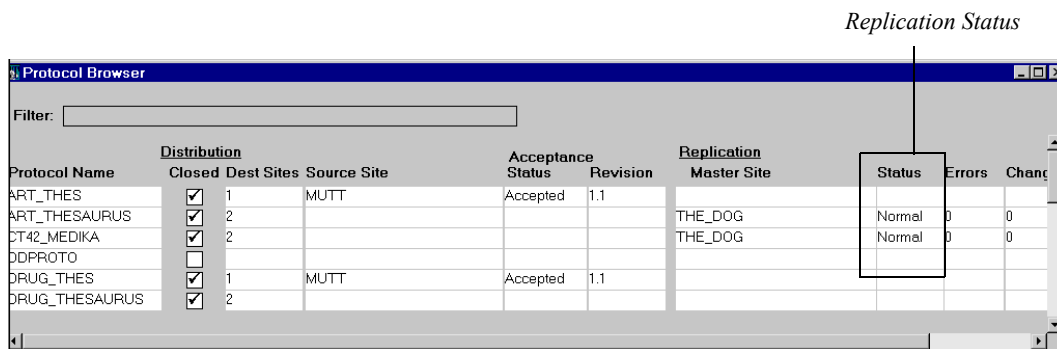
While a protocol is locked, replication commands that manipulate data are unavailable.

Note: A protocol in Locked status cannot accept metadata changes.

Replication Status

A protocol or account in a replication environment has a Replication Status that indicates where the protocol or account is in the replication workflow.

The Replication Status of each protocol at a site is displayed in the Protocol Browser:



What are the possible Replication statuses?

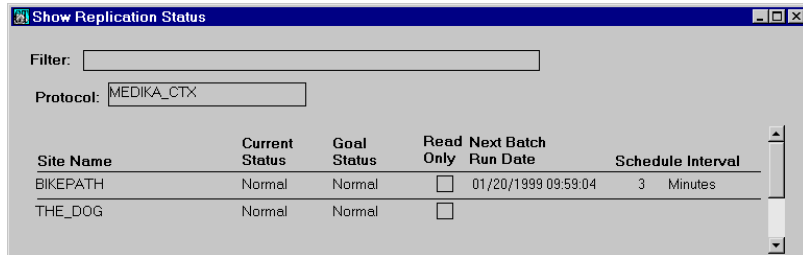
The following table lists and describes the possible Replication statuses:

Replication Status:	Description:
Normal	Data in the protocol or account is replicating according to the replication schedule.
Waiting	After a Replication Subordinate site has requested participation in a replication environment, it is waiting to be invited by the Replication Master site.
Halting	Multisite is synchronizing all data in the protocol or account at all sites in the replication environment.

Replication Status:	Description:
Halted	The protocol or account is halted.
Data Loading	The site was invited, and preexisting data at that site is being uploaded.
Invited	The Replication Subordinate site has been invited by the Replication Master site, but replication has not begun.
Invitation Accepted	The Replication Subordinate site has accepted the invitation from the Replication Master site.
Dropping	The Replication Subordinate site is in the process of being uninvited from the replication environment by the Replication Master site.
Resuming	The protocol or account, which was halted, is in the process of resuming replication.
Master Halting	The Replication Master site is in the process of halting.
Subordinate Halting	The Replication Subordinate site is in the process of halting.
Subordinate Halted	The Replication Subordinate site has halted, and data needs to be synchronized.
Registering	The protocol or account failed to register at the Replication Master site.
Inviting	The Replication Subordinate site is in the process of being invited by the Replication Master site.
Uploading	Preexisting data is being uploaded from the Replication Subordinate site.

Showing site replication statuses

When you show site replication statuses, you open the Show Replication Status window, which contains certain read-only information about replication at each site in the replication environment for the selected protocol or account:



The following table lists and describes the columns in the Show Replication Status window:

Column:	Description:
Site Name	The name of the site specified during the core server installation.
Current Status	The status of replication at the site. For a list of possible Replication Statuses, see page 126.
Goal Status	The goal status of replication at the site: <ul style="list-style-type: none"> • Halted – If the protocol or account has been halted and synchronization is not complete. • Normal – If the protocol or account has been resumed.
Read Only	Indicates if the site has been invited into the replication environment as a read-only site.
Next Batch Run Date	The next date and time that replication is scheduled to run from the site.
Schedule and Interval	The scheduled interval for replication from the site.

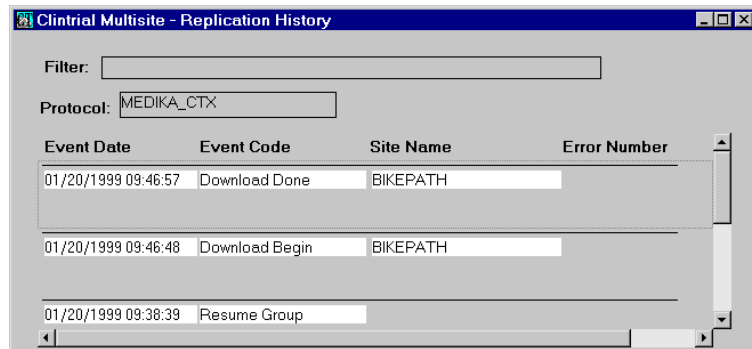
Reviewing replication history and restrictions

You can review the following information about replication of a specific protocol or account:

- Replication history
- Replication restrictions

Reviewing replication history

Replication history is information about replication activity for the selected protocol or account. The following figure shows the Replication History window:



Event Date	Event Code	Site Name	Error Number
01/20/1999 09:46:57	Download Done	BIKEPATH	
01/20/1999 09:46:48	Download Begin	BIKEPATH	
01/20/1999 09:38:39	Resume Group		

What is in the Replication History window?

If you are working from a Replication Subordinate site, the Replication History window contains information about data that is uploaded to the Replication Master site for the selected protocol or account.

If you are logged in to the Replication Master site, the Replication History window contains information about data that is downloaded to the Replication Subordinate sites for the selected protocol or account.

Each row in the Replication History window describes a specific replication event.

The following table lists and describes the columns in the Replication History window:

Column:	Description:
Event Date	The date and time that the replication activity started.
Event Code	A brief description of the status of the replication event. The Event Codes are listed following this table.
Site Name	The name of the site to which data was replicated from the current site.
Error Number	The Clintrial software or Oracle error code.

What are the Event Codes?

The following table lists and describes the Event Codes that can be displayed in the Replication History window:

Event Code:	Description:
Accepting Invitation	A Replication Subordinate is accepting the invitation.
Accepted Invitation	A Replication Subordinate has accepted the invitation.
Clear Errors	An error that occurred during the uploading of data is being cleared. (See the Error Number field for the number of the error being cleared.)
Download Begin	The Replication Master site has started downloading data to the Replication Subordinate site.
Download Done	The Replication Master site has completed downloading data.
Download Error	There was an error during the downloading of data. (See the Error Number field.)
Download While Halting	An error occurs because a download is occurring while the protocol is halted.
Drop Client	The Replication Master is disinviting a Replication Subordinate.

Event Code:	Description:
Dropping	A Replication Subordinate is accepting the disinvitation from the protocol.
Finishing Invitation	A Replication Subordinate has completed the invitation process.
Halt Client	The data has been synchronized among all sites in the replication environment, and the protocol is halted.
Halt Group	The Replication Master site has halted the protocol or account and is waiting while data is synchronized at all sites.
Halting	A Replication Subordinate is halting.
Initial Download	The Replication Master site is downloading data to a Replication Subordinate.
Initial Uploading	A Replication Subordinate site is uploading data to the Replication Master after the invitation.
Redo Download Errors	Following an error on the previous attempt, the Replication Master site is trying to download data again.
Redo Upload Errors	Following an error on the previous attempt, the Replication Master site is trying to upload data again.
Resume Client	A Replication Subordinate is resuming.
Resume Group	The Replication Master site has resumed replication for the protocol or account.
Upload	A Replication Subordinate site has started uploading data to the Replication Master site.
Upload Done	The Replication Subordinate site has completed uploading.

For a listing of the abbreviations for these codes, as stored in the CTSRP.REPAUDIT table, see the *Reference Guide*.

Purging the replication history

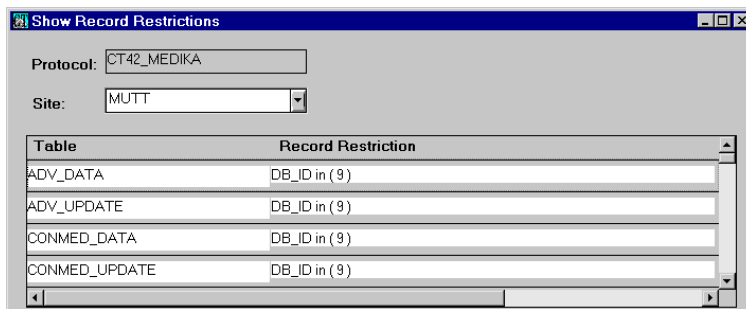
You use the Purge command to delete rows from the Replication History window with a date prior to the date you enter.

Reviewing replication restrictions

Replication restrictions are SQL clauses that you create to select a subset of records in a protocol for replication. You set replication restrictions from the Replication Master site for each Replication Subordinate site.

You review replication restrictions at the Replication Master site.

The following figure shows the Show Record Restrictions window:



The following table lists and describes the columns in the Show Record Restrictions window:

Column:	Description:
Table	The table in the selected protocol.
Record Restriction	The SQL clause used to create the restriction.

Working with replication errors

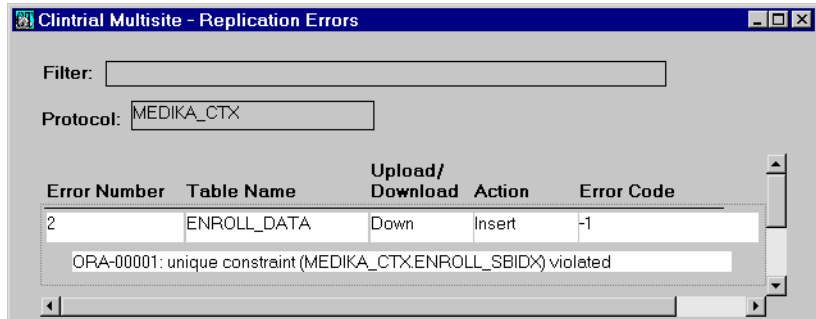
You can review errors that occurred during replication.

Replication errors, whether they occurred during uploading or downloading, are recorded at the Replication Subordinate site that participated in the replication, because the data stored at the Replication Master site is presumed to be correct.

Replication Errors window

Replication errors are displayed in the Replication Errors window. Each row in the Replication Errors window describes a specific replication error.

The following figure shows the Replication Errors window:



The following table lists and describes the different columns of information in the Replication Errors window:

Column:	Description:
Error Number	The number that identifies the replication error.
Table Name	The name of the table for which the replication error occurred.
Upload/Download	Indicates whether the error occurred during uploading or downloading.
Action	Indicates the action that caused the replication error.
	Insert indicates that the error occurred when the replication attempted to add a new row of data.
	Update indicates that the error occurred when the replication attempted to modify an existing row of data.
	Delete indicates that the error occurred when the replication attempted to delete an existing row of data.

Column:	Description:
Error Code	The Oracle or Clintrial software error number reported for the number.

Working with replication errors

When reviewing replication errors, you can do the following:

- Retry the upload, for errors in replication of data from the Replication Subordinate site to the Replication Master site.
- Retry the download, for errors in replication of data from the Replication Master site to the Replication Subordinate site.
- Remove the error record, to have Multisite no longer try to replicate the record.



Caution: You can only remove duplicate records or records no longer owned at the current site. When you remove a duplicate or unowned record, the record remains at the site. For more information on working with duplicate errors, see the next section.

Working with duplicate errors

If the same subject is enrolled at two different sites, or the same records are entered in a Type 0 panel, before replication takes place, a unique constraint error is generated when the second instance, or duplicate, of the subject or record replicates.

Note: Duplicate errors may also be the result of Oracle environment problems.

To resolve duplicate errors, you must log in to one of the two sites that contains the subject or record, and use global change or global delete in Manage to change the subject identifier or grouping item value so that the subject or record is not a duplicate.

Replication Environment Report

The Replication Environment Report displays the names of all replicating protocols and replicating accounts in a Multisite system, and their master site.

To run this report, log in to the Multisite Master site and from the **Reports** menu, select **Replication Environment**.

6

Working with Functions and Base Tables

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Overview

Multisite enables you to send functions and base tables from one site to another site in a Multisite environment.



Caution: Modifications to functions and tables that you copy to other sites are neither controlled nor tracked as they are for protocols and codelists in distribution.

Working with functions

You can send customized functions from one site to another site in a Multisite environment.

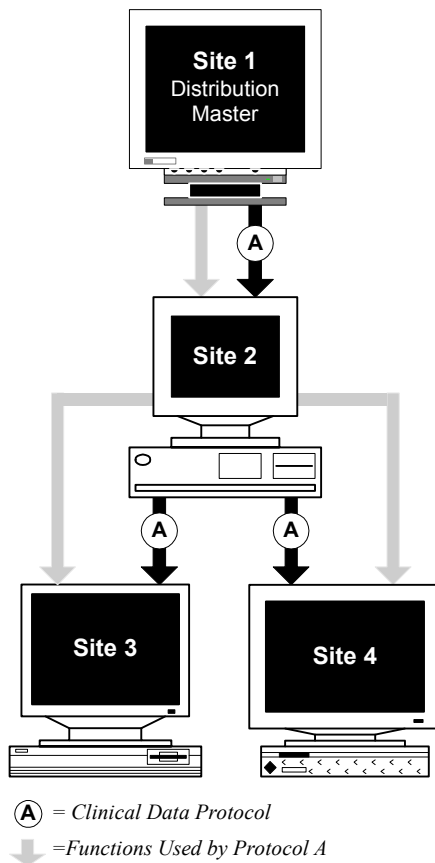
Note: In this chapter, and in the Multisite user interface, the term function is used to refer to a PL/SQL stored *function*, *procedure*, or *package*. However, where the distinction between these different types of database objects is essential, the specific type of object is identified.

You may want to send functions from one site to another site if you have distributed a protocol that contains rules, derivations, or data-entry processing procedures that use functions you created at the Source site.



Caution: You cannot use Multisite to work with functions larger than 128K.

The following figure shows how you might send functions from one site to another site with a distributed protocol:



Sending functions from a Source site

You can send functions from a Source site only when:

- The functions are owned by the accounts specified in the PROC_ACCOUNT protocol parameter or the PROC_SITE_ACCOUNT system parameter. For information on these parameters, see *Admin and Design*.
- The status of the functions is Valid.
- The account that owns the functions is identical at the Source site and Destination site.
- The Destination site is registered for distribution at the Source site, as described on page 54.

When you send functions, you select the Destination site, the account that contains the functions, and the functions.

Note: You must send the header and body of a package separately.



Caution: Synonyms are not sent with functions. Therefore, you must create the required synonyms at each Destination site. Otherwise, functions that depend on synonyms might not compile at the Destination site, or the object resolution may be incorrect. If object resolution is not correct, run-time errors that are difficult to diagnose are likely to occur.

After you send a function to a Destination site, you must accept that function at that site.

If you send a function to a site to which you already sent a previous version of the function, and that previous version of the function has not been accepted at the Destination site, the most recent version overwrites the previous version. Therefore, when the function is accepted at the Destination site, only the most recent version is accepted.

Accepting functions

You accept functions by using the Accept Functions Browser, which is described on page 39.

Using the Accept Functions Browser, you can accept the function at the Destination site, or delete the function without accepting it.



Caution: If you accept a function that already exists at the site, the most recent version overwrites the previous version. Therefore, you should be careful to use distinct names for functions, so that you do not unintentionally overwrite one function with a different function.

If the account that owns the function does not exist at the Destination site, you cannot accept the function. You must first create the account.

When you accept a function at a Destination site:

- The new function replaces any other version of the function.
- The function is compiled automatically.

Note: You must accept the header of a package first, then accept the body of the package.

Copying base tables

You can copy tables that are used by a thesaurus protocol or a view codelist from one site to another site in a Multisite environment.

When you copy a base table from a Source site, you insert the records in that table into the identical table at the Destination site.



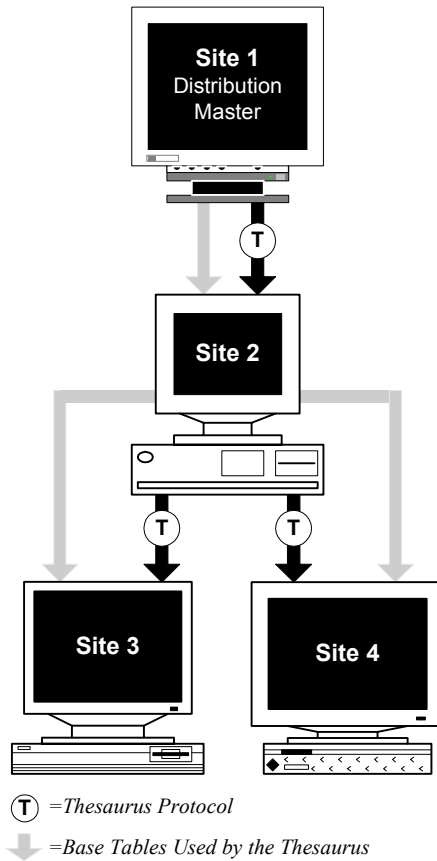
Caution: Before you can copy a base table from a Source site, the account that contains the table, as well as the table itself, must exist at the Destination site.

You can only copy base tables to a Destination site if the associated thesaurus protocol or view codelist has been distributed to that site. However, the thesaurus protocol or view codelist does not have to be accepted at the Destination site.



Caution: There is no acceptance step when you are copying base tables. When you copy the base table to a Destination site, the base table overwrites the table of the same name at that site. Records in the table that existed at the Destination site before you copied the base table are deleted.

The following figure shows how you might copy thesaurus base tables with a distributed thesaurus protocol:



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7

Admin and Multisite

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Overview

This chapter describes how Admin works differently in a Multisite environment, and contains the following sections:

- Users and usergroups
- Access rights and access levels

Users and usergroups

Users and usergroups are not replicated in a Multisite environment. You must define users and usergroups at each site, just as you would in a non-Multisite environment.

Access rights and access levels

This section describes the:

- Access rights and access levels for Multisite
- Access levels for read-only protocols in replication

Access rights and access levels for Multisite

The following table lists and describes the non-protocol access rights and access levels for Multisite:

Access Right:	Access Levels:
Distribute	<p>None — The user or usergroup cannot access any distribution-related windows in Multisite.</p> <p>Read — The user or usergroup can access browsers and read-only windows related to codelist or protocol distribution, or the copying of base tables and functions. The user or usergroup cannot take any distribution-related actions on codelists or protocols, nor can the user or usergroup copy base panels or functions.</p> <p>Full — The user or usergroup can complete all distribution-related tasks for codelists and protocols, and copy base tables and functions.</p>
Replicate	<p>None — The user or usergroup cannot access any replication-related windows in Multisite.</p> <p>Read — The user or usergroup can access browsers and read-only windows related to protocol or account replication. The user or usergroup cannot take any replication-related actions on protocols or accounts.</p> <p>Full — The user or usergroup can complete all replication-related tasks for protocol replication and account replication.</p>

Read-only protocols in replication

If a site in a replication environment for a protocol has been designated as read-only, then you can only assign the access level Read for certain protocol-specific access rights, as follows:

- Enter: Merged and Unmerged access rights
- Manage: Global, Other, Coding

8

Design and Multisite

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Overview

This chapter describes how Design works differently in a Multisite environment, and contains the following sections:

- Working with distributed protocols
- Working with distributed codelists
- Working with flags and notes in a replication environment

Working with distributed protocols

This section describes the following tasks related to working with distributed protocols:

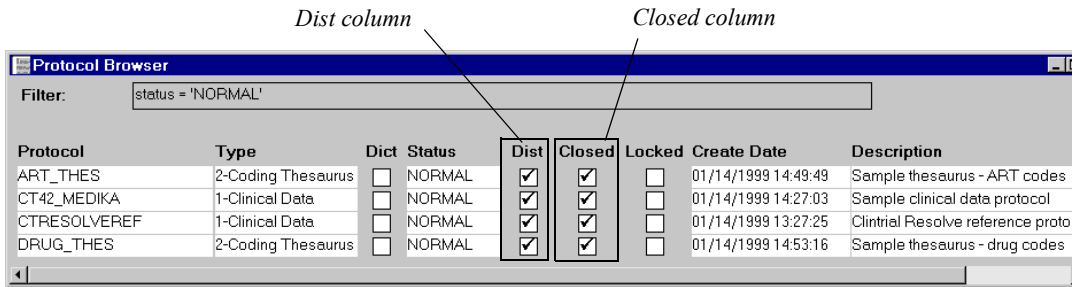
- The Protocol Browser
- Distributing searchlists
- Accepting view protocols
- Modifying protocols
- Deleting protocols
- Installing database tables
- Compiling thesaurus views

The Protocol Browser

The Protocol Browser contains two columns related to distribution:

- The Dist column, which, when checked, indicates that the protocol is in distribution.
- The Closed column, which, when checked, indicates that the protocol is at a Distribution Subordinate site, or that the protocol is at the Distribution Master site and closed for revision.

The following figure shows the Protocol Browser:



Distributing searchlists and parent protocols

When you distribute a protocol, the protocol's searchlist is also distributed. The value of the Parent Protocol attribute is also distributed.

When you accept the protocol at the Destination site, Multisite checks whether the protocols in the searchlist, as well as the Parent Protocol, are present. If protocols in the searchlist are not present at the Destination site, these protocols are deleted from the distributed protocol's searchlist.

If the Parent Protocol is not present at the Destination site, this attribute is cleared for the protocol at that site.

Accepting view protocols

If the base protocol does not exist at a Destination site for a view protocol, an error occurs when you try to accept the view protocol.

Modifying protocols

You can only modify a protocol in distribution, and modify or delete the objects contained in the protocol, at the Distribution Master site. Before you can modify the protocol at the Distribution Master site, you must open the protocol for revision. For information about opening protocols for revision, see page 84 of this guide.



Caution: If you or another user is working with a distributed protocol in Design at the Distribution Master site, when you first distribute the protocol or when you close the protocol for revision, the protocol and the objects it contains can still be modified. The protocol is not unmodifiable until you close all windows and set the protocol.

Deleting protocols

To delete a protocol from a Distribution Subordinate site, you must first detach the site from its Source site. Detaching a site removes the site from distribution for the protocol and enables you to modify or delete the protocol at that site.

You cannot delete a protocol from the Distribution Master as long as the Distribution Master site has Destination sites for the protocol. To delete a protocol from the Distribution Master site, you must first detach all the Destination sites for the protocol.

For information about detaching Destination sites, see page 95 of this guide.

Installing database tables

After you accept a protocol for the first time at each Destination site, you must install database tables for each panel contained in the protocol, even if the database tables were installed at the Source site.

Distributing revisions of protocol

When you distribute a revision of a protocol, you do not have to install panels that existed in the previous revision. These panels remain installed at Destination sites when you accept a revision of a protocol.



Caution: If you add a new panel to the protocol at the Distribution Master site, then distribute the revision, you must install that panel at each Destination site.

Deinstalling panel tables

After you distribute a protocol, you can only deinstall tables for panels if the protocol is not in replication.

Deinstalling panel metadata

After you distribute a protocol, you cannot deinstall metadata for panels contained in the protocol, even if you open the protocol for revision at the Distribution Master site.



Caution: Because you cannot deinstall panel metadata, you cannot delete items in a protocol that is in distribution.

If you must deinstall panels in a distributed protocol:

1. Detach all Destination sites. For information about detaching Destination sites, see page 95 of this guide.
2. Deinstall the panels at the site that was the Distribution Master site and make the necessary panel revisions.
3. Delete the protocol from all the sites that were Distribution Subordinate sites.
4. Distribute the protocol as if you are doing so for the first time.

Compiling validation procedures

When you install database tables at a Destination site after accepting a protocol for the first time, validation procedures are compiled automatically.



Caution: Functions called by rules and derivations are not distributed with protocols. Because validation procedures depend on functions being present at the current site, validation procedures that are valid at a Source site may be invalid at the Destination site. You may have to send functions from the Source site to the Destination site for validation procedures to be valid. For information about working with functions, see Chapter 6 of this guide.

Compiling thesaurus views

For a distributed coding thesaurus protocol, you typically need to take an additional step to create the tables on which the thesaurus views are based at each Distribution Subordinate site.

For thesaurus views based on Clintrial software panels, you must create tables for those panels after you accept the initial distribution of the coding thesaurus protocol. Thesaurus views become valid when you create the tables.

You compile thesaurus views after you accept the initial distribution of the thesaurus protocol, and after you accept each revision of the thesaurus protocol.



Caution: Base tables used by thesaurus views are not distributed with protocols. Because thesaurus views may depend on base tables being present at the current site, thesaurus views that are valid at a Source site may be invalid at the Destination site. You must create tables at the Destination site if they do not exist, then compile the thesaurus views that use the tables. You can also copy base tables from the Source site to the Destination site to ensure that the same data is used for coding at both sites. For information about working with base tables, see Chapter 6 of this guide.

Working with distributed codelists

This section describes the following tasks related to working with distributed codelists:

- The Codelist Browser
- Compiling view codelists and subset codelists
- Modifying codelists
- Deleting codelists
- Deleting codelist values

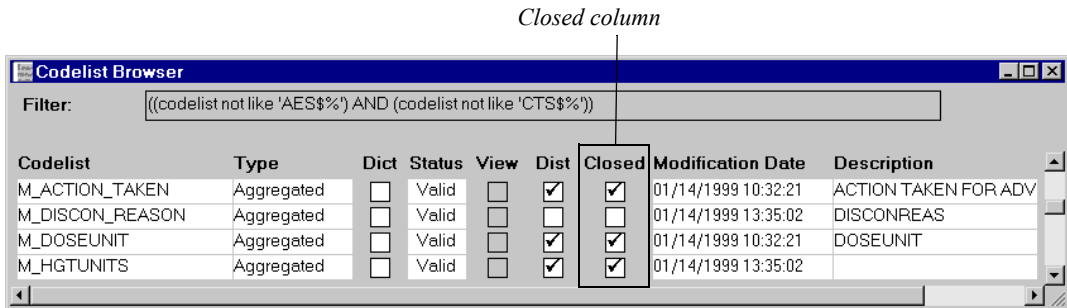
The Codelist Browser

The Codelist Browser contains a Closed column, which, when checked, indicates that the codelist is in distribution. When a codelist is marked Closed, you cannot edit or delete the codelist.

The Closed column is checked for:

- A distributed codelist at a Distribution Subordinate site
- A distributed codelist at the Distribution Master site, except when the codelist is open for revision

The following figure shows the Codelist Browser:



Compiling view codelists and subset codelists

You must compile view codelists and subset codelists at each Distribution Subordinate site. You compile view codelists and subset codelists after you accept the initial distribution of the codelist, and after you accept each revision of the codelist.

If a view codelist is based on a panel, you must import or distribute to the site the protocol containing the panel before compiling the view codelist.



Caution: Base tables used by view codelists are not distributed with codelists. Because view codelists may depend on base tables being present at the current site, view codelists that are valid at a Source site may be invalid at the Destination site. You must create tables at the Destination site if they do not exist, then compile the view codelists that use the tables. You can also copy base tables from the Source site to the Destination site to ensure that the same data is used for view codelists at both sites. For information about working with base tables, see Chapter 6 of this guide.

Modifying codelists

You can only modify a codelist in distribution at the Distribution Master site. Before you can modify the codelist at the Distribution Master site, you must open the codelist for revision. For information about opening codelists for revision, see page 84 of this guide.



Caution: If you or another user is working with a distributed codelist in Design at the Distribution Master site, when you first distribute the codelist or when you close the codelist for revision, the codelist can still be modified. However, once you refresh the Codelist Browser, you can no longer modify the codelist.

Deleting codelists

To delete a codelist from a Distribution Subordinate site, you must first detach the site from its Source site. Detaching a site removes the site from distribution for the codelist and enables you to modify or delete the codelist at that site.

You cannot delete a codelist from the Distribution Master site as long as the Distribution Master site has Destination sites for the codelist. To delete a codelist from the Distribution Master site, you must first detach all the Destination sites for the codelist.

For information about detaching Destination sites, see page 95 of this guide.

Deleting codelist values

For a codelist in distribution, you can only delete codelist values at the Distribution Master site. Before you can delete codelist values at the Distribution Master site, you must open the codelist for revision. For information about opening codelists for revision, see page 84 of this guide.

Note: You cannot delete codelist values for a codelist that is referenced by an item.

When you accept a revision of a codelist for which you deleted codelist values at a Destination site, Design checks whether the codelist is referenced by any items in the database. If the codelist is not referenced by any items, the codelist values are deleted at the Destination site.

If the codelist is used by one or more items at the Destination site:

- The status of the codelist values that were deleted at the Distribution Master site is Invalid.
- The codelist values remain in the database because they may be used by existing clinical data.
- You can no longer use the codelist values when entering or editing clinical data.

Working with flags and notes in a replication environment

This section describes the following tasks related to working with flag definitions and note classes in Design, when the current site is part of a replication environment for the CTS account:

- Ownership of Clintrial software-supplied flags and notes
- Creating flags and notes
- Modifying flags and notes
- Deleting flags and notes

Ownership of Clintrial software-supplied flags and notes

When you set up a replication environment for the CTS account, the Replication Master site assumes ownership of the Clintrial software-supplied flags and notes.

Creating flags and notes

If you create a flag or note at the Replication Master site for the CTS account, the object downloads to all the Replication Subordinate sites in the replication environment for the CTS account.

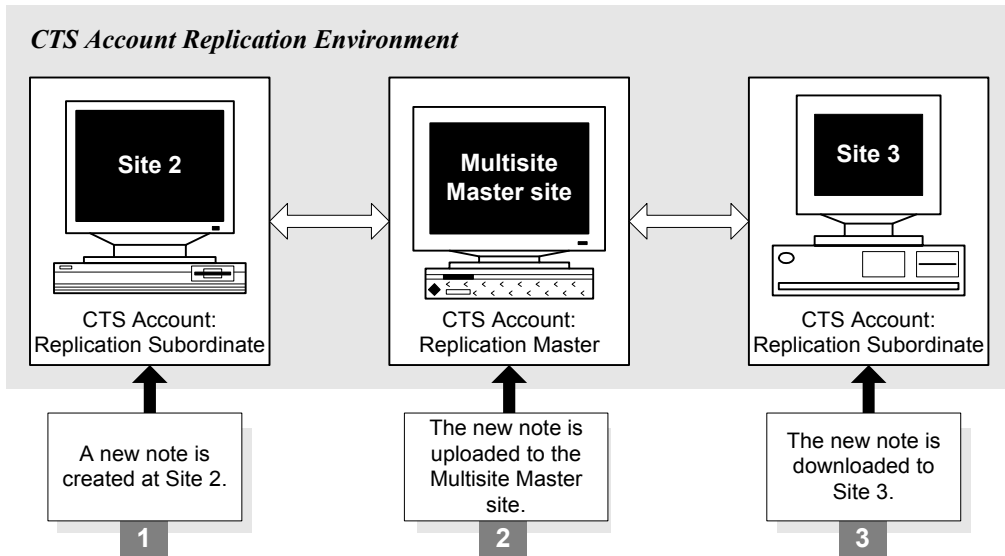
If you create a flag or note at a Replication Subordinate site for the CTS account, the object is uploaded to the Replication Master site. After uploading to the Replication Master site, the new flag or note is downloaded to other Replication Subordinate sites in the replication environment for the CTS account.

Note: The Multisite Master site must be the Replication Master site for the CTS account.



Caution: If a Replication Subordinate site is invited into the replication environment for the CTS account as Read Only, the site cannot create flags or notes.

The following figure shows the uploading and downloading of a new note in a replication environment for the CTS account:



Modifying flags and notes

You can only modify a flag or note in a replication environment for the CTS account at the site that owns the object. You cannot modify a flag or note at any other site in the replication environment unless you first transfer ownership of the object.

When you modify a flag or note, the modifications are uploaded and downloaded in the replication environment just as new flags and notes are replicated.

Deleting flags and notes

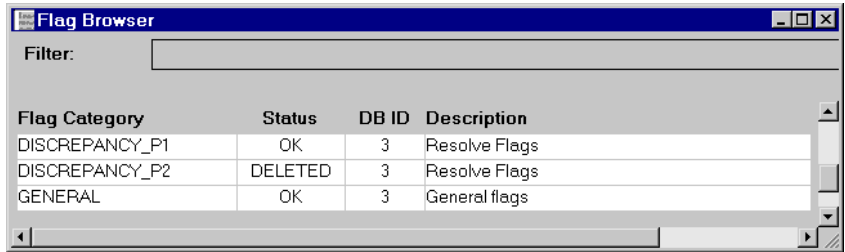
You can only delete a flag or note when the CTS account is in a replication environment at the site that owns the object. You cannot delete a flag or note at any other site in the replication environment unless you first transfer ownership of the object.

When you delete a flag or note:

- The status of the flag or note is Deleted at all sites in the replication environment for the CTS account.

- The flag or note remains in the CTS account because it may be used by existing clinical data.
- You can no longer use the flag or note when entering or editing clinical data.

The following figure shows the Flag Browser, with a deleted flag:



The screenshot shows a window titled "Flag Browser" with a "Filter:" input field. Below it is a table with the following data:

Flag Category	Status	DB ID	Description
DISCREPANCY_P1	OK	3	Resolve Flags
DISCREPANCY_P2	DELETED	3	Resolve Flags
GENERAL	OK	3	General flags

9

Enter and Multisite

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Ownership of observations 164

Attaching flags and notes in a replication environment 164

Overview

This chapter describes how Enter works differently in a Multisite environment, and contains the following sections:

- The Navigator
- Type 0 panels
- Attaching flags and notes in a replication environment

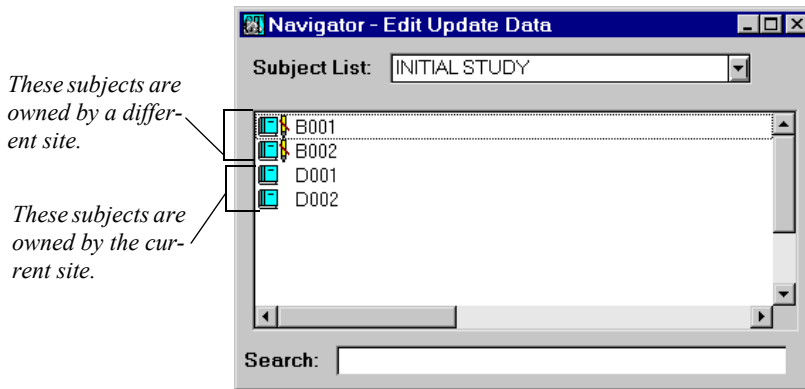
The Navigator

This section describes the following features in the Navigator that are functional only when the current protocol is in a replication environment:

- The display of subject ownership in the Navigator
- The SITE subject list
- Replication of repeating blocks and study pages

Display of subject ownership in the Navigator

The following figure shows the Navigator and indicates which subjects are owned by the current site and which subjects are owned by another site in the replication environment. Subjects that are owned by a different site have an icon to the right of the study book:



You can enter and edit clinical data for subjects that are owned by the current site.

You can open blocks and study pages and view clinical data for subjects that are not owned by the current site; however, you cannot modify or delete clinical data for these subjects. When you view a study page for a subject that is not owned by the current site, all menu commands used to edit or delete clinical data are unavailable.

The SITE subject list

The SITE subject list is created automatically when the current protocol is in a replication environment. When you select the SITE subject list, only subjects owned by the current site appear in the Navigator.

You cannot edit or delete the SITE subject list.

Replication of repeating blocks and study pages

The designer may set up an undetermined number of repeating blocks and repeating study pages. The data-entry operator may then create repeating blocks and repeating study pages as needed, that is, dynamically.

When the data-entry operator dynamically creates a repeating block or repeating study page, metadata to define the block or study page is created. During data entry, this metadata exists at the current site only. Then, when the clinical data in the repeating block or repeating study page replicates to other sites in the replication environment, the metadata to define the repeating block or repeating study page is created automatically at those sites.

Because it is impossible for a single site to control the number of repeating blocks and repeating study pages created when a protocol is in a replication environment, the maximum number of repeating blocks and repeating study pages set by the designer is ignored.

Type 0 panels

This section describes how Enter works with the following characteristics of Type 0 panels when the current protocol is in a replication environment:

- Ownership of records
- Ownership of observations

Ownership of records

Records in a Type 0 panel may be owned by different sites. A site originally has ownership of a record in a Type 0 panel if the record was entered at that site.

You can edit clinical data in records that are owned by the current site.

You can view clinical data in records that are not owned by the current site, but you cannot modify or delete clinical data in these records. Records that are not owned by the current site are shaded; all menu commands used to edit or delete clinical data are unavailable.

Ownership of observations

All records that are part of an observation must be owned by the same site.

When you transfer ownership of records grouped in an observation, you must transfer ownership of all the records in an observation. For information on transferring ownership, see page 121 of this guide.

Attaching flags and notes in a replication environment

The following rules apply to flags and notes in a replication environment:

- You can only attach flags and notes to data owned by the current site.
- The flag or note replicates with the data.
- The flag or note cannot be modified or deleted at a site that does not own the data to which it is attached.

10 Manage and Multisite

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- Batch loading data into Type 5 panels 169
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- Coding at each site in a replication environment 169
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Overview

This chapter describes how Manage works differently in a Multisite environment, and contains the following sections:

- General information
- The CT_MEDDRA protocol
- Batch loading records in a replication environment
- Coding clinical data in a replication environment

General information

This section contains the following information about Manage in a Multisite environment:

- Error Log entries in a replication environment
- Auditing data in a replication environment

The MedDRA protocol

You can distribute the MedDRA protocol, CT_MEDDRA, just as you distribute other protocols in Multisite.

Because the CT_MEDDRA protocol must be available at every site where data is entered for coding against MedDRA, you must either import CT_MEDDRA at one site and then distribute it and replicate its data to the other sites, or import the protocol at every site. A combination of these techniques is also acceptable.

If you want to make changes to CT_MEDDRA and want the changes to be centralized, then import CT_MEDDRA at the Distribution Master site, make changes there, and distribute the protocol to Distribution Subordinate sites.

Otherwise, you can import CT_MEDDRA at each site.

In a Multisite environment, if you use MedDRA, you must not only distribute the CT_MEDDRA protocol to all participating replication sites, but it is recommended that you log in to the CTPROC account at each site in SQL*Plus and execute the functions in the `ct_meddra_util.create_meddra_indexes` and `ct_meddra_util.create_medra_functions` packages.

For more information on these functions, see the MedDRA-related functions section of the *Reference Guide*.

Error Log entries in a replication environment

Entries in an Error Log are local to each site. These entries do not replicate to other sites in the replication environment.

You can only use the Error Log to edit records that are owned by the current site.

Editing data in a replication environment

You can only edit records that are owned by the current site. Therefore, if you use Global Change or Global Delete on a set of records that includes records that are owned by another site, the change or deletion affects only those records that are owned by the current site.

Validating and merging records

You can only validate and merge records that are owned by the current site.

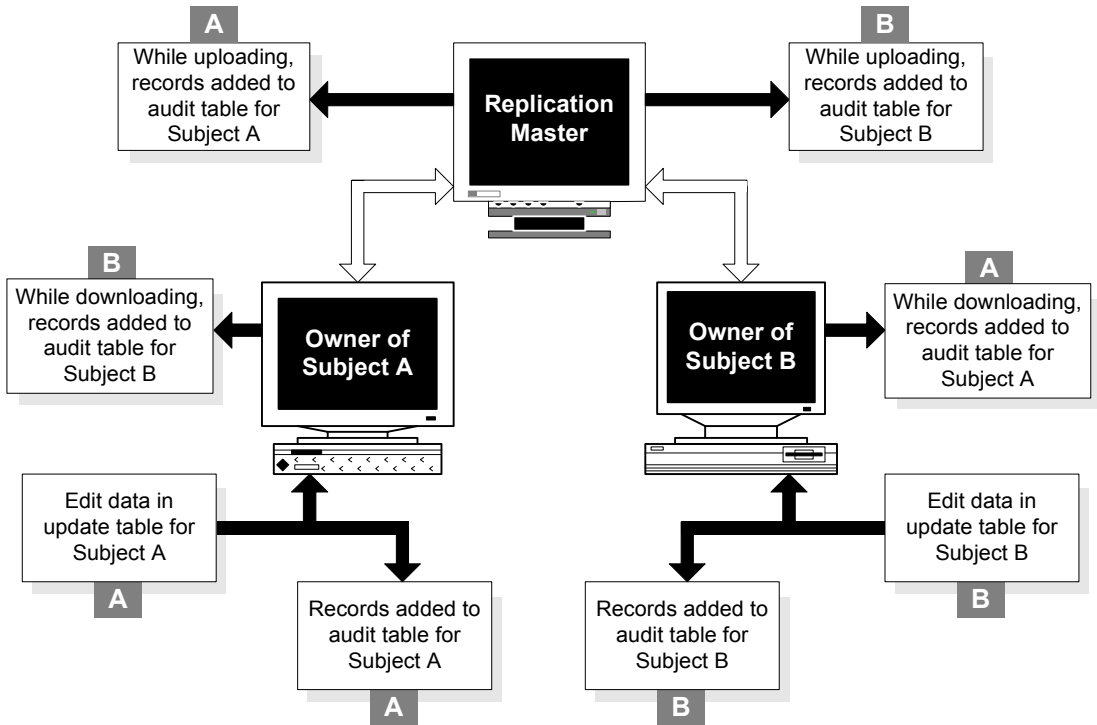
Auditing data in a replication environment

In a replication environment, auditing occurs at the audit start point when the modification to the data is:

- Made at the current site
- Received, through replication, at the current site

Records in audit tables are not replicated, and are specific to each site in a replication environment. Therefore, audit reports may contain different information and different sites for a single protocol. Because trusted data is stored at the Replication Master site, the Replication Master site's audit information is the most comprehensive.

The following figure shows how auditing occurs in a replication environment. (It is assumed that the audit start point for the protocol is ENTRY.)



Batch loading records in a replication environment

This section contains the following information about batch loading records in a replication environment:

- Batch loading data into Type 1 to Type 4 panels
- Batch loading data into Type 5 panels
- Batch loading data into Type 0 panels

Batch loading data into Type 1 to Type 4 panels

You can batch load data into Type 1 to Type 4 panels only for subjects that are owned by the batch-loading site. All the batch-loaded data is owned by the batch-loading site.

If a record is batch loaded for a subject that is not owned by the batch-loading site, the record fails the screening process. Then, you must transfer ownership of the subject to the batch-loading site before you can screen the batch-loaded data.

Batch loading data into Type 5 panels

When you batch load data into Type 5 panels, or enrollment panels, the batch-loaded data is owned by the current site. The screening process does not transfer ownership of the data to different sites because the subjects, defined in the Type 5 panel, are enrolled in the protocol at the current site.

Batch loading data into Type 0 panels

When you batch load data into Type 0 panels, the batch-loaded data is initially owned by the current site. However, the observations for the batch-loaded data may be owned by different sites in the replication environment.

When you group batch-loaded data, Manage automatically transfers the ownership of the record to the site that owns the observation.

Coding clinical data in a replication environment

In a replication environment, you can interactively or automatically code clinical data for a subject only at the site that owns that subject. You can manage the coding of clinical data by:

- Coding clinical data interactively or automatically at each site in the replication environment
- Coding all clinical data in the protocol interactively or automatically at a central site in the replication environment

This section contains information about these two ways of coding clinical data in a replication environment.

Coding at each site in a replication environment

You can only code clinical data for subjects owned by the current site. To ensure that clinical data for subjects owned by different sites is coded consistently, you must create a replication environment for the coding thesaurus protocol that

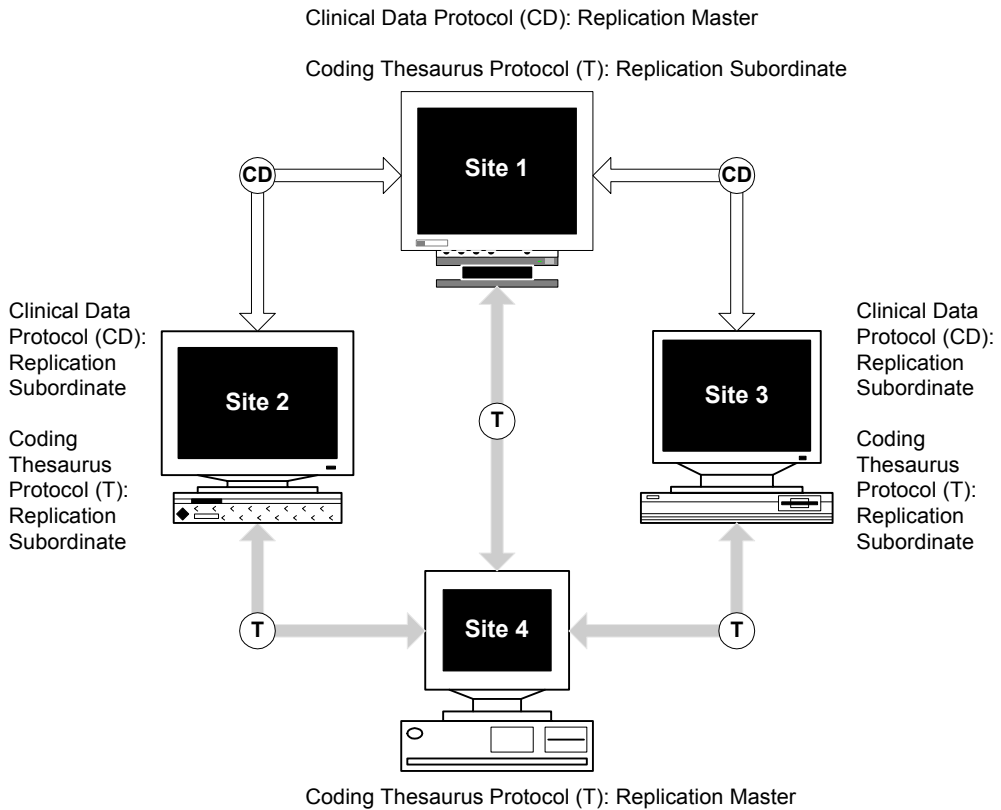
overlaps the replication environment for the clinical data protocol. Creating an overlapping replication environment for the coding thesaurus protocol – that is, a replication environment that includes the same sites as the clinical data protocol replication environment – ensures that if you modify coding thesaurus data at one site, those modifications are available when coding at another site.

To ensure consistent coding for a protocol in replication, and to improve the success of automatic coding, you can add synonyms to the coding thesaurus protocol. These synonyms then replicate to all the sites where coding occurs, and therefore improve the performance of automatic coding throughout the replication environment.

New and modified coding thesaurus data replicates throughout the replication environment as does all the clinical data for that subject, according to the replication restrictions that you set.

The following figure shows an example of two overlapping replication environments: a clinical data protocol replication environment and a coding thesaurus protocol replication environment. In this example, you code clinical data at the site where each subject is owned, either Site 1, Site 2, or Site 3. You

can add synonyms to the coding thesaurus protocol at any of the four sites, and these synonyms are made available to the other sites through the replication of the coding thesaurus protocol.



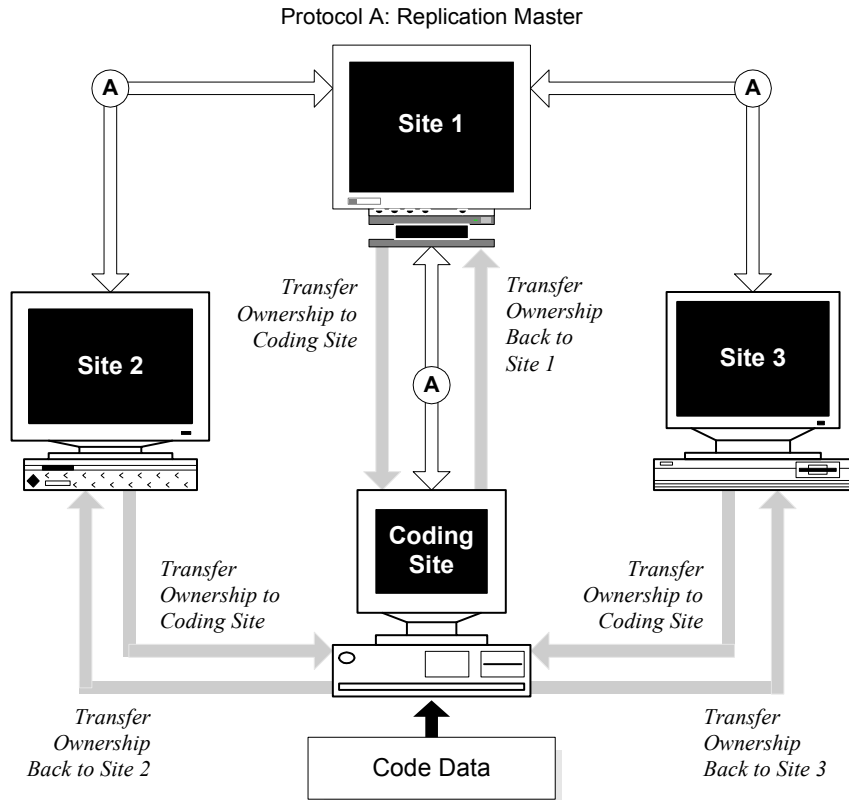
Coding at a central coding center

When a central coding center is responsible for coding clinical data in a protocol that is in a replication environment, you must transfer ownership of a subject to the central coding center site before clinical data for that subject can be coded.

After clinical data is coded, you can transfer ownership of the subject from the central coding center site back to the site that originally owned the subject.

The following figure shows an example of a replication environment for a clinical data protocol (A) with a central coding center. In this example, subjects are enrolled and clinical data is entered at Site 1, Site 2, and Site 3. Subjects are transferred to the Coding Site for clinical data coding, then transferred back to the original owning site.

Note: Each thesaurus protocol used by a clinical data protocol must be at the destination site. Otherwise, you cannot accept the clinical data protocol at that destination site. However, when there is a central coding center, you do not need to set up replication for coding thesaurus data. In this example, there is no need for the coding thesaurus protocol to be in replication, because it is only used at the coding site.



11 Retrieve and Multisite

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 - Creating queries in distributed protocols 174
 - Clintrial software-supplied MedDRA queries 174

Queries in distributed protocols

This chapter describes how Retrieve works differently in a Multisite environment, and contains the following sections:

- Distributing queries with protocols
- Creating queries in distributed protocols

Distributing queries with protocols

Public queries are distributed with a protocol. Private queries are not distributed with a protocol.

Creating queries in distributed protocols

If a protocol has been distributed, you can create a private query in the protocol at the Distribution Master site or any Distribution Subordinate site.

You can never create a public query at a Distribution Subordinate site. You can create a public query at the Distribution Master site only when the protocol is open for revision. You can view changes to a public query in the Comparison Details report.

If you want to create a new public query in a distributed protocol:

1. Open the protocol for revision at the Distribution Master site.
2. Create the new public query.
3. Close the protocol for revision.
4. Distribute the revision of the protocol to all Destination sites.
5. Accept the revision of the protocol at all Destination sites.

Clintrial software-supplied MedDRA queries

In a Multisite environment, if you use MedDRA, you must not only distribute the CT_MEDDRA protocol to all participating replication sites, but it is recommended that you execute the `ct_meddra_util.create_meddra_functions` at each site as well. When you execute `create_meddra_functions`, you create functions used in Clintrial software-supplied Retrieve queries to return a higher level term code (HLT), as well as the code for the lower level term (LLT).

These functions can also be used in SELECT statements in SQL Tools or in derivations.

For more information on these functions, see the MedDRA-related functions in the *Reference Guide*. For more information on the Clintrial software-supplied MedDRA queries that use these functions, see the *Retrieve* section of *Enter, Resolve, and Retrieve*.

12 *Classify and Multisite*

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Overview

This chapter describes how Classify works differently in a Multisite environment, and contains the following sections:

- Working with Classify objects in a replication environment
- Classify sites
- Examples of Classify replication environments
- Codelists used by Classify

Working with Classify objects in a replication environment

Three types of Classify objects are replicated in a replication environment as part of the CTCLASSIFY account:

- Omission records
- Synonym solutions
- Support elements

This section contains information about:

- Creating Classify objects
- Modifying support elements
- Deleting support elements

Creating Classify objects

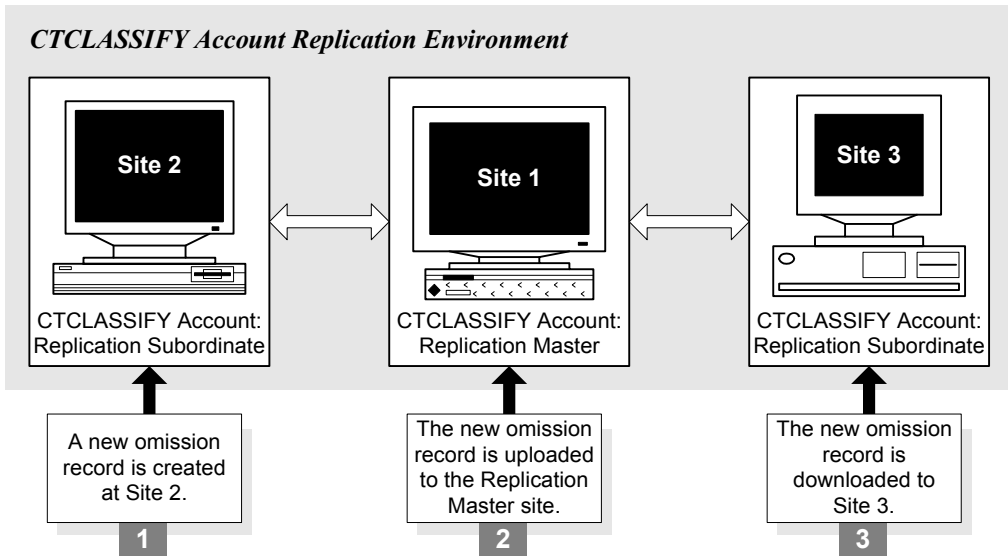
If a Classify object is created at the Replication Master site for the CTCLASSIFY account, the object downloads to all the Replication Subordinate sites for the CTCLASSIFY account.

If a Classify object is created at a Replication Subordinate site for the CTCLASSIFY account, the object uploads to the Replication Master site. After uploading to the Replication Master site, the new Classify object downloads to other Replication Subordinate sites.



Caution: If a Replication Subordinate site is invited into the replication environment for the CTCLASSIFY account as Read Only, the site cannot create Classify objects.

The following figure shows the uploading and downloading of an omission record in an account replication environment for the CTCLASSIFY account:



Modifying support elements

You can only modify a support element in a replication environment at the site that owns the support element. You cannot modify support elements at any other site unless you first transfer ownership.

When you modify a support element, the modifications upload and download throughout the replication environment.

Deleting support elements

You can only delete a support element in a replication environment from the site that owns the support element. You cannot delete a support element at any other site unless you first transfer ownership.

Classify sites

The two types of sites related to the tasks that you perform in Classify are the:

- Autocoding site, and the
- Omission handling site

The autocoding site and the omission handling site may be different sites in the replication environment. These sites may also be the same site, in which case the sites are referred to as *colocated*.

What is an autocoding site?

An *autocoding site* is the site at which users perform autocoding using Manage. Every record whose normalized term matches a term in the thesaurus is coded. Every coding failure results in the creation of an omission record.

For information about coding in a replication environment, see page 169 of this guide.

What is an omission handling site?

An *omission handling site* processes omissions and ultimately purges them using Classify.

The omission's type is determined by three attributes:

- The autocoding site that produced it
- The clinical data protocol
- The coding thesaurus protocol

If your replication environment includes multiple omission handling sites, you must specify which omission handling site handles each type of omission, as explained in the next section.

Multiple omission handling sites

If there are multiple omission handling sites in the replication environment that are accepting synonym solutions in the same coding thesaurus, there are two potential problems, which are described in this section.



Caution: If there are multiple omission handling sites in the replication environment that are accepting synonym solutions in the same coding thesaurus, all synonym tables must have a unique index on the TEXT column, and duplicate errors should be resolved, as described on page 134 of this guide, to correct coding discrepancies.

Identical synonym solutions

If synonyms with the same text and code are created at different sites:

- If the synonym at one site has replicated, you cannot accept the synonym at the second site.
- If neither synonym has replicated before both synonyms are accepted:
 - If there is a unique index on the TEXT column, the second synonym to replicate causes a replication error.
 - If there is not a unique index on the TEXT column, a duplicate synonym exists after both synonyms have replicated.

Synonym solutions with identical text but different codes

If synonyms with the same text and different codes are created at different sites:

- If the synonym at one site has replicated, you cannot accept the synonym at the second site.
- If neither synonym has replicated before both synonyms are accepted:
 - If there is a unique index on the TEXT column, the second synonym to replicate causes a replication error. If the site where the second synonym was entered is also an autocoding site, there are clinical data records that were coded with the synonym which has been deleted from the coding thesaurus protocol in replication.
 - If there is not a unique index on the TEXT column, after replication, each site has two synonyms with the same text and different codes. If both sites are also autocoding sites, records may be coded differently at each site. Furthermore, future autocoding is compromised because it is unclear which of the two codes should be used.

How to identify sites

To identify sites:

1. Start Classify and log in to the Replication Master site for the CTCLASSIFY account.
2. From the **Configuration** menu, select **Autocoding Sites or Omission Handling Sites**. A dialog box opens, displaying all previously specified sites.

Note: The **Configuration** menu is enabled only if your access level is Full for both Accept (in Classify) and Replication (in Multisite).

3. If you want to add a new site, allocate space by selecting **Insert Row** from the **Edit** menu. The Select Site dialog box opens.
4. Select a site from the drop-down list, and click **OK**.



Caution: Before you can identify sites in Classify, you must register the site for replication in Multisite, as described in Chapter 3.

What is a site pairing?

A *site pairing* is an association between one omission handling site and every autocoding site, clinical protocol, and coding thesaurus protocol grouping. Your site pairing specifications determine where each type of omission record is directed for processing.

Example

For example, suppose that one autocoding site is processing one study's records, and that it is coding both adverse events and drug names. Because there is one site and one protocol but two coding thesauruses, there are two autocoding site/protocol/thesaurus groups, each of which must be assigned an omission handling site. If your company processes all omissions at one site, you would assign the same omission handling site to both groups; if your company maintains topic-specific sites for use by specialized coding experts, you would assign a different omission handling site to each group.

A single site

Whether the autocoding and omission handling sites that process a particular type of omission reside in the same database instance determines what happens when an omission handling user accepts a solution. When the autocoding site

and the omission handling site are the same site, or colocated, autocoding is automatically applied to every record for which a Verbatim or Synonym solution has been accepted, those omissions are automatically labeled Solved.

Multiple sites

If the autocoding site and the omission handling site are different sites, an autocoding site user must invoke autocoding after the processed omissions (and thesauruses, in the case of synonym solutions) replicate back to that site. Until then, the omissions are labeled Solution Pending.

The following table provides details about how both site-location models process the acceptance of all three solution types assuming that the AUTOCODE_RECODE_ALL parameter for the clinical data protocol is set to Yes, which is required for Classify.

Sites:	Change Verbatim:	Create Synonym:	Request More Information:
Colocated Sites	Status changes to Solved.	Status changes to Solved for that omission and any matching ones.	Status changes to Solution Applied once a flag is added to the source record or a discrepancy record is created.
		<p><i>Note:</i> Synonym solutions are autoproposed if the verbatim, thesaurus, algorithm, and omission handling sites are identical.</p>	

Sites:	Change Verbatim:	Create Synonym:	Request More Information:
Non-colocated Sites	<p>Status changes to Solved if the verbatim change was autocoded.</p> <p>Otherwise, the status changes to Solution Pending, and the omission replicates back to the autocoding site. Once autocoding runs, the omission's status changes to Solution Applied. After autocoding runs again, it changes to Solved.</p> <p><i>Note:</i> This solution type requires two invocations of the autocoder.</p>	<p>Status changes to Solution Pending for that omission and any matching ones, and both the omission and thesaurus replicate back to the autocoding site. Once autocoding runs, the omission's status changes to <i>Solved</i>. See the previous Note in this table for information about autoproposed solutions.</p>	<p>Status changes to Solution Pending, and the omission replicates back to the autocoding site. Once autocoding runs, a flag is added to the source record or a discrepancy record is created, and the omission's status changes to Solution Applied.</p>

Note: A new Error omission status, which is relevant only to Multisite users, indicates that the change to the verbatim text, creation of a discrepancy record, or application of a flag did not occur due to a validation or resource depletion error. If you are not using Multisite, Classify displays an error message if an anticipated change cannot be implemented.

How to specify a site pairing

- To specify a site pairing:
1. Start Classify and log in to the Replication Master site for the CTCLASSIFY account.
 2. From the **Configuration** menu, select **Mapping**. The Mappings dialog box opens, listing all previously specified groups and their associated omission handling sites.
 3. To define a new site pairing, from the **Edit** menu, select **Insert Row**. The Specify Mapping dialog box opens.
 4. Make selections from the drop-down lists of autocoding sites, protocols, and thesauruses, and then click **OK**.
 5. Once the group's attributes display in a single row, complete the associated Omission Handling Site field.

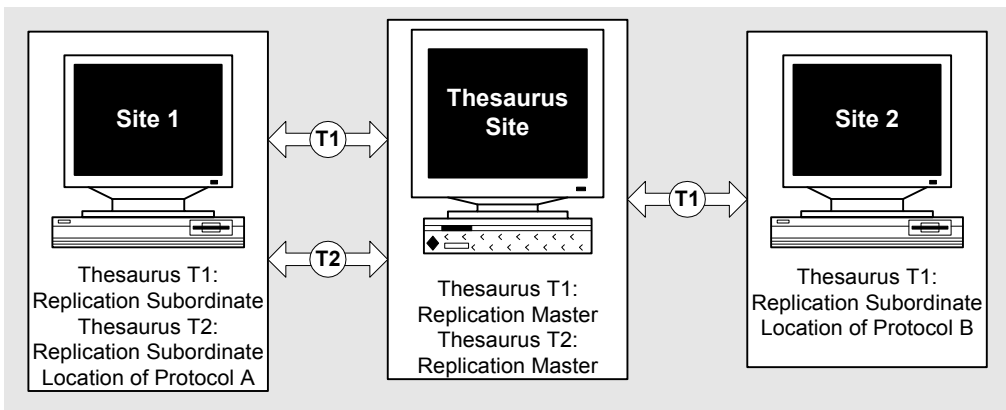
Note: Do not use an asterisk (*) as a wildcard character in the Omission Handling Site field.

Examples of Classify replication environments

This section contains three examples of replication environments that you could set up to use with Classify.

Example A

The following figure shows two coding thesaurus protocol replication environments. The CTCLASSIFY account is not in replication.



In this figure:

- The Thesaurus T1 replicates between the Thesaurus Site and Site 1, and between the Thesaurus Site and Site 2.
- The Thesaurus T2 replicates between the Thesaurus Site and Site 1.
- Protocol A and Protocol B are not in replication.
- Protocol A uses both Thesaurus T1 and Thesaurus T2.
- Protocol B uses only Thesaurus T1.
- All Manage and Classify activities happen for Protocol A at Site 1.
- All Manage and Classify activities happen for Protocol B at Site 2.
- If Site 1 or Site 2 adds synonyms to T1 or T2, these synonyms upload to the Thesaurus Site and download to other Replication Subordinate sites.

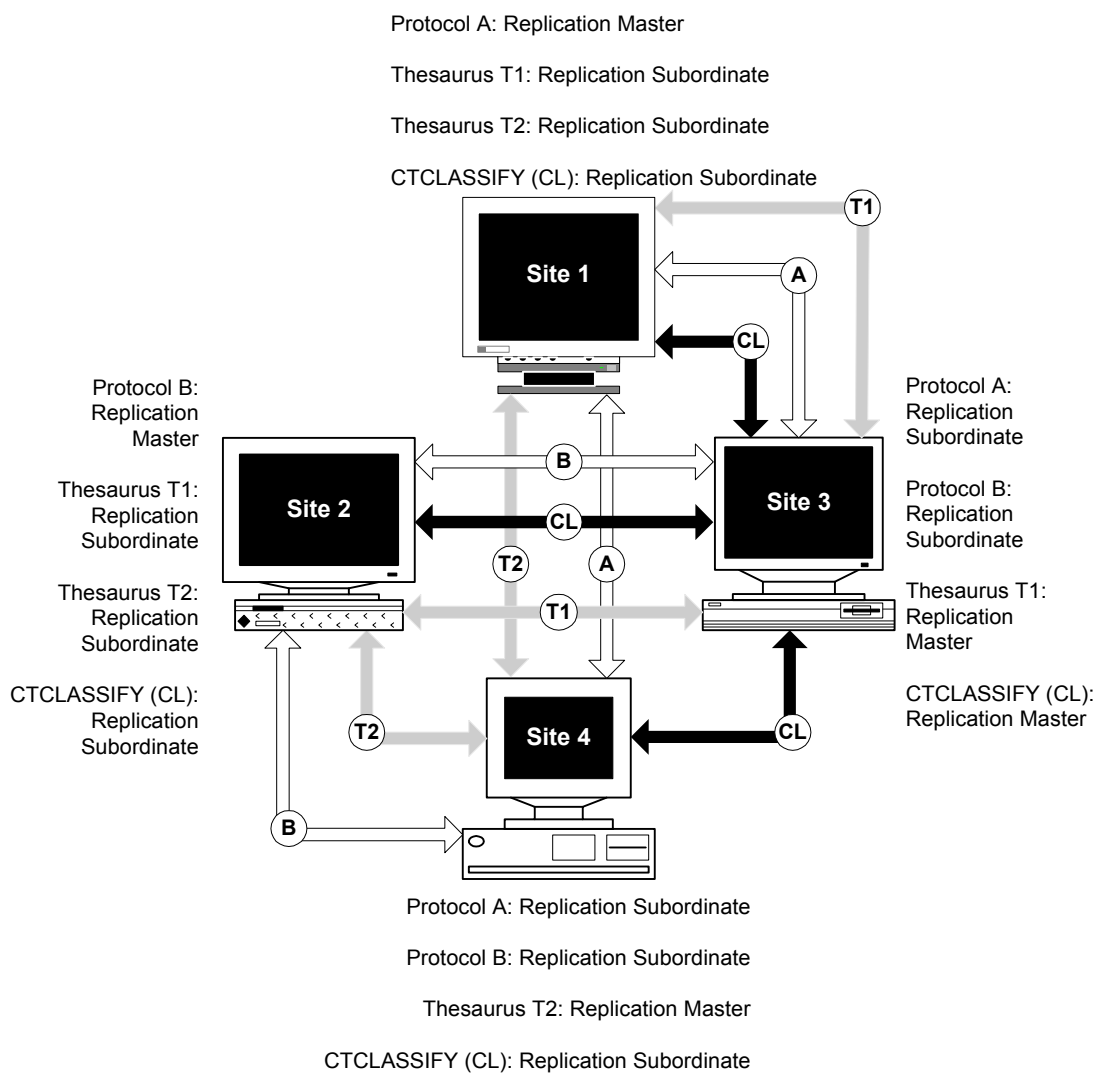
Example B

The following figure shows a Classify replication environment with two levels:

- One level for centralized omission management
- One level for centralized dictionary management

In this figure:

- Clear lines represent clinical data protocol replication.
- Shaded lines represent coding thesaurus protocol replication.
- Black lines represent CTCLASSIFY account replication.



The following table lists and describes the objects in this figure:

Object:	Description:
Thesaurus T1	<p>Replicates between Site 3 and Site 1, and between Site 3 and Site 2.</p> <p>Synonyms added at Site 1, Site 2, or Site 3 replicate to the other two sites.</p>
Thesaurus T2	<p>Replicates between Site 4 and Site 1, and between Site 4 and Site 2.</p> <p>Synonyms added at Site 1, Site 2, or Site 4 replicate to the other two sites.</p>
Protocol A	<p>Replicates between Site 1 and Site 3, and between Site 1 and Site 4.</p> <p>Uses both Thesaurus T1 and Thesaurus T2.</p> <p>Coding in Manage is done at the site where clinical data was entered.</p> <p>Omission records are generated at Site 1.</p> <p>For coding targets that use Thesaurus T1, omission records are handled at Site 3.</p> <p>For coding targets that use Thesaurus T2, omission records are handled at Site 4.</p>

Object:	Description:
Protocol B	<p data-bbox="672 199 1209 269">Replicates between Site 2 and Site 3, and between Site 2 and Site 4.</p> <p data-bbox="672 321 1088 355">Uses both Thesaurus T1 and Thesaurus T2.</p> <p data-bbox="672 407 1209 477">Coding in Manage is done at the site where clinical data was entered.</p> <p data-bbox="672 529 1061 564">Omission records are generated at Site 2.</p> <p data-bbox="672 616 1155 685">For coding targets that use Thesaurus T1, omission records are handled at Site 3.</p> <p data-bbox="672 737 1155 807">For coding targets that use Thesaurus T2, omission records are handled at Site 4.</p>
CTCLASSIFY account	<p data-bbox="672 841 1196 911">Solutions generated at Site 3 or Site 4 are replicated as part of the CTCLASSIFY account to all other sites.</p>

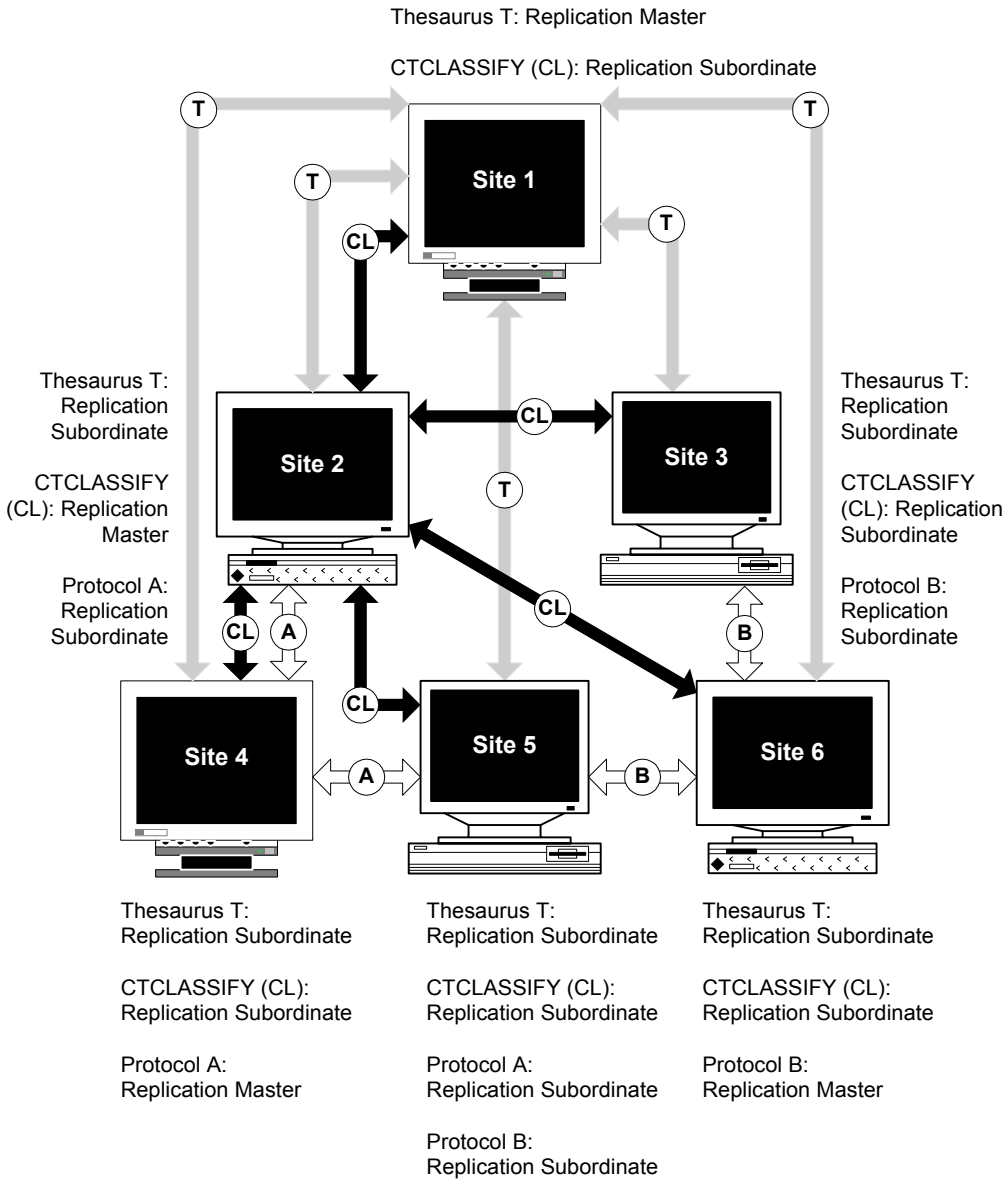
Example C

The following figure shows a Classify replication environment with three levels:

- One level for centralized omission management
- One level for centralized dictionary management
- One level for data entry and coding in Manage

In this figure:

- Clear lines represent clinical data protocol replication.
- Shaded lines represent coding thesaurus protocol replication.
- Black lines represent CTCLASSIFY account replication.



The following table lists and describes the objects in this figure:

Object:	Description:
Thesaurus T	<p>Replicates between Site 1 and each site in the Multisite environment. For Site 4, Site 5, and Site 6, Thesaurus T replicates as read-only data.</p> <p>If Site 1, Site 2, or Site 3 adds synonyms, these synonyms are replicated to each site in the Multisite environment.</p>
Protocol A	<p>Replicates between Site 4 and Site 2, and between Site 4 and Site 5.</p> <p>Coding in Manage is done at the site where clinical data was entered.</p> <p>Omission records are generated at Site 4 and Site 5.</p> <p>Omission records are handled at Site 2.</p>
Protocol B	<p>Replicates between Site 6 and Site 3, and between Site 6 and Site 5.</p> <p>Coding in Manage is done at the site where clinical data was entered.</p> <p>Omission records are generated at Site 5 and Site 6.</p> <p>Omission records are handled at Site 3.</p>
CTCLASSIFY account	<p>Solutions generated at Site 2 or Site 3 are replicated as part of the CTCLASSIFY account to all other sites.</p>

Codelists used by Classify

Classify uses two codelists that are created during the Classify server installation for which there are requirements when Classify is used in a replication environment:

- CTS\$THESA_ALGO_STEP
- CTS_CTG_DSC_TXT

CTS\$THESA_ALGO_STEP codelist

The CTS\$THESA_ALGO_STEP codelist must be maintained separately at each site in the CTCLASSIFY account replication environment.



Caution: You must not distribute the CTS\$THESA_ALGO_STEP codelist in the CTCLASSIFY account replication environment.

CTS_CTG_DSC_TXT codelist

The CTS_CTG_DSC_TXT codelist, which stores text fragments for the Predefined Message field in the Request More Info dialog box, may be distributed to sites in the CTCLASSIFY account replication environment. The Replication Master site of the CTCLASSIFY account should be the Distribution Master site for this codelist.

13 *Lab Loader and Multisite*

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Overview

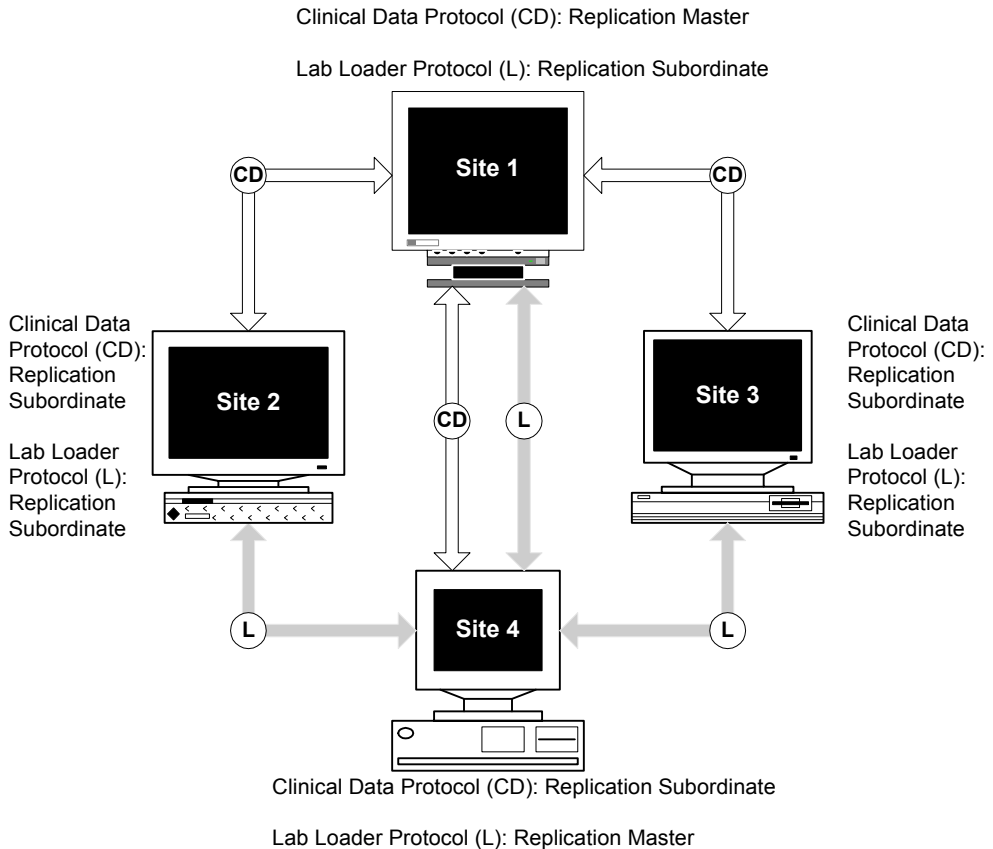
This chapter describes how Lab Loader works differently in a Multisite environment, and contains the following sections:

- Configuring a replication environment for a Lab Loader protocol
- Transfer maps in a replication environment
- Working with lab data in a replication environment
- Transferring lab data in a replication environment

Configuring a replication environment for a Lab Loader protocol

To use Lab Loader to transfer laboratory data from a source protocol into a destination protocol that is in a replication environment, you must configure a replication environment for the Lab Loader protocol that overlaps the sites in the destination protocol's replication environment.

The following figure shows two overlapping replication environments, one for a clinical data protocol and one for the Lab Loader protocol:



The remainder of this section discusses:

- Distributing a Lab Loader protocol
- Distributing transfer maps and control files

Distributing a Lab Loader protocol

You distribute Lab Loader protocols just as you distribute clinical data protocols, which is described in Chapter 4.

Note: If you try to distribute a Lab Loader protocol to a site that does not have Lab Loader installed, the distribution fails.

Note: It is strongly recommended that you distribute the protocol CTL_REFERENCE and replicate its data to any site running the validations using that data. Also, Lab Loader must be installed on all the sites to access the functions.

Distributing transfer maps and control files

When you distribute a Lab Loader protocol, the transfer maps and control files for that protocol are also distributed.

You can only modify or add transfer maps and control files at the Distribution Master site, before the first distribution of the Lab Loader protocol, or when the Lab Loader protocol is open for revision. For information about opening a protocol for revision, see page 84 of this guide.



Caution: To create transfer maps and control files, you must ensure that the Distribution Master site for the Lab Loader protocol contains the panel metadata for the clinical data protocol into which you will transfer data. Therefore, you must distribute the clinical data protocol to the Lab Loader protocol's Distribution Master site before creating transfer maps and control files.

Transfer maps in a replication environment

This section describes rules for transfer maps when the Lab Loader protocol is in a replication environment.

Mapping the destination protocol name

You must map the destination protocol name to the same column in the source protocol panel for all transfer maps, or all transfer maps must implicitly have the same destination protocol by not specifying the pseudo item destination protocol.

Mapping the subject_item

If the destination panel is Type 1-4, you must map the subject_item to the same column in the source protocol panel for all maps.

Destination panels

If the Lab Loader protocol is in a replication environment, all destination panels in a single transfer map must be either:

- A single Type 0 panel, or
- Subject-related panels (Type 1-4)

Working with lab data in a replication environment

This section contains the following information:

- Batch loading lab data
- Validating data



Caution: Before you can process batch-loaded lab data in a Lab Loader protocol, for Type 1-4 destination panels, you must ensure that all data in the enrollment panel of the destination protocol has been replicated to the batch-loading site. For Type 0 destination panels, you must ensure that all rows in the panels have been replicated to the batch-loading site.

Batch loading and screening lab data

You must batch load and screen lab data into the Lab Loader protocol at the Replication Master site for the Lab Loader protocol.

The Replication Master site initially owns the batch-loaded lab data through the screening process.

Validating data

In a replication environment, you validate batch-loaded lab data at the batch-loading site.

This section describes what happens during the validation process for:

- Type 1-4 destination panels
- Type 0 destination panels

Type 1-4 panels

For destination panels of Type 1-4, the validation process:

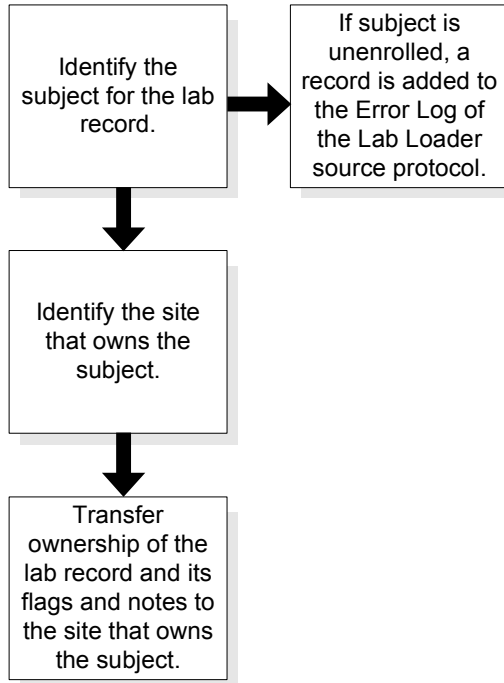
1. Identifies the subject for the lab data record, by using the first appropriate transfer map found to identify the destination protocol.
2. Identifies the site that owns the subject by using the enrollment panel of the destination protocol.
3. Transfers ownership of the lab data record, as well as any attached item flags and notes, to the site that owns the corresponding subject.

If a record belongs to an unenrolled subject, the record fails validation. Records in the Error Log that have failed validation remain at the Replication Master site and are not replicated.



Caution: It is possible for Lab Loader records that are grouped in an observation to get transferred to different sites because the subjects in the observation's records are different.

The following figure shows the validation process for lab data in Type 1-4 destination panels:



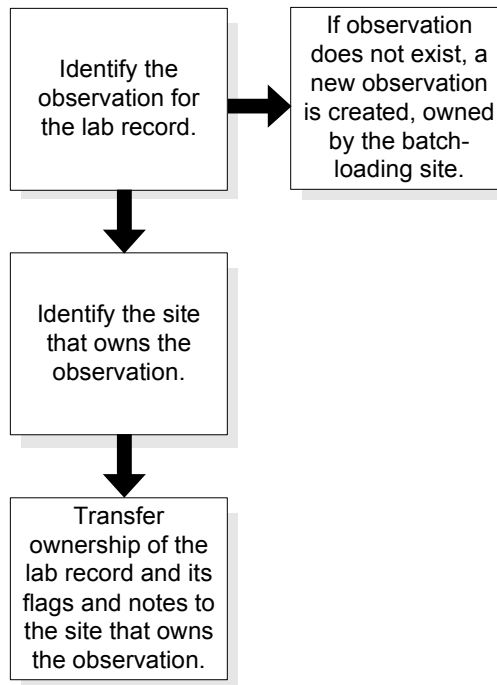
Type 0 panels

For destination panels of Type 0, the validation process:

1. Identifies the observation for the lab data record.
2. Identifies the site that owns the observation.
3. Transfers ownership of the lab data record, as well as any attached flags and notes, to the site that owns the corresponding observation.

If a record belongs to an observation that does not exist, the record becomes the first record in a new observation that is owned by the batch-loading site.

The following figure shows the validation process for lab data in a Type 0 destination panel:



Transferring lab data in a replication environment

This section contains the following information related to transferring lab data in a replication environment:

- Replicating lab data
- Transferring replicated lab data
- Workflow

Replicating lab data

After lab data is validated at the Replication Master site for the Lab Loader protocol, the lab data then replicates to the sites that own the corresponding subjects.

When setting up replication for a Lab Loader protocol, you should set replication restrictions so that each site only receives lab data records for the subjects that it owns.



Caution: If you do not set such replication restrictions, and a site receives lab data for subjects that it does not own, replication and transfer performance will decrease.

Transferring replicated lab data

You transfer replicated lab data at the site in the replication environment that owns the Lab Loader record.

Transfer failures

When a record fails to transfer, the ownership of the record, as well as the ownership of the flag that gets attached to identify this transfer failure and any other flags and notes attached to the record, transfers back to the site where the record was batch-loaded, which is the Lab Loader protocol's Replication Master site. You must resolve transfer errors at this Replication Master site and then perform the transfer again.



Caution: If any record in an observation defined in the Lab Loader source protocol fails to transfer, ownership of all records in the observation is transferred back to the Lab Loader protocol's Replication Master site.

Transfers with errors

If a record transfers successfully with Report errors, the ownership of the record, as well as the error records generated, remains at the site that owns the subject in the clinical data protocol. You must resolve these errors at the site that owns the subject.

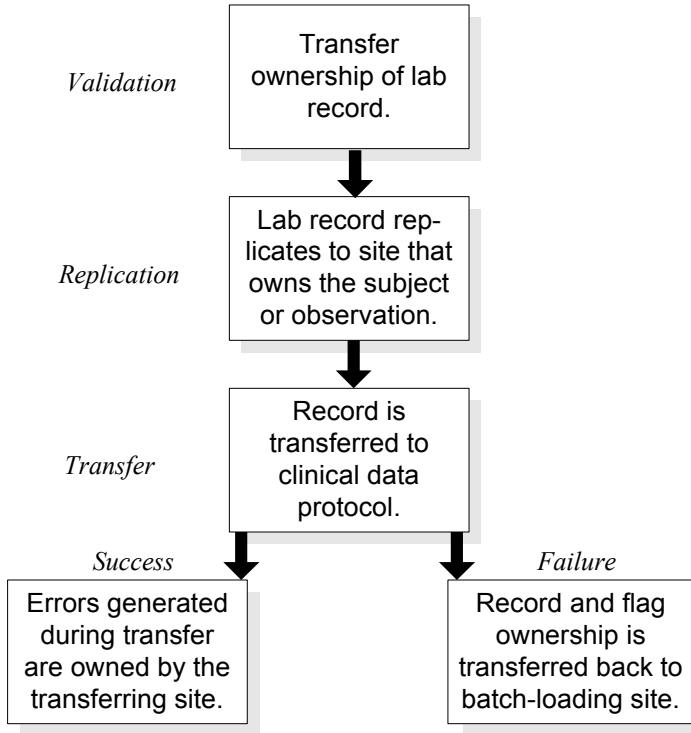
Transfer errors caused by change of subject ownership

When the ownership of a subject in a clinical data protocol changes between the times of validation and the transfer of lab data, the lab records for that subject fail to transfer, and ownership of these records is returned to the batch-loading site.

Once replication has updated these records at the batch-loading site, you must:

1. Ensure that the Replication Master site has an up-to-date Enrollment panel for the clinical data protocol.
2. Rerun validation on the lab data. Validation then correctly identifies the site that owns the subject and reassigns ownership to the lab data record.

The following figure shows the workflow for transferring replicated lab data:



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General information

This chapter describes how Resolve works differently in a Multisite environment, and contains the following sections:

- The Resolve protocol
- Setting up protocols for use with Resolve
- Working with Discrepancy records

The Resolve protocol

You can distribute the Resolve protocol, CTRESOLVEREF, just as you distribute other protocols in Multisite.

Because the CTRESOLVEREF protocol must be available at every site where Resolve is used, you must either import CTRESOLVEREF at one site and then distribute it and replicate its data to the other sites, or import the protocol at every site. A combination of these techniques is also acceptable.

If you want all changes to CTRESOLVEREF to be centralized, then import CTRESOLVEREF at the Distribution Master site, make changes there, and distribute the protocol to Distribution Subordinate sites.

Otherwise, you can import CTRESOLVEREF at each site.

Setting up protocols for use with Resolve

If you want a distributed protocol to be set up for Resolve at each site, you must take the following steps:

1. At the Distribution Master site, set up the protocol for Resolve. From the **Setup** menu, select **Setup for Resolve**.



Caution: You can set up a protocol for Resolve only if it has not been distributed, or if it is open for revision. If a protocol that does not contain the VCT_ERRORSTATUS and VCT_ERRORITEM panels was already distributed, you must open this protocol for revision at the Distribution Master site before you run Setup for Resolve.

2. Distribute the protocol.
3. At each Distribution Subordinate site:
 - a. Accept the protocol.
 - b. Install database tables.

- c. Set up the protocol for Resolve.

Working with discrepancy records

When using Resolve for a protocol that is in replication, you can only modify discrepancy records for subjects owned at the current site. Records owned by other sites are accessible only in read-only mode.

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A Multisite Glossary

In this glossary you will find definitions related to Multisite.

For the main Clintrial software glossary, see *Reference Guide*.

Note: You can also access an online version of this glossary using the Multisite Help.

A

account replication

The movement of data in accounts other than protocols among multiple sites. Account replication allows users at different sites to enter and use shared account data.

D

data ownership

The ability of a site in a replication environment for a protocol or account to modify or delete data.

data downloading

The replication of data from the Replication Master site to the Replication Subordinate sites in the replication environment.

data uploading

The replication of data from a Replication Subordinate site, where the data was entered, to the Replication Master site.

Destination site

A site that accepts a distributed codelist or protocol. A Distribution Subordinate site is always a Destination site, whether the codelist or protocol is distributed to it from the Distribution Master site or from another Distribution Subordinate site. A Distribution Master site for a codelist or protocol is never a Destination site for that same object.

distribution

The movement and management of metadata objects among multiple sites. Using Multisite, you copy, or distribute, metadata objects from one site to one or more other sites, as well as control and track revisions of those objects across sites.

Distribution Master site

The site that initially creates and distributes a codelist or protocol. You distribute a codelist or protocol from the Distribution Master site to one or more Distribution Subordinate sites. The Distribution Master site is the only site that can modify a codelist or protocol that it has distributed.

distribution password

The password that provides security for the connection between the CTSRM accounts at two sites.

Distribution Subordinate site

A site to which you distribute a codelist or protocol, and that accepts the distributed codelist or protocol. There can be multiple Distribution Subordinate sites for each codelist or protocol in distribution.

M

Multisite environment

A set of sites that are linked and participate in distribution, or distribution and replication.

Multisite Master site

The site at which you register all sites that participate in replication. The Multisite Master site can also be a Replication Master site or Replication Subordinate site in any given replication environment. There is only one Multisite Master site in a Multisite environment.

P

protocol replication

The movement of data in a protocol among multiple sites, allowing users at different sites to work with data in a single protocol. Data entered at different sites moves, or replicates, to other sites that are participating in replication for that protocol.

proxy account

An account at one site that allows another site to connect to and perform operations at the site. Proxy accounts enable sites to connect to each other in the Multisite environment.

R

Remote site

A site in a replication environment that is not always connected by a network to other sites in the replication environment. Remote sites are always Replication Subordinate sites. A Replication Master site cannot be a remote site.

replication

The movement of data in a protocol or account among multiple sites. There are two types of replication: protocol replication and account replication.

replication environment

A set of sites within the Multisite environment that participate in replication for a specific protocol or account. There is one replication environment for a protocol or account in replication. A single site can participate in multiple replication environments.

Replication Environment Report

A report that can be accessed from the Multisite Master site that lists the protocols in replication and their master sites.

Replication Master site

The site in the replication environment that sets up replication for a specific protocol or account, and where trusted data for that protocol or account is stored.

replication restrictions

SQL clauses that you create to select a subset of records in a protocol for replication. You set replication restrictions from the Replication Master site for each Replication Subordinate site.

Replication Subordinate site

A site in the replication environment that collects data for a specific protocol or account and replicates that data to the Replication Master site.

S

site

An Oracle database instance that is used as a Clintrial software database instance in a Multisite environment. Sites can exist on different servers that are connected by a network. Multiple sites can also exist on a single server.

snapshot

Information about the codelist or protocol metadata that is captured at the time that you open the object for revision.

Source site

A site that distributes a codelist or protocol. A Distribution Master site is always a Source site. A Distribution Subordinate site is a Source site if it distributes a codelist or protocol to another Distribution Subordinate site.

synchronization

The process of ensuring that all new or modified data is uploaded to the Replication Master site and downloaded to each Replication Subordinate site before the protocol or account is halted.

T

trusted data

Data that has been successfully replicated from Replication Subordinate sites to the Replication Master site, and now resides at the Replication Master site.

B Sample Multisite Environments

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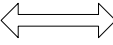
Overview

This appendix shows and explains five examples of Multisite environments. Examples A and B show Multisite environments in which only distribution takes place. Examples C, D, and E show Multisite environments with one or more replication environments.

Note: In the following examples that include replication, the Multisite Master site is not shown. You should assume that a Multisite Master site is always present, but not involved in the distribution or replication of the protocols shown.

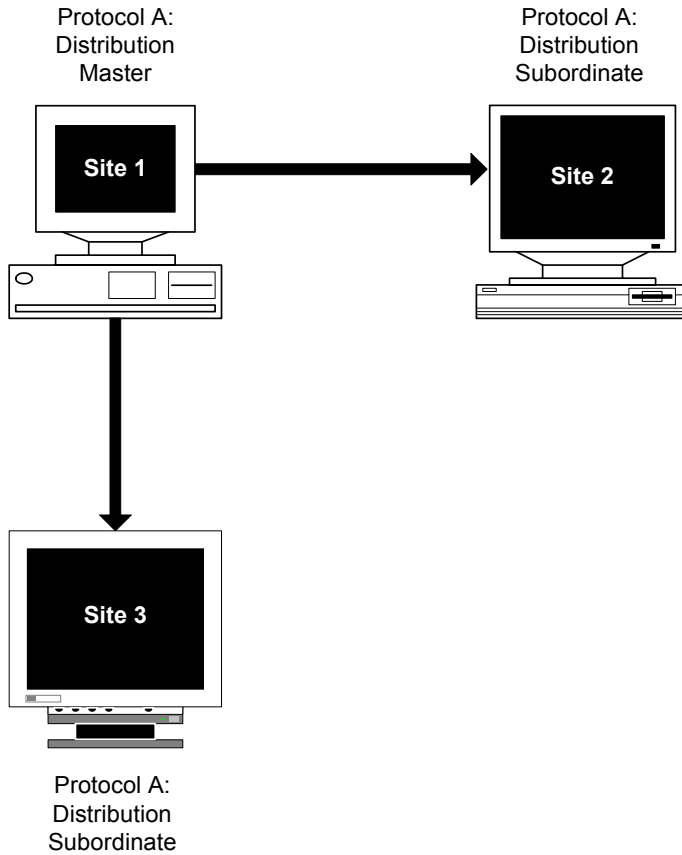
Conventions

In the following figures, as in all figures showing Multisite environments in this guide, the following conventions are used:

Symbol:	Description:
	A one-directional, solid line indicates the distribution of an object from one site to another site.
	A two-directional, clear line indicates replication of clinical data between a Replication Master site and a Replication Subordinate site.

Example A: Simple protocol distribution

The following Multisite environment shows a Protocol A distributed from a Distribution Master site (Site 1) to two Distribution Subordinate sites (Site 2 and Site 3):



What these sites can do

In Example A:

Site(s):	Can:	But cannot:
1	<ul style="list-style-type: none">• Create and modify Protocol A.• Distribute Protocol A to Site 2 and Site 3.• Modify and redistribute Protocol A.	
2 and 3	<ul style="list-style-type: none">• Accept Protocol A from Site 1.• Copy objects from Protocol A into other protocols.• Distribute Protocol A to other Distribution Subordinate sites.	<ul style="list-style-type: none">• Create or modify objects in Protocol A.

Why set up the environment in Example A?

You may want to create a Multisite environment similar to Example A if you want to build and control revisions to a dictionary protocol at a central location, Site 1.

At Site 2 and Site 3, you could then use the protocol as a dictionary by copying its objects into other protocols.

By distributing a dictionary protocol in this Multisite environment, you can ensure that clinical data protocols created at Site 2 and Site 3 are copying identical objects, thus enforcing metadata consistency in different studies at different sites.

How to set up the environment in Example A

To create the Multisite environment shown in Example A, complete the steps in the following table:

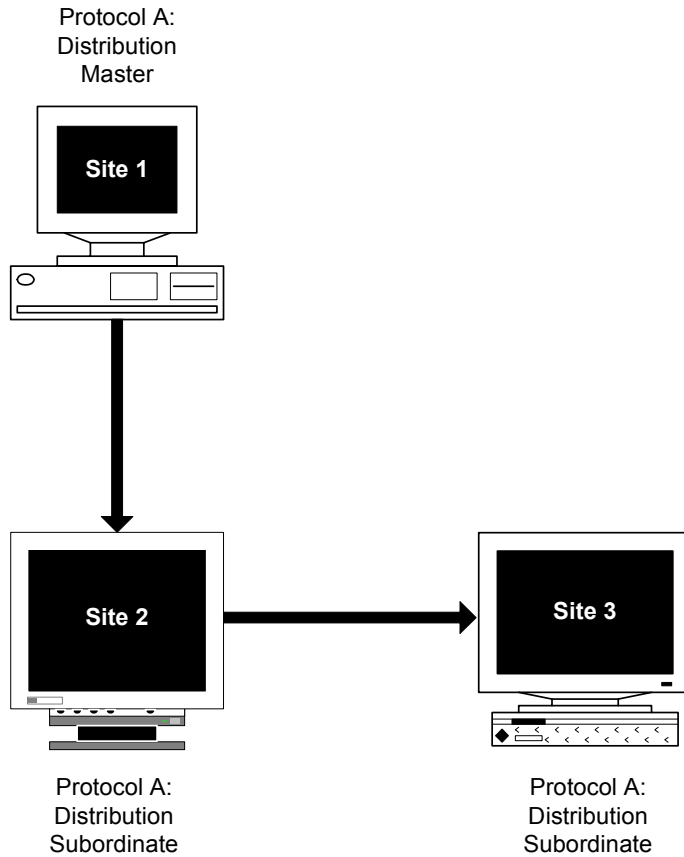
Step:	Task:	At site(s):	See:
1.	Create Protocol A.	1	<i>Admin and Design</i>

Step:	Task:	At site(s):	See:
2.	Register Site 2 and Site 3 for distribution.	1	Page 54
3.	Distribute Protocol A to Site 2 and Site 3.	1	Page 79
4.	Accept Protocol A.	2 and 3	Page 82
5.	To modify Protocol A, open Protocol A for revision.	1	Page 84
6.	Modify Protocol A.	1	<i>Admin and Design</i>
7.	Close Protocol A for revision.	1	Page 85
8.	Distribute the revision of Protocol A to Site 2 and Site 3.	1	Page 79
9.	Accept the revision of Protocol A.	2 and 3	Page 82

Note: If Protocol A uses functions or thesaurus base tables, you must copy the functions or thesaurus base tables to Site 2 and Site 3. For information, see Chapter 6.

Example B: Protocol distribution across three sites

The following Multisite environment shows a Protocol A distributed from a Distribution Master site (Site 1) to a Distribution Subordinate site (Site 2), and then distributed from Site 2 to another Distribution Subordinate site (Site 3):



What these sites can do

In Example B:

Site(s):	Can:	But cannot:
1	<ul style="list-style-type: none">• Create and modify Protocol A.• Distribute Protocol A to Site 2.• Modify and redistribute Protocol A.	
2	<ul style="list-style-type: none">• Accept Protocol A from Site 1.• Copy objects from Protocol A into other protocols.• Distribute Protocol A to other Distribution Subordinate sites.	<ul style="list-style-type: none">• Create or modify objects in Protocol A.
Site 3	<ul style="list-style-type: none">• Accept Protocol A from Site 2.• Use Protocol A as a data dictionary when building other protocols.• Distribute Protocol A to other Distribution Subordinate sites.	<ul style="list-style-type: none">• Create or modify objects in Protocol A.• Accept revisions of Protocol A from Site 1.

Why set up the environment in Example B?

In the Multisite environment shown in Example B, Protocol A might be revised several times at Site 1 and distributed each time to Site 2. When satisfied with the revisions, you can distribute Protocol A to Site 3.

How to set up the environment in Example B

To create the Multisite environment shown in Example B, complete the steps followed in creating the Multisite environment in Example A, shown in the table on page 219. In addition, complete the following steps:

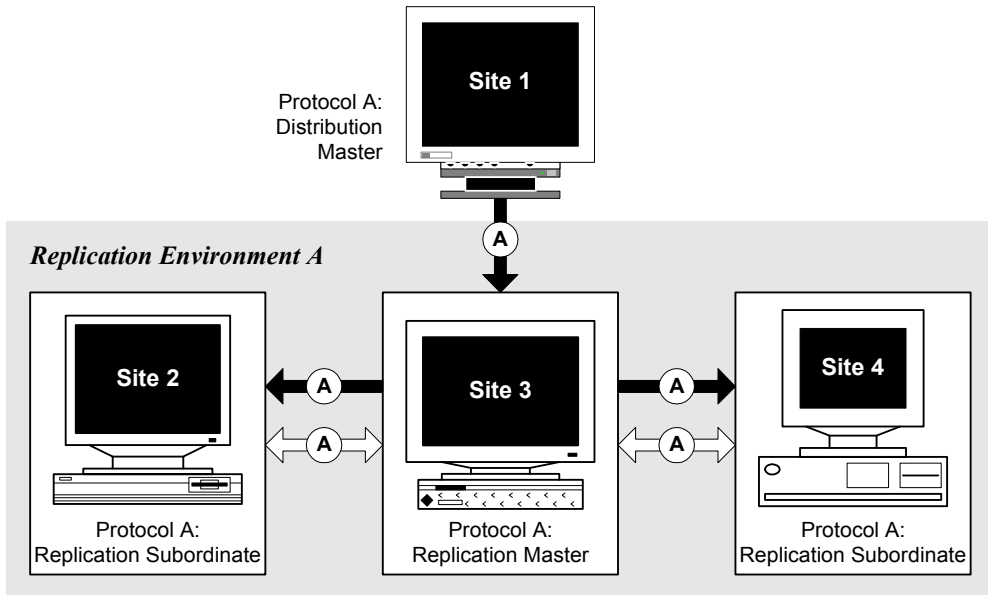
Step:	Task:	At site(s):	See:
1.	Create Protocol A.	1	<i>Admin and Design</i>
2.	Register Site 2 for distribution.	1	Page 54

Step:	Task:	At site(s):	See:
3.	Distribute Protocol A to Site 2.	1	Page 79
4.	Accept Protocol A.	2	Page 82
5.	To modify Protocol A, open Protocol A for revision.	1	Page 84
6.	Modify Protocol A.	1	<i>Admin and Design</i>
7.	Close Protocol A for revision.	1	Page 85
8.	Distribute the revision of Protocol A to Site 2.	1	Page 79
9.	Accept the revision of Protocol A.	2	Page 82
10.	Register Site 3 for distribution.	2	Page 54
11.	Distribute Protocol A to Site 3.	2	Page 80
12.	Accept Protocol A.	3	Page 82

Note: If Protocol A uses functions or thesaurus base tables, you must copy the functions or thesaurus base tables to Site 2 and Site 3. For information, see Chapter 6.

Example C: Simple protocol replication

The following Multisite environment shows Protocol A distributed from a Distribution Master site (Site 1) to a Distribution Subordinate site (Site 3), which then becomes the Replication Master site. Site 2 and Site 4 then become Replication Subordinate sites.



What these sites can do

In Example C:

Site(s):	Can:	But cannot:
1	<ul style="list-style-type: none"> • Create and modify Protocol A. • Use Protocol A as a data dictionary when building other protocols. • Distribute Protocol A to Site 3. • Modify and redistribute Protocol A. 	<ul style="list-style-type: none"> • Complete any tasks related to replication.

Site(s):	Can:	But cannot:
3	<ul style="list-style-type: none"> • Accept Protocol A from Site 1. • Use Protocol A as a data dictionary when building other protocols. • Distribute Protocol A to other Distribution Subordinate sites. • Register Protocol A for replication. • Invite Site 2 and Site 4 into the replication environment. • Set replication restrictions. • Transfer ownership of subjects in Protocol A. • Schedule replication. • Send changes. • Fetch changes. • Stop replication. • Halt or resume replication. 	<ul style="list-style-type: none"> • Create or modify objects in Protocol A.
2 and 4	<ul style="list-style-type: none"> • Accept Protocol A from Site 3. • Use Protocol A as a data dictionary when building other protocols. • Distribute Protocol A to other Distribution Subordinate sites. • Request participation from Site 3. • Transfer ownership of subjects owned at the site. • Schedule replication. • Send changes. • Fetch changes. • Stop replication. 	<ul style="list-style-type: none"> • Create or modify objects in Protocol A. • Accept revisions of Protocol A from a site other than Site 3. • Set replication restrictions. • Halt or resume the protocol.

Why set up the environment in Example C?

You may want to create the Multisite environment shown in Example C to collect clinical data for a protocol at three different sites. Each site enters data for its own subjects. The protocol is created and modified at a site that is not part of the replication environment.

How to set up the environment in Example C

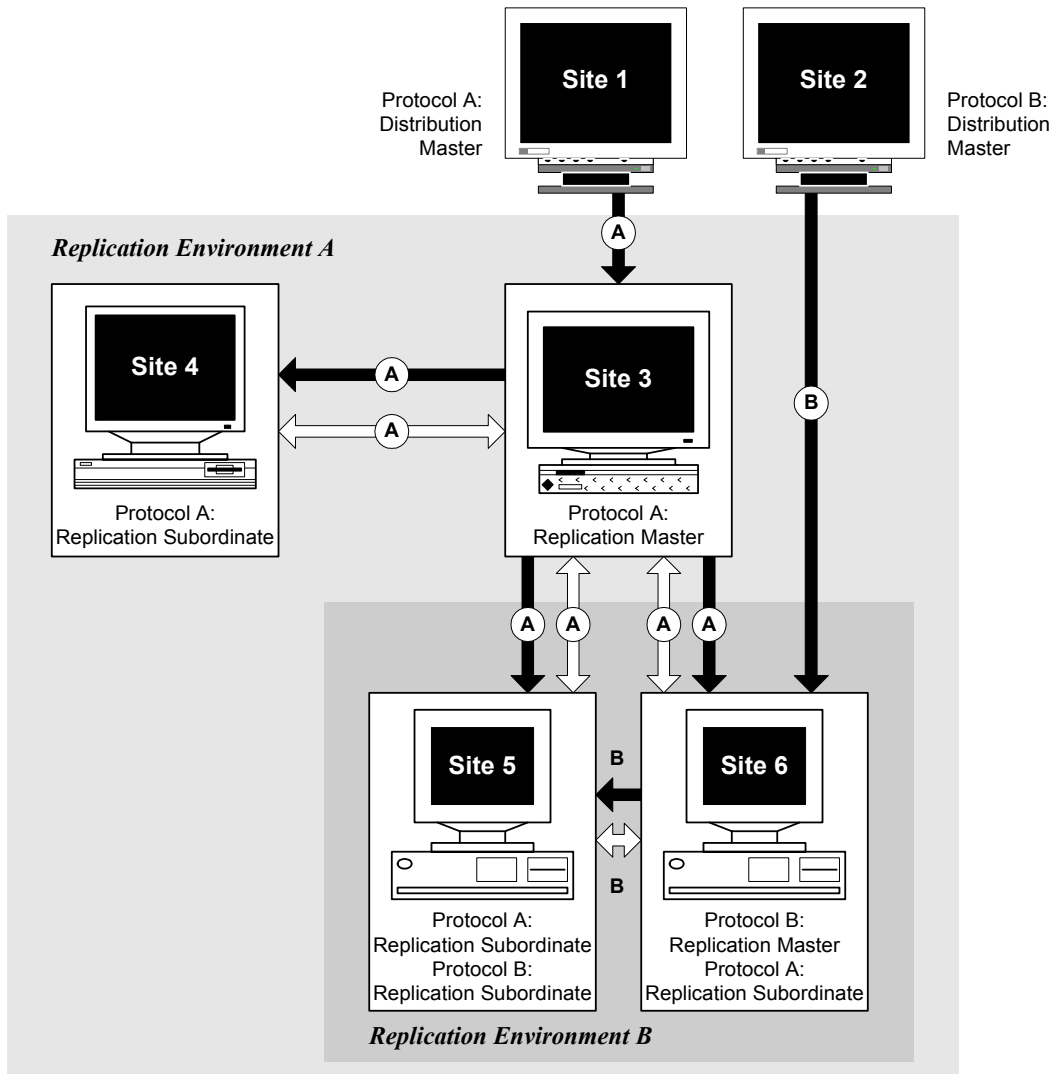
To create the Multisite environment shown in Example C, complete the steps in the following table:

Step:	Task:	At site(s):	See:
1.	Create Protocol A.	1	<i>Admin and Design</i>
2.	Register Site 3 for distribution.	1	Page 54
3.	Distribute Protocol A to Site 3.	1	Page 79
4.	Accept Protocol A.	3	Page 82
5.	Register Site 2 and Site 4 for distribution.	3	Page 54
6.	Distribute Protocol A to Site 2 and Site 4.	3	Page 80
7.	Accept Protocol A.	2 and 4	Page 82
8.	Initialize replication sites.	2, 3, and 4	Page 60
9.	Register Site 2, Site 3, and Site 4 for replication.	Multisite Master	Page 61
10.	Register Protocol A for replication.	3	Page 113
11.	Request Participation from Site 3.	2 and 4	Page 115
12.	Invite Site 2 and Site 4.	3	Page 116
13.	Schedule replication.	2, 3, and 4	Page 119
14.	Set replication restrictions.	3	Page 122

Note: If Protocol A uses functions or thesaurus base tables, you must copy the functions or thesaurus base tables to Site 2, Site 3, and Site 4. For information, see Chapter 6.

Example D: Multiple replication environments

The following Multisite environment shows two replication environments, for Protocol A and Protocol B. Site 5 and Site 6 participate in both replication environments.



What these sites can do

In Example D:

Site(s):	Can:	But cannot:
1	<ul style="list-style-type: none">• Create and modify Protocol A.• Use Protocol A as a data dictionary when building other protocols.• Distribute Protocol A to Site 3.• Modify and redistribute Protocol A.• Backload data from Site 3.	<ul style="list-style-type: none">• Complete any tasks related to replication.• Complete any tasks related to Protocol B.
2	<ul style="list-style-type: none">• Create and modify Protocol B.• Use Protocol B as a data dictionary when building other protocols.• Distribute Protocol B to Site 6.• Modify and redistribute Protocol B.• Backload data from Site 6	<ul style="list-style-type: none">• Complete any tasks related to replication.• Complete any tasks related to Protocol A.
3	<ul style="list-style-type: none">• Accept Protocol A from Site 1.• Use Protocol A as a data dictionary when building other protocols.• Distribute Protocol A to other Distribution Subordinate sites.• Register Protocol A for replication.• Invite Site 4, Site 5, and Site 6 into the replication environment for Protocol A.• Set replication restrictions.• Transfer ownership of subjects in Protocol A.• Schedule replication.• Send changes.• Fetch changes.• Stop replication.• Halt or resume replication.	<ul style="list-style-type: none">• Create or modify objects in Protocol A.• Complete any tasks related to Protocol B.

Site(s):	Can:	But cannot:
4	<ul style="list-style-type: none"> • Accept Protocol A from Site 3. • Use Protocol A as a data dictionary when building other protocols. • Distribute Protocol A to other Distribution Subordinate sites. • Request participation from Site 3. • Transfer ownership of subjects owned at Site 4. • Schedule replication. • Send changes. • Fetch changes. • Stop replication. 	<ul style="list-style-type: none"> • Create or modify objects in Protocol A. • Accept revisions of Protocol A from a site other than Site 3. • Set replication restrictions. • Halt or resume the protocol. • Complete any tasks related to Protocol B.
5	<p>For Protocol A:</p> <ul style="list-style-type: none"> • Accept Protocol A from Site 3. • Use Protocol A as a data dictionary when building other protocols. • Distribute Protocol A to other Distribution Subordinate sites. • Request participation from Site 3. • Transfer ownership of subjects owned at Site 5. • Schedule replication. • Send changes. • Fetch changes. • Stop replication. <p>For Protocol B:</p> <ul style="list-style-type: none"> • Accept Protocol B from Site 6. • Use Protocol B as a data dictionary when building other protocols. • Distribute Protocol B to other Distribution Subordinate sites. • Request participation from Site 6. • Transfer ownership of subjects owned at Site 5. • Schedule replication. • Send changes. • Fetch changes. • Stop replication. 	<p>For Protocol A:</p> <ul style="list-style-type: none"> • Create or modify objects in Protocol A. • Accept revisions of Protocol A from a site other than Site 3. • Set replication restrictions. • Halt or resume the protocol. <p>For Protocol B:</p> <ul style="list-style-type: none"> • Create or modify objects in Protocol B. • Accept revisions of Protocol B from a site other than Site 6. • Set replication restrictions. • Halt or resume the protocol.

Site(s):	Can:	But cannot:
6	<p>For Protocol A:</p> <ul style="list-style-type: none"> • Accept Protocol A from Site 3. • Use Protocol A as a data dictionary when building other protocols. • Distribute Protocol A to other Distribution Subordinate sites. • Request participation from Site 3. • Transfer ownership of subjects owned at Site 6. • Schedule replication. • Send changes. • Fetch changes. • Stop replication. <p>For Protocol B:</p> <ul style="list-style-type: none"> • Accept Protocol B from Site 2. • Use Protocol B as a data dictionary when building other protocols. • Distribute Protocol B to other Distribution Subordinate sites. • Register Protocol B for replication. • Invite Site 5 into the replication environment for Protocol B. • Set replication restrictions. • Transfer ownership of subjects in Protocol B. • Schedule replication. • Send changes. • Fetch changes. • Stop replication. • Halt or resume replication. 	<p>For Protocol A:</p> <ul style="list-style-type: none"> • Create or modify objects in Protocol A. • Accept revisions of Protocol A from a site other than Site 3. • Set replication restrictions. • Halt or resume the protocol. <p>For Protocol B:</p> <ul style="list-style-type: none"> • Create or modify objects in Protocol B. • Accept revisions of Protocol B from a site other than Site 2.

Why set up the environment in Example D?

The Multisite environment shown in Example D contains two replication environments, with two sites (Site 5 and Site 6) participating in both. You may want to create such a Multisite environment when sites participate in multiple studies.

How to set up the environment in Example D

To create the Multisite environment shown in Example D, complete the steps in the following table:

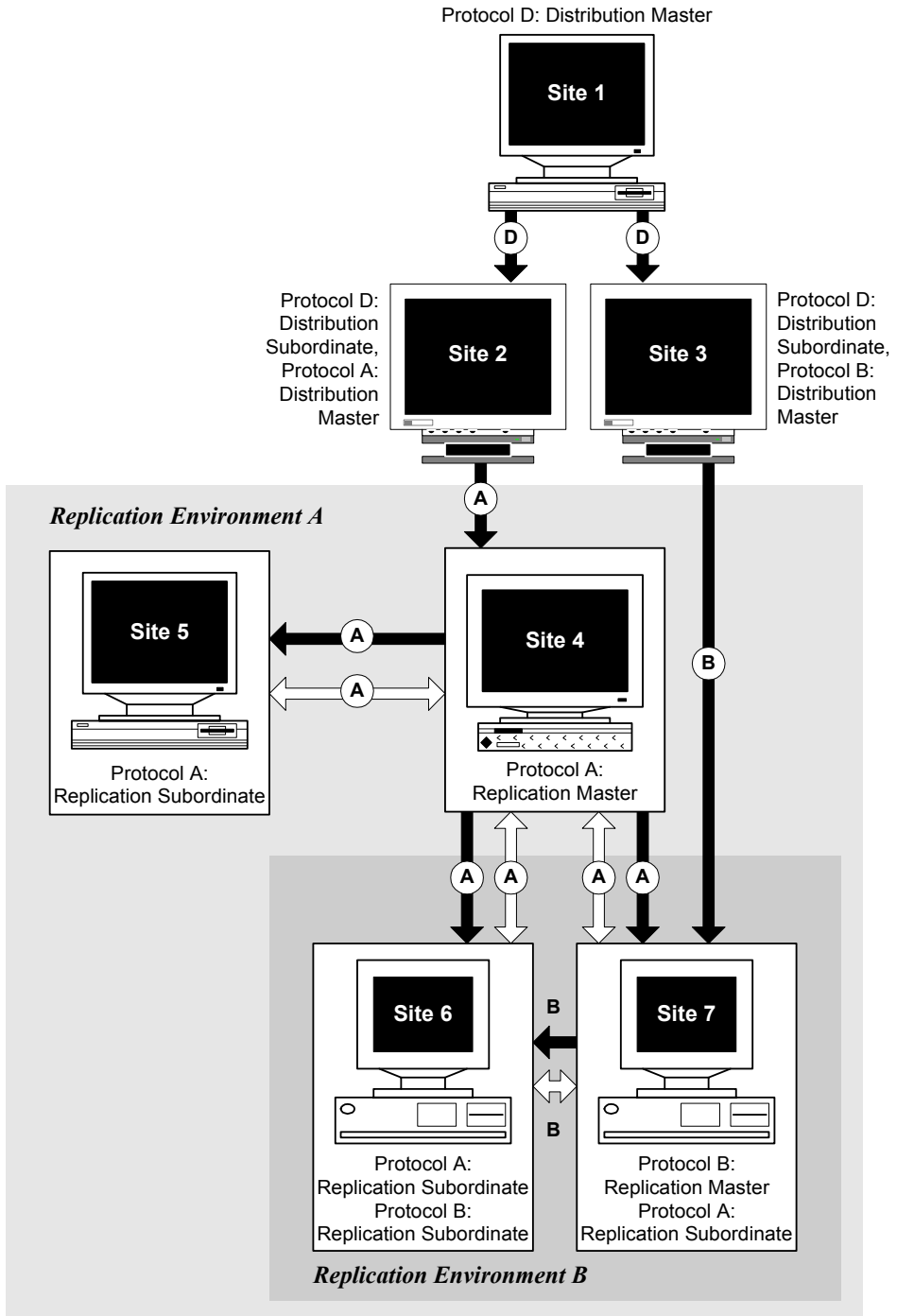
Step:	Task:	At site(s):	See:
1.	Create Protocol A.	1	<i>Admin and Design</i>
2.	Register Site 3 for distribution.	1	Page 54
3.	Distribute Protocol A to Site 3.	1	Page 79
4.	Accept Protocol A.	3	Page 82
5.	Create Protocol B.	2	<i>Admin and Design</i>
6.	Register Site 6 for distribution.	2	Page 54
7.	Distribute Protocol B to Site 6.	2	Page 79
8.	Accept Protocol B.	6	Page 82
9.	Register Site 4, Site 5, and Site 6 for distribution.	3	Page 54
10.	Distribute Protocol A to Site 4, Site 5 and Site 6.	3	Page 80
11.	Accept Protocol A.	4, 5, and 6	Page 82
12.	Register Site 5 for distribution.	6	Page 54
13.	Distribute Protocol B to Site 5.	6	Page 80
14.	Accept Protocol B.	5	Page 82
15.	Initialize replication sites.	3, 4, 5, and 6	Page 60
16.	Register Site 3, Site 4, Site 5, and Site 6 for replication.	Multisite Master	Page 61
17.	Register Protocol A for replication.	3	Page 113

Step:	Task:	At site(s):	See:
18.	Request Participation from Site 3.	4, 5, and 6	Page 115
19.	Invite Site 4, Site 5, and Site 6.	3	Page 116
20.	Schedule replication for Protocol A.	3, 4, 5, and 6	Page 119
21.	Set replication restrictions for Protocol A.	3	Page 122
22.	Register Protocol B for replication.	6	Page 113
23.	Request Participation from Site 6.	5	Page 115
24.	Invite Site 5.	6	Page 116
25.	Schedule replication for Protocol B.	5 and 6	Page 119
26.	Set replication restrictions for Protocol B.	6	Page 122

Note: If Protocol A or Protocol B uses functions or thesaurus base tables, you must copy the functions or thesaurus base tables to all sites to which you distributed the protocol. For information, see Chapter 6.

Example E: Multiple replication environments and complex distribution

The following Multisite environment shows the same replication environment as in the previous example, with the addition of a site (Site 1) that creates a standard dictionary protocol (Protocol D) that is used to create Protocol A and Protocol B:



What these sites can do

In Example E:

Site(s):	Can:	But cannot:
1	<ul style="list-style-type: none">• Create and modify Protocol D.• Use Protocol D as a data dictionary when building other protocols.• Distribute Protocol D to Site 2 and Site 3.• Modify and redistribute Protocol D.	<ul style="list-style-type: none">• Complete any tasks related to replication.• Complete any tasks related to Protocol A or Protocol B.
2	<ul style="list-style-type: none">• Accept Protocol D from Site 1.• Use Protocol D as a data dictionary when building other protocols.• Create and modify Protocol A.• Use Protocol A as a data dictionary when building other protocols.• Distribute Protocol A to Site 4.• Modify and redistribute Protocol A.	<ul style="list-style-type: none">• Create or modify objects in Protocol D.• Complete any tasks related to replication.• Complete any tasks related to Protocol B.
3	<ul style="list-style-type: none">• Accept Protocol D from Site 1.• Use Protocol D as a data dictionary when building other protocols.• Create and modify Protocol B.• Use Protocol B as a data dictionary when building other protocols.• Distribute Protocol B to Site 7.• Modify and redistribute Protocol B.	<ul style="list-style-type: none">• Create or modify objects in Protocol D.• Complete any tasks related to replication.• Complete any tasks related to Protocol A.

Site(s):	Can:	But cannot:
4	<ul style="list-style-type: none"> • Accept Protocol A from Site 2. • Use Protocol A as a data dictionary when building other protocols. • Distribute Protocol A to other Distribution Subordinate sites. • Register Protocol A for replication. • Invite Site 5, Site 6, and Site 7 into the replication environment for Protocol A. • Set replication restrictions. • Transfer ownership of subjects in Protocol A. • Schedule replication. • Send changes. • Fetch changes. • Stop replication. • Halt or resume replication. 	<ul style="list-style-type: none"> • Create or modify objects in Protocol A. • Complete any tasks related to Protocol B or Protocol D.
5	<ul style="list-style-type: none"> • Accept Protocol A from Site 4. • Use Protocol A as a data dictionary when building other protocols. • Distribute Protocol A to other Distribution Subordinate sites. • Request participation from Site 4. • Transfer ownership of subjects owned at Site 5. • Schedule replication. • Send changes. • Fetch changes. • Stop replication. 	<ul style="list-style-type: none"> • Create or modify objects in Protocol A. • Accept revisions of Protocol A from a site other than Site 4. • Set replication restrictions. • Halt or resume the protocol. • Complete any tasks related to Protocol B or Protocol D.

Site(s):	Can:	But cannot:
6	<p>For Protocol A:</p> <ul style="list-style-type: none"> • Accept Protocol A from Site 4. • Use Protocol A as a data dictionary when building other protocols. • Distribute Protocol A to other Distribution Subordinate sites. • Request participation from Site 4. • Transfer ownership of subjects owned at Site 6. • Schedule replication. • Send changes. • Fetch changes. • Stop replication. <p>For Protocol B:</p> <ul style="list-style-type: none"> • Accept Protocol B from Site 7. • Use Protocol B as a data dictionary when building other protocols. • Distribute Protocol B to other Distribution Subordinate sites. • Request participation from Site 7. • Transfer ownership of subjects owned at Site 6. • Schedule replication. • Send changes. • Fetch changes. • Stop replication. 	<p>For Protocol A:</p> <ul style="list-style-type: none"> • Create or modify objects in Protocol A. • Accept revisions of Protocol A from a site other than Site 4. • Set replication restrictions. • Halt or resume the protocol. <p>For Protocol B:</p> <ul style="list-style-type: none"> • Create or modify objects in Protocol B. • Accept revisions of Protocol B from a site other than Site 7. • Set replication restrictions. • Halt or resume the protocol.

Site(s):	Can:	But cannot:
7	<p>For Protocol A:</p> <ul style="list-style-type: none"> • Accept Protocol A from Site 4. • Use Protocol A as a data dictionary when building other protocols. • Distribute Protocol A to other Distribution Subordinate sites. • Request participation from Site 4. • Transfer ownership of subjects owned at Site 7. • Schedule replication. • Send changes. • Fetch changes. • Stop replication. <p>For Protocol B:</p> <ul style="list-style-type: none"> • Accept Protocol B from Site 3. • Use Protocol B as a data dictionary when building other protocols. • Distribute Protocol B to other Distribution Subordinate sites. • Register Protocol B for replication. • Invite Site 6 into the replication environment for Protocol B. • Set replication restrictions. • Transfer ownership of subjects in Protocol B. • Schedule replication. • Send changes. • Fetch changes. • Stop replication. • Halt or resume replication. 	<p>For Protocol A:</p> <ul style="list-style-type: none"> • Create or modify objects in Protocol A. • Accept revisions of Protocol A from a site other than Site 4. • Set replication restrictions. • Halt or resume the protocol. <p>For Protocol B:</p> <ul style="list-style-type: none"> • Create or modify objects in Protocol B. • Accept revisions of Protocol B from a site other than Site 3.

Why set up the environment in Example E?

The Multisite environment shown in Example E contains two replication environments, with two sites (Site 6 and Site 7) participating in both. You may want to create such a Multisite environment when sites participate in multiple

studies, but you must enforce metadata consistency by having a dictionary protocol (Protocol D) used to create the clinical data protocols.

How to set up the environment in Example E

To create the Multisite environment shown in Example E, complete the steps in the following table:

Step:	Task:	At site(s):	See:
1.	Create Protocol D.	1	<i>Admin and Design</i>
2.	Register Site 2 and Site 3 for distribution.	1	Page 54
3.	Distribute Protocol D to Site 2 and Site 3.	1	Page 79
4.	Accept Protocol D.	2 and 3	Page 82
5.	Create Protocol A.	2	<i>Admin and Design</i>
6.	Register Site 4 for distribution.	2	Page 54
7.	Distribute Protocol A to Site 4.	2	Page 79
8.	Accept Protocol A.	4	Page 82
9.	Create Protocol B.	3	<i>Admin and Design</i>
10.	Register Site 7 for distribution.	3	Page 54
11.	Distribute Protocol B to Site 7.	3	Page 79
12.	Accept Protocol B.	7	Page 82
13.	Register Site 5, Site 6, and Site 7 for distribution.	4	Page 54
14.	Distribute Protocol A to Site 5, Site 6, and Site 7.	4	Page 80

Step:	Task:	At site(s):	See:
15.	Accept Protocol A.	5, 6, and 7	Page 82
16.	Register Site 6 for distribution.	7	Page 54
17.	Distribute Protocol B to Site 6.	7	Page 80
18.	Accept Protocol B.	6	Page 82
19.	Initialize replication sites.	4, 5, 6 and 7	Page 60
20.	Register Site 4, Site 5, Site 6, and Site 7 for replication.	Multisite Master	Page 61
21.	Register Protocol A for replication.	4	Page 113
22.	Request Participation from Site 4.	5, 6, and 7	Page 115
23.	Invite Site 5, Site 6, and Site 7.	4	Page 116
24.	Schedule replication for Protocol A.	4, 5, 6, and 7	Page 119
25.	Set replication restrictions for Protocol A.	4	Page 122
26.	Register Protocol B for replication.	7	Page 113
27.	Request participation from Site 7.	6	Page 115
28.	Invite Site 6.	7	Page 116
29.	Schedule replication for Protocol B.	6 and 7	Page 119
30.	Set replication restrictions for Protocol B.	7	Page 122

Note: If Protocol A or Protocol B uses functions or thesaurus base tables, you must copy the functions or thesaurus base tables to all sites to which you distributed the protocol. For information, see Chapter 6.

C *Server Naming Conventions*

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Naming conventions with Multisite

If you will be using Multisite Distribution, or Multisite Distribution and Multisite Replication, Oracle 10g Net Services and Global Database Names must adhere to certain conventions.

Oracle 10g Net Services Names

Oracle 10g Net Services Names must adhere to the following conventions:

- Uniqueness – Must be unique across all database instances in a Multisite environment.
- Consistency – Used to access database instances running Multisite must be consistent across all database instances in a Multisite environment.
- Fully qualified name – Must be fully qualified.
- Length – Can have a maximum length of 60 characters.

Global database names

Global Database Names must adhere to the following conventions:

- Uniqueness – Must be unique across all database instances in a Multisite environment.
- Fully qualified – Must be fully qualified.
- Length – Can have a maximum length of 40 characters.

Note: Oracle recommends (but does not require) that the Global Name, the Clintrial Site Name and the Site Service Name be identical to the database instance name.

The database instance name, set during the creation of the database, may be viewed by using this command in SQL Plus:

```
SQL>SELECT name FROM v$database
```

It is recommended that you confirm the database instance name before starting Clintrial Core Server installation. We recommend that this name be used for the definition of the Global Name, Clintrial Site Name and the Clintrial Service Name.

The Global Name (**Global Name** in the Multisite Site browser) is defined during Clintrial core server installation, and is derived from the instance global name. The instance global name may be viewed by using this command in SQL Plus:

```
SQL>SELECT global_name FROM sys.global_name;
```

The Clintrial Site Name (**Site** in the Multisite Site browser) is defined during Clintrial Core Server installation, and may be viewed by using this command in SQL Plus:

```
SQL>SELECT name FROM cts.database WHERE TYPE = 1
```

The Clintrial Site Service Name (**Service Name** in the Multisite Site browser) is defined during Clintrial Multisite Distribution installation, and captured in CTINST.LOG. It may be viewed by using this command in SQL Plus:

```
SQL>SELECT SQLNET FROM cts.database WHERE TYPE = 1
```


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