ORACLE

CLINTRIAL™

Manage, Classify, and Lab Loader

release 4.7.1

Part Number: E27578-01

Contents

Preface

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:
Release Notes	The *Release Notes* document describes enhancements introduced and problems fixed in the current release, upgrade considerations, release history, and other late-breaking information.
Known Issues	The *Known Issues* document provides detailed information about the known issues in this release, along with workarounds, if available. **Note:** The most current list of known issues is available on the Phase Forward Extranet. 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.
Getting Started	The *Getting Started* guide: • 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.
Admin and Design	The *Admin and Design* document describes how to use: • 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.
Secure Configuration Guide	The *Secure Configuration Guide* 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:
Reference Guide	The *Reference Guide* provides: • 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.
Manage, Classify, and Lab Loader	The *Manage, Classify, and Lab Loader* document describes how to use: • 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.
Enter, Resolve, and Retrieve	The *Enter, Resolve, and Retrieve* document describes how to use: • 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.
Multisite	The *Multisite* document describes: • How to distribute codelists and protocols. • How to set up a replication environment. • How other Clintrial modules work differently in a Multisite environment.
Quick Reference Card for Enter	The *Quick Reference for Enter* lists Enter module menu commands and shortcut keys.

Conventions

The following conventions are used in the Clintrial software books:

Convention:	**Description:**
Italics	Italics are used to indicate the following: • 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.

1 Introduction to the Clintrial Software

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 25.

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

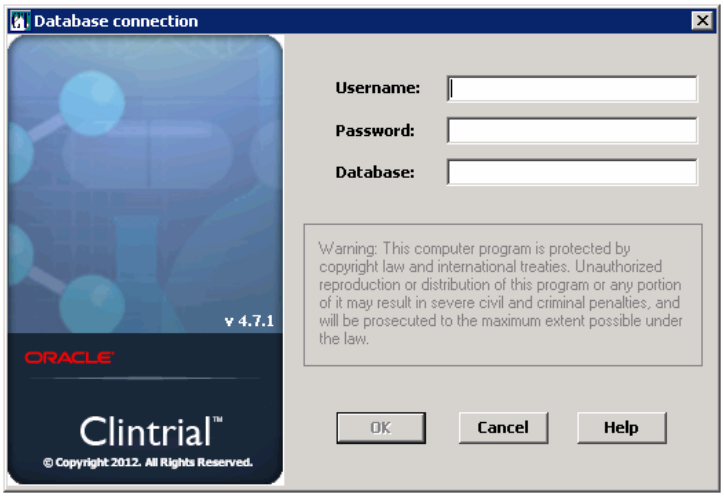
Use the Resolve extended module to manage discrepancy and resolution capabilities that support the work you perform in other Clintrial software modules. You can:

- 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 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

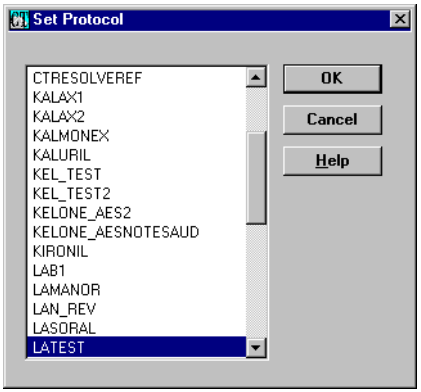
You can start any of the installed Clintrial software modules from the Switchboard **Run** menu. When you start the Switchboard, you provide a user name, password, and database service name. Each time that you start a different Clintrial software module from Switchboard, the Clintrial software uses the 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 fromthe 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

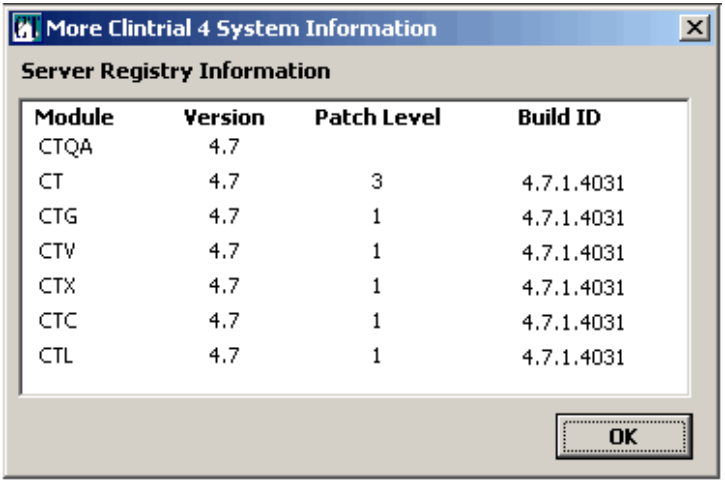
To modify the password for your user account, from the **File** menu, select **Password**. More complete instructions appear in the Clintrial software Basics Help.

How to access the Server Registry Information

You can access the Server Register 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**.

Manage, Classify, and Lab Loader

Manage

2 Introduction to Manage

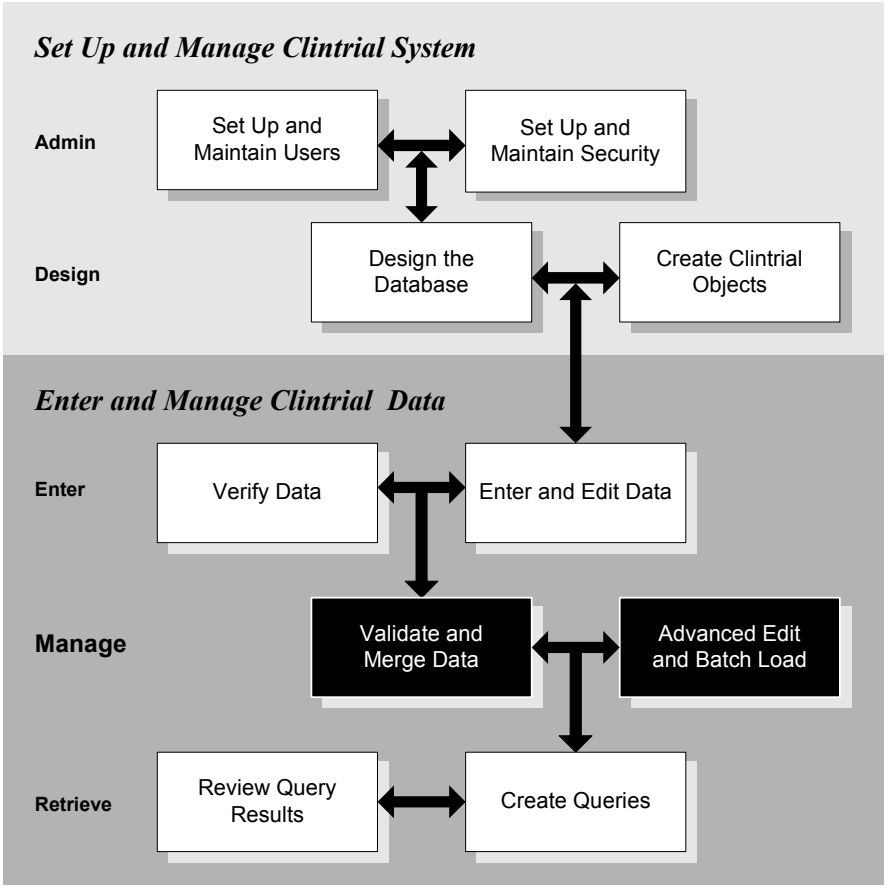
Overview

The Clintrial software Manage module is the core module that you use to perform the following clinical data management tasks:

- Batch load data.
- Code clinical terms using industry-standard coding thesauruses.
- Validate the data.
- Merge data (that is, move data that has passed validation to data tables).
- Globally modify or delete records.
- Review and correct errors.
- View logs and reports.
- View reports of audit data.

How Manage fits in the Clintrial software workflow

The following figure shows how Manage fits in the Clintrial software workflow:



Who are Manage users?

Manage users are generally data managers who are familiar with the Clintrial software database structure and have the required access rights to work with records in clinical data tables.

Clintrial software protocols and panels

A Clintrial software *protocol* is a logical container that organizes the Clintrial software objects and clinical data for a clinical study. It is an Oracle account that consists of database tables that store:

- Metadata used to manage the data in the protocol
- Clinical data, flags, notes, and discrepancies associated with clinical data
- One or more views of the clinical data stored in the protocol

What is a panel?

A *panel* is a collection of logically related or clinically related items. For example, the EXAM panel might define items for physical examination results. When a panel is installed, three Oracle database tables are created (an update table, a data table, and an audit table) for storing clinical data. The items in the panel are the columns of the underlying Oracle database tables.

Panel types

As you work with Manage, you may need to know the differences between different panel types, which are assigned in Design. The following table summarizes the panel types:

Panel type:	Description:
0	Stores non-subject related data, such as laboratory normal ranges. No context items are included in a Type 0 panel.
1	Stores one record per subject; that is, a single record that is collected only once for each subject, such as demographic data. A subject item is required for a Type 1 panel.
2	Stores multiple records per subject; that is, multiple records collected once in a clinical study for each subject, such as previous medications. The data is related to a single visit. A subject item is required for a Type 2 panel.
3	Stores one record per subject visit; for example, a subject's vital signs. A subject item and block key item are required for a Type 3 panel.

Panel type:	Description:
4	Stores multiple records collected for each subject visit; for example, adverse experiences. A subject item and a block key item are required for a Type 4 panel.
5	Stores one record for each subject in a study, to uniquely identify the subject. This type of panel is also called the enrollment panel. Subjects must be enrolled before data can be entered for them. There can be only one active enrollment panel for each protocol at any given time. A subject item is required for a Type 5 panel.

Types of database tables

A *database table* is an Oracle database table that stores clinical data or metadata. For each installed panel, the following three database tables exist:

- *Update table* — An Oracle database table that stores data when it is first entered in the Clintrial software. The update table is a holding area for clinical data while it is being manipulated. The name of the update table is *panel-name*_UPDATE.
- *Data table* — An Oracle database table that stores data that has passed validation. The name of the data table is *panel-name*_DATA.
- *Audit table* — An Oracle database table that stores copies of clinical data records as they existed before modification or deletion. The name of the audit table is *panel-name*_AUDIT.

A record can be in either the update table or the data table, but not in both tables.

Clintrial software items

An *item* is a Clintrial software object that represents a piece of data; for example, the data that is collected in a field on a case report form (CRF).

Items are defined within panels, and each item corresponds to a column in a table. For example, the DMG panel might contain the items SEX, AGE, and RACE. The update table, data table, and audit table for the DMG panel would include the columns SEX, AGE, and RACE.

System items

A *system item* is one of eight items that are attached automatically to each record to help identify and manage records. For example, the status of each record is stored as a system item. For descriptions of the system items, see the *Reference Guide* or the *Design* section in *Admin and Design.*

Context items

A *context item* is an item that provides context information, such as subject or visit, for clinical data records. Context items are defined in the CONTEXT panel.

What is the subject item?

The *subject item* is a context item used in enrollment that uniquely identifies the subject in the clinical data tables in a study. Typically, the subject item is the patient number, or another unique identifier. Internally, the Clintrial software associates the subject item with the SUBJECT_ID system item, for which the Clintrial software generates a unique value.

Note: In this guide and in the Manage Help, the subject item is often referred to as the *subject identifier.*

What is the block key item?

The *block key item* is the context item that is used to access data by block within a study book. Typically, the block key item is the visit number. For example, the block key item might be VISITNO.

The *block key value* is the value given to the block key item. For example, the block key values in a study book might be:

- 0 (Block Title: Baseline Visit)
- 1 (Block Title: Visit 1)
- 2 (Block Title: Visit 2)
- 3 (Block Title: Final Visit)

If a study book includes repeating blocks, then a block repeat key item is used, along with the block key item, to access data by block. The *block repeat key item* uniquely identifies data in a repeating block. For example, if a block is used more than once in the study book, then the day number could distinguish multiple uses of the block. The block repeat key item might be DAYNO.

The following example shows a repeating block (Visit 3) that has been used twice, once for Day 90 and once for Day 100:

Block key value —— Visit: 3 Day: 90 —— *Block repeat key value*
Page: Vitals Signs
Page: Joint Assessment
Page: Adverse Events Occurrence 1

Visit: 3 Day: 100
Page: Vitals Signs
Page: Joint Assessment
Page: Adverse Events Occurrence 1

What is the page key item?

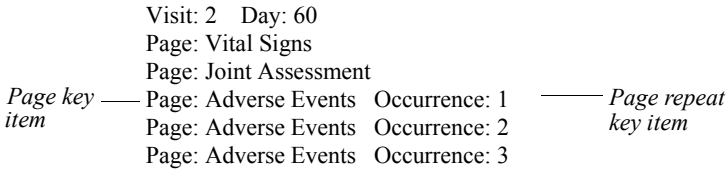
The *page key item* is the context item that is used to access data by study page within a block. Typically, the page key item is the page number. For example, the page key item might be PAGENO.

The page key value is the value given to the page key item. For example, the page key values in a study book might be:

- 1 (Page Title: Vital Signs)
- 2 (Page Title: Joint Assessment
- 3 (Page Title: Adverse Experience)

If a block includes repeating pages, then a page repeat key item is used, along with the page key item, to access data by page within a block. The *page repeat key item* uniquely identifies data in a repeating page within a block. For example, if a page is used more than once in the block, then the page occurrence number could distinguish multiple uses of the page.

The following example shows a repeating page (Adverse Events) that has been used three times, for occurrences 1, 2, and 3:



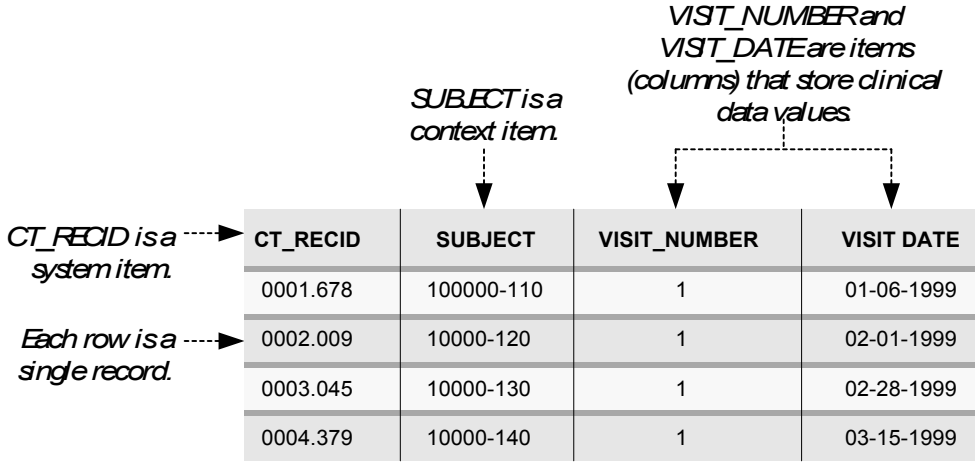
Type 0 and Type 5 panels

For a Type 0 or Type 5 panel, a study book always includes only one block and one page.

Clintrial software records and record statuses

A *record* is the data stored in one row in a database table. Depending on the panel type, the data collected in a study page is stored in one or more records in the database.

The following figure shows the organization of a database table:



What is grouping?

Grouping is an automatic process performed during screening that collects repeating records into observations for batch-loaded records. An *observation* is a group of records in a page section that contains repeating items, or a group of records in a non-subject study book that has been configured for grouping. Grouping is only meaningful for records in a Type 0 panel (non-subject data), a Type 2 panel, where multiple records can exist for the same subject, or a Type 4 panel, where multiple records can exist for the same subject visit.

For example, suppose you batch load data for multiple adverse events observed during a subject visit. When the records are grouped, all the events become part of the same observation.

The CT_RECID system item indicates whether records are part of the same observation. For records that are part of an observation, the base of the CT_RECID is the same and the last three digits are different. The following example shows three records for the ADVERSE panel that are all part of the same observation:

CT_RECID	SUBJECT-_ID	VISITNO	PAGENO
1,SQLOAD.LL?Min001.001	10	2	1
1,SQLOAD.LL?Min001.002	10	2	1
1,SQLOAD.LL?Min001.003	10	2	1

What is a record status?

The Clintrial software assigns a *record status* to records to track them internally as they go through various stages of data management. The status of a record is stored in the STATUS system item.

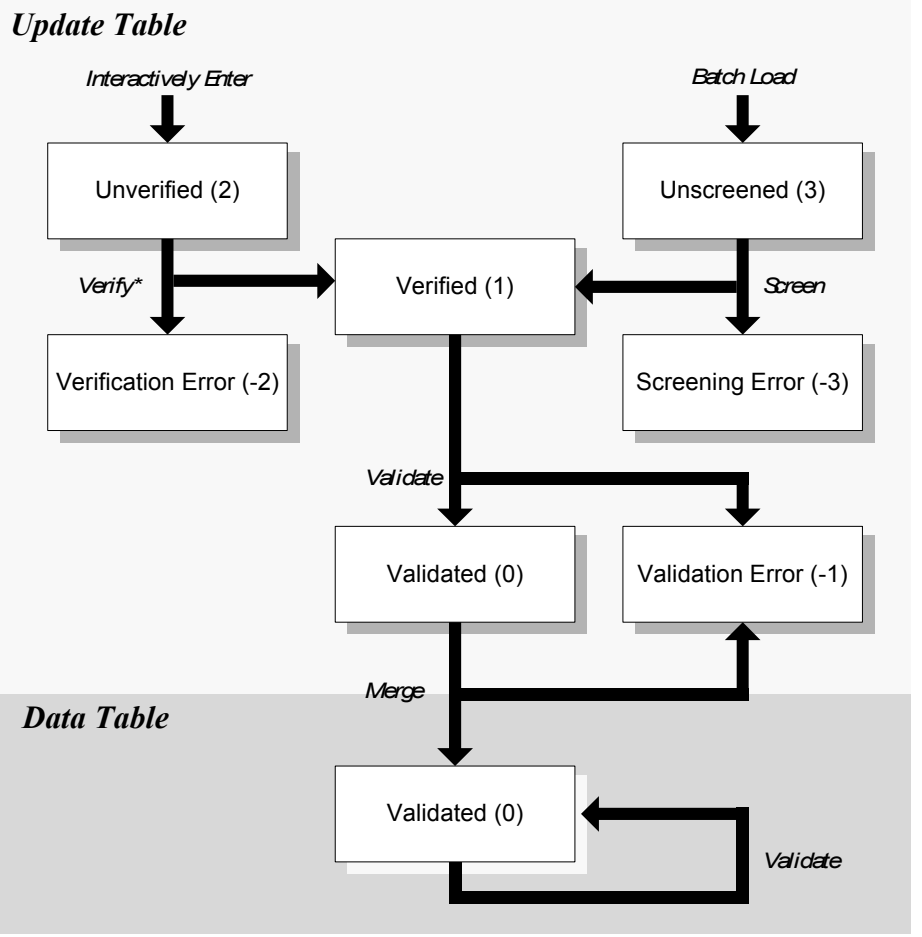
As you perform certain data management tasks for records in the update table, the Clintrial software automatically changes the record status. Once the record is in the data table, its status cannot change and will always be Validated (0).

List of record statuses

The following table summarizes possible record statuses for records in the update table or data table:

Status:	Description:	Table:	Code:
Unscreened	The record was entered with batch loading, but has not yet been screened.	Update	3
Unverified (or Entered)	The record was entered interactively, but has not yet been verified.	Update	2
Verified	The record passed verification (for interactively entered data) or screening (for batch-loaded data).	Update	1
Validated	The record passed validation.	Update or Data	0
Validation Error	The record failed validation or merging.	Update	– 1
Verification Error	The record failed verification (for interactively entered data).	Update	– 2
Screening Error	The record failed screening (for batch-loaded data).	Update	– 3

The following figure shows how record statuses change during the different Manage tasks:



* If verification is not required, then an Unverified record can be validated.

Data management tasks

The following data management tasks are performed in Manage:

- Batch loading
- Screening
- Coding
- Validating

- Merging
- Global changes and deletions
- Error Log viewing
- Auditing

Batch loading

As an alternative to interactive data entry with Enter, you can batch load data using Manage. *Batch loading* is the process of taking data that is stored in an ASCII file and placing that data directly into a Clintrial software database table.

Screening

Screening is a combination of several tasks performed from one single menu command. You screen records after data is batch loaded into the clinical data protocol. When you screen records, Manage performs the following tasks:

- *Updates the system items*. Updating the system items in all records that were successfully batch loaded into the database table supplies values for the internal items that the Clintrial software uses to uniquely identify records.
- *Groups the records into observation*s, if grouping items are indicated in Design. Grouping the records organizes batch-loaded records into observations. An *observation* is a group of records in a page section that contains repeating items, or a group of records in a non-subject study book that has been configured for grouping. For example, you might group multiple blood tests that were taken on one sample into a single observation.
- *Applying data checks to batch-loaded data*. Applying data checks to batch-loaded data applies the same checks that are applied to interactively entered data.

Screening also ensures that the batch-loaded data is entered correctly in the update table.

Once data passes screening, you can validate, edit, and merge the records in the same way that you do data that is entered interactively.

Coding

Coding is the process of assigning a standard code from a *coding thesaurus* to a value that has been entered for an item. Your designer decides which items in panels can be coded and which thesauruses will be used. The Clintrial software provides a means to use industry-standard thesauruses, such as the MedDRA (Medical Dictionary for Drug Regulatory Affairs) dictionary.

Validation

Validation, also called data cleaning, is the process of running a validation procedure on clinical data to apply any derivations defined and to check for logic and consistency. Data either passes or fails validation.

Each panel has one associated validation procedure. The *validation procedure* is a PL/SQL procedure that is built automatically from the derivations and rules associated with the panel:

- *Derivations* calculate values of items that the designer has set up as "derived" based on constants or on the values of other items.
- *Rules* check that the clinical data meets the requirements of the clinical protocol.

Merging

Merging is the process of moving data that has passed validation from the update table to the data table. Only data that has passed validation can be merged.

Global change and global deletion

Global change is the process of changing the value of one or more items in multiple records. *Global deletion* is the process of deleting multiple records. Before making actual changes or deletions, you can preview the results.

Error Log

The *Error Log*, available from the **Reports** menu, is a cumulative log of errors that occurred during screening, validation, merge, global change, and global deletion. If you have appropriate privileges, you can edit a record that you select from the Error Log.

Auditing

Auditing is the process of tracking changes made to clinical data and of tracking notes associated with clinical data. The designer determines which Clintrial software panels and tasks are audited.

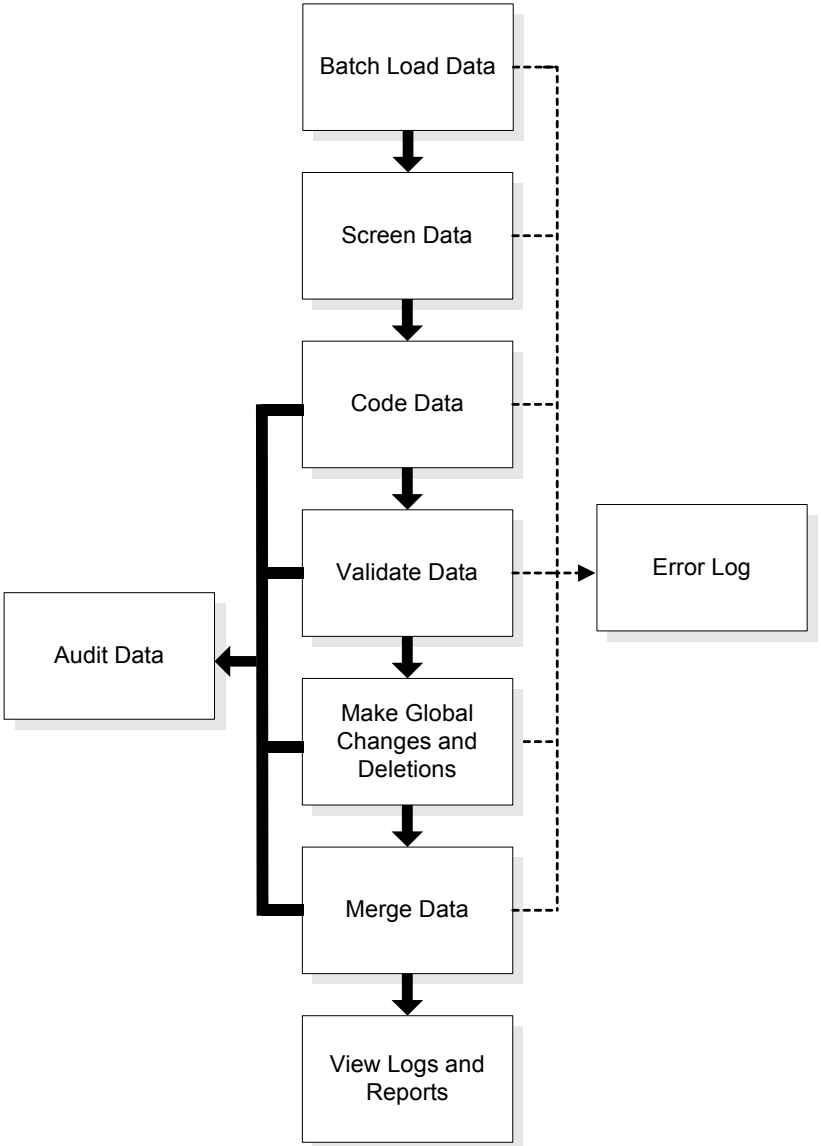
The *audit report* shows differences between the record as it was before a change and the record as it is after a change. It also shows records that have been deleted from the update table or data table when auditing is in effect.

Sample Manage workflow

The activities performed in Manage do not necessarily follow a linear workflow. Most activities may be performed at any time, or simultaneously.

Global changes and deletions are included, although they are not necessarily part of the typical workflow, and you can make them at any time. Coding can also be performed at any time.

The following figure shows a typical workflow within Manage:



Required access rights and access levels

After you set up a protocol for use with Manage, you assign access rights to users for the protocol in Admin. An *access right* is a predefined set of Clintrial software activities that can be associated with a usergroup or a user. Some access rights relate to activities that require access to protocols and must be associated with a protocol as well as with a usergroup or user.

Access levels determine what type of access users have to the activities defined by an access right. By selecting an appropriate access level, you grant users or usergroups the ability to perform certain activities.

For more information on access rights and access levels, see the *Admin* section in *Admin and Design*.

List of Manage protocol access rights

The following table lists the Manage protocol access rights and access levels:

Access right:	User can:	Access levels:
Coding	Code data using values from a coding thesaurus.	Full — Can code, view coding reports, and purge coding reports. Read — Can view coding reports, but cannot code or purge coding reports. None — Cannot code or view coding reports. ***Note**:* Coding access cannot be applied to View protocols.

Access right:	User can:	Access levels:
Global	Make global changes and deletions.	Full — Can make global changes and deletions, view global change and global deletion reports, and purge global change and global deletion reports. Read — Can view global change and global delete reports, but cannot perform global changes or global deletions or purge global change and global deletion reports. None — Cannot make global changes and deletions, view global change and global delete reports, or purge global change and global deletion reports. ***Note**:* Global access cannot be applied to View protocols.

Access right:	User can:	Access levels:
Other	Perform Manage activities other than code or make global changes and deletions.	Full — Can perform all Manage tasks. Can generate Audit Subjects Reports. Can view reports, except Coded Item Report. Can purge reports, except Global Change Report, Global Delete Report, Coded Item Report. Read — Can view reports for other tasks, but cannot perform these tasks or purge reports. Can create and print Audit Subjects Reports. Cannot view Coded Item Report. None — Cannot perform these Manage tasks, or view reports for these tasks. ***Note:*** Other access cannot be applied to View protocols.

Note: If you plan to edit records directly from the Error Log, you must also have the Unmerged protocol access right for Enter, with the Full access level. If you plan to edit records in the data table from the Error Log, you must have the Merged protocol access right for Enter, with the Full access level.

Setting your user preferences

System parameters define characteristics of the work environment for all users of an Oracle database instance to which the users connect through the Clintrial software.

You set system parameters in Admin.

User preferences are a subset of system parameters. Default values for user preferences come from corresponding system parameters. Each user can change the default values of the parameters for use in their account by changing the user preferences.

Your Clintrial software administrator will set default user preferences in Admin when the Clintrial software is installed. You can change the default Manage user preferences in Manage.

Manage user preferences

The following table lists the user preferences that are available in Manage:

User preference:	**Description:**
ERRLOG_DISPLAY-_ITEM Default: None	Name of an additional item to be displayed in the Error Log for Type 0 panels.
SELECT_BY_PAGE Default: No	If Yes, records are selected by study page for validation and merge. If No, records are selected by panel.
AUDIT_ITEM_LIST Default: None	Name of an additional context item to be included in the Audit Report. The subject item, block key item, block repeat key item, page key item, and page repeat key item are included by default.

3 Batch Loading Data

Overview

Batch loading is the process of taking data that is stored in an ASCII file and placing that data directly into a Clintrial software database table. You can batch load any type of data; for example, clinical data, thesaurus data, or enrollment data.

The batch-loading process includes the following steps:

1. Create a control file. The control file specifies the relationship between the data in the input file and the items in the Clintrial software database.
2. Batch load the data (that is, the input file).
3. Screen the batch-loaded data. The screening process:
   - Updates the system items.
   - Groups the records into observations, if grouping items are specified in Design.
   - Applies data checks to batch-loaded data.
4. Optionally, edit or delete the unscreened data.

Update table and data table

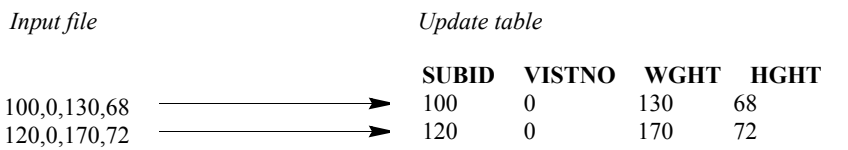
When you batch load data, it is stored initially in the update table for the specified panel. After the data has passed screening, you can validate the data, and then merge it (that is, move the data to the data table).

Caution: Enrollment data must be in the data table for the Clintrial software to recognize that a subject is enrolled. Therefore, after batch loading enrollment data for new subjects, you must screen, validate, and merge the enrollment data before other data can be entered for the new subjects.

What is an input file?

An *input file* is an ASCII file that contains lab data to be batch loaded into the Clintrial software. Each line in the file represents a record composed of fields. Each field contains data that, when it has been batch loaded into the Clintrial software, will be stored as an item in the update table for the panel into which it was loaded. The input file may use a delimiter, such as a comma, to separate values for fields.

The following example shows how the values in a two-line input file would be stored as items in the update table after batch loading:



Creating a control file

A *control file* serves as the interface between the input file and the Clintrial software database table. The control file:

- Interprets the organization and format of data in the input file for Oracle SQL Loader.
- Provides instructions on how Oracle SQL Loader loads data from the input file into the database table.

You can create multiple control files for a panel. Also, you can use the same control file to load one or more input files into the update table for a specified panel.

Note: You can only select one panel at a time for which to create a control file. Data can only be batch loaded into one panel at a time, and the data must be loaded into the panel's update table. To load data from an input file into more than one panel, you must create multiple control files and run the batch load for each panel.

What is the default control file?

When you create a control file, the Clintrial software creates a default version of the control file, based on the panel definition. You must edit the control file to match the structure and order of the data that you will be batch loading.

File formats

You can create a control file in either of the following formats:

- Fixed format

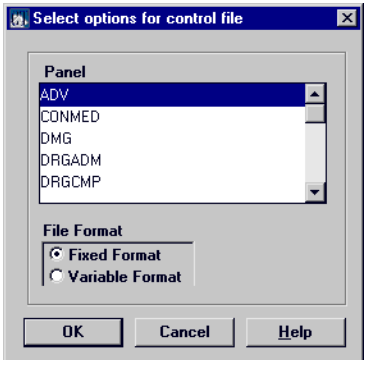
  In a fixed format input file, the data values have a specified length, and each value begins at a fixed location in the record. No delimiters separate the values.

- Variable format

  In a variable format input file, the data values do not have to be a specified length, and may not begin at the same location in each record. Delimiters that you specify, such as commas, separate the values. The same delimiter must be used for all records in the input file.

How to begin

To create a default control file, from the **Load** menu, select **Control File >> New**. The Select options for control file dialog box opens:



Select the panel for which you are creating the control file, and the format of the control file. The Clintrial software creates and displays a default control file for the panel. You can edit the control file as described in "Editing a control file" on page 56. If you indicate that you want to save the file, you can specify a location for it.

Fixed format control file

The following is an example of a fixed format control file:

```
-------------------------------------------------------------------
-- Control file for loading data into:
--      MEDIKA_CLINICAL.LAB_UPDATE
-------------------------------------------------------------------
```

```
LOAD DATA

APPEND
INTO TABLE MEDIKA_CLINICAL.LAB_UPDATE

TRAILING NULLCOLS

(STATUS              constant     3,
CT_RECID             sequence     (count),
SUBJECT_ID           constant     0,
SUBJECT              position(1:10)     "RTRIM(LTRIM(:SUBJECT))",
VISNO                position(11:20)    "RTRIM(LTRIM(:VISNO))",
PAGENO               position(21:30)    "RTRIM(LTRIM(:PAGENO))",
PAGERPT              position(31:40)    "RTRIM(LTRIM(:PAGERPT))",
VISRPT               position(41:50)    "RTRIM(LTRIM(:VISRPT))",
PROTID               position(51:60)    "RTRIM(LTRIM(:PROTID))",
VISDATE              position(61:74)    DATE "YYYYMMDDHH24MISS"
                                        NULLIF VISDATE=BLANKS,
SUBJINIT             position(75:84)    "RTRIM(LTRIM(:SUBJINIT))",
DAYNO                position(85:94)    "RTRIM(LTRIM(:DAYNO))",
LABNAME              position(95:104)   "RTRIM(LTRIM(:LABNAME))",
TEST_UNITS_HEM       position(105:114)
"RTRIM(LTRIM(:TEST_UNITS_HEM))",
RELEV                position(115:122)  NULLIF RELEV=BLANKS,
RESULT               position(123:132)  "RTRIM(LTRIM(:RESULT))",
TEST_TYPE            position(133:142)  "RTRIM(LTRIM(:TEST_TYPE))",
TEST_NAME            position(143:152)  "RTRIM(LTRIM(:TEST_NAME))",
LABNO                position(153:162)  "RTRIM(LTRIM(:LABNO))",
URNGUIDE             position(163:172)  "RTRIM(LTRIM(:URNGUIDE))",
TEST_UNITS_CHM       position(173:182)
"RTRIM(LTRIM(:TEST_UNITS_CHM))"
)
```

Variable format control file

The following is an example of a variable format control file:

```
-----------------------------------------------------------------------
-- Control file for loading data into:
--      MEDIKA_CLINICAL.LAB_UPDATE
```

```
--------------------------------------------------------------------------

LOAD DATA

APPEND
INTO TABLE MEDIKA_CLINICAL.LAB_UPDATE

-- Note: Change @ to your file's separator character and adjust the 'ENCLOSED BY' clause
FIELDS TERMINATED BY '@' OPTIONALLY ENCLOSED BY ""

TRAILING NULLCOLS

(STATUS              constant     3,
CT_RECID             sequence     (count),
SUBJECT_ID           constant     0,
SUBJECT              "RTRIM(LTRIM(:SUBJECT))",
VISNO               "RTRIM(LTRIM(:VISNO))",
PAGENO               "RTRIM(LTRIM(:PAGENO))",
PAGERPT              "RTRIM(LTRIM(:PAGERPT))",
VISRPT              "RTRIM(LTRIM(:VISRPT))",
PROTID              "RTRIM(LTRIM(:PROTID))",
VISDATE              DATE "YYYYMMDDHH24MISS" NULLIF VISDATE=BLANKS,
SUBJINIT             "RTRIM(LTRIM(:SUBJINIT))",
DAYNO               "RTRIM(LTRIM(:DAYNO))",
LABNAME              "RTRIM(LTRIM(:LABNAME))",
TEST_UNITS_HEM       "RTRIM(LTRIM(:TEST_UNITS_HEM))",
RELEV               NULLIF RELEV=BLANKS,
RESULT              "RTRIM(LTRIM(:RESULT))",
TEST_TYPE            "RTRIM(LTRIM(:TEST_TYPE))",
TEST_NAME            "RTRIM(LTRIM(:TEST_NAME))",
LABNO               "RTRIM(LTRIM(:LABNO))",
URNGUIDE             "RTRIM(LTRIM(:URNGUIDE))",
TEST_UNITS_CHM       "RTRIM(LTRIM(:TEST_UNITS_CHM))"
)
```

Editing a control file

Once the default control file is built, you can edit it to meet the input file requirements. For example, if the data type, width, position, or format of data in the input file differs from those in the control file, you can edit the control file, if necessary, to correspond to the input file.

How to begin

From the **Load** menu, select **Control File >> Edit**.

When you finish editing the control file, you must save the control file. The default file name extension for the control file is *panel-name*.ctl; for example, lab.ctl.

Items in the control file

The default control file lists all items in the panel. The control file must include specifications for some of the system items, although values for the system items are not included in the input file. When you load the input file, the Clintrial software assigns values to the system items of the batch-loaded data. You will then need to screen the data to update the system items as described in "Screening batch-loaded data" on page 61.

Changes you may want to make

When you edit the default control file, you can make the following changes:

- If necessary, reorder the items in the control file to match the order of values in the input file.
- Delete items for which the input file does not contain values. For example, if the input file does not contain any values for the item BIRTH_DATE, you could delete BIRTH_DATE from a fixed format control file.
- Add conversion instructions, such as instructions for converting date formats.
- Adjust the ENCLOSED BY clause to contain the character that is used in the input file to indicate character strings.
- For a variable format control file, change the delimiter from '@' to the character that is used as a field delimiter in the input file. For example, ','.
- For a fixed format control file, change an item's fixed size.

Note: You do not need to batch load every field from the records in the input file.

Delimiters

A variable format control file must indicate the delimiter that is used in the input file.

For example, if the input file is a comma-separated (.csv) file, then the delimiter is a comma. In the control file, replace the default delimiter (@) with a comma:

FIELDS TERMINATED by ‘,’

Trailing null values

By default, a control file includes the following line:

TRAILING NULLCOLS

This line indicates that if not enough values are supplied by the record in the input file, then the items in the panel will be given the value Null when the record is batch loaded.

Date format

The control file must specify the date format that is used in the input file.

For example, if the input file contains the date 03-17-1999 00:00:00, then the control file must specify the date format of the item as:

DATE “MM-DD-YYYY HH24:MI:SS”

Character strings

The control file must specify the character that is used to indicate character strings in the input file. In the control file, you must enclose the character in single quotation marks.

For example, if the double quotation mark is used to indicate character strings in the input file, then the control file must specify:

OPTIONALLY ENCLOSED by ‘”’

NULLIF clause

For items of the data type NUMBER or DATE, the default control file contains a NULLIF clause. The default NULLIF clause treats an item as Null if the value in the input file is blank.

You can edit the NULLIF clause in the control file so that an item is treated as Null if the value in the input file is another value; for example, a period (.).

LTRIM and RTRIM clauses

For items of the data type TEXT, the default control file includes the following:

- An LTRIM clause, which trims leading blanks
- An RTRIM clause, which trims trailing blanks

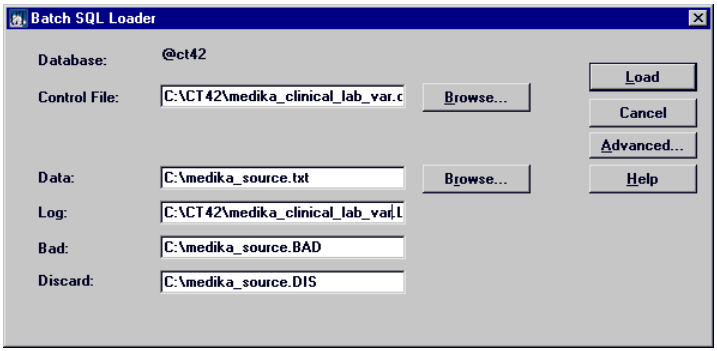
Loading the data

To batch load data, you must have the Oracle SQL Loader tool installed on your computer. You must use the 32-bit version of SQL Loader.

Before batch loading, you may want to check a sampling of records in each input file to ensure that the positions and formats match the corresponding control file.

For more information on supported versions of SQL Loader with the Clintrial software, see the *Reference Guide*.

From the **Load** menu, select **Load Data**. The Batch SQL Loader dialog box opens:



In this dialog box, you specify the names and locations of the control file and input file. The Clintrial software saves the files in this dialog box as defaults for the next session. You can change these defaults.

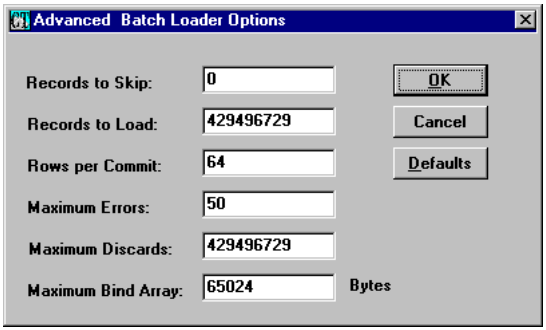
You can also specify the names and locations of the following files, which will be created by the batch-load process:

File:	Description:
Log file	Provides information about the batch-loading process, such as the number of records loaded into the update table, and the number of errors that occurred. This file is optional, but recommended. The default name of the file is the control file name, followed by the extension .log. By default, the file is stored in the same directory as the control file. You can change the default file name and location.
Bad file	Lists records that were rejected by SQL Loader; for example, if a value exceeds its maximum length or the data is invalid for the data type. These records are not loaded into the update table. This file is optional. You may want to manually edit this file, rename it, and reload it as an input file. The default name of the file is the input file name, followed by the extension .BAD. By default, the file is stored in the same directory as the input file. You can change the default file name and location.

File:	Description:
Discard file	Lists records that did not meet the selection criteria for batch loading. The records are not loaded into the update table. This file is optional. The default name of the file is the input file name, followed by the extension .DIS. By default, the file is stored in the same directory as the input file. You can change the default file name and location.

Advanced SQL Loader options

If you click **Advanced** in the Batch SQL Loader dialog box, then the Advanced Batch Loader Options dialog box opens:



The following table describes the options that you can set in the Advanced Batch Loader Options dialog box:

Option:	Description:	SQL Loader parameter:
Records to Skip	The number of logical records from the beginning of the file that should not be loaded. Use this option to continue loads that have been interrupted.	SKIP
Records to Load	The number of logical records to load after skipping the number of records specified in Records to Skip.	LOAD
Rows per Commit	The number of rows in the bind array.	ROWS

Option:	Description:	SQL Loader parameter:
Maximum Errors	The number of insert errors to allow before SQL Loader terminates with an error.	ERRORS
Maximum Discards	The number of discards to allow before SQL Loader terminates with an error.	DISCARDMAX
Maximum Bind Array	The maximum size of the bind array (in bytes).	BINDSIZE

How to check results

To determine whether the batch load completed successfully, you must view the log file. From the **Reports** menu, select **Batch Load Log**.

Screening batch-loaded data

Screening is a combination of several tasks performed from one single menu command. You screen records after data is batch loaded into the clinical data protocol. When you screen records, Manage performs the following tasks:

- *Updates the system items.* The *system items* are internal items within every record that the Clintrial software uses to uniquely identify the records. Updating the system items assigns values to the items CT_RECID and SUBJECT_ID. The values assigned are equivalent to the values assigned when you interactively enter records through Enter.
- *Groups the records into observations*, if grouping items are indicated in Design. Grouping the records organizes batch-loaded records into observations. An *observation* is a group of records in a page section that contains repeating items, or a group of records in a non-subject study book that has been configured for grouping. For example, you might group multiple blood tests that were taken on one sample into a single observation. Records grouped into a single observation are displayed as a repeating group in a study page in Enter, and exist collectively in the update and data tables.
- *Applies data checks to batch-loaded data*. Applying data checks applies the same checks that are applied when you interactively enter data in Enter. The data checks are:
  - Confirming that subjects are enrolled.

- Confirming that subject, block, and page keys are defined.
- Confirming that block repeat and page repeat keys are defined, if they will be used.
- Confirming that subset keys are defined, if they will be used.
- Confirming that a master record exists for a detail record.
- Confirming that the master key is unique.
- Confirming that grouping items have values, if grouping items are defined for Type 0 panels. Confirms that default grouping items have values for Type 2 and Type 4 panels.
- Confirming that values are provided for mandatory items.
- Confirming that a code for an item with an attached codelist exists in the codelist.
- Applying the range checks (upper and lower limits) that are defined for items.
- Confirming that a value exists in the checklist for an item with an attached checklist.

Additionally, each record for a non-Type 0 panel must have a SUBJECT_ID system item other than 0, and each record must minimally have a valid block key and page key.

About system item assignment

When you first batch load a record, the Clintrial software assigns values to system items as follows:

- The MERGE_DATETIME value is initially the same as the ENTRY_DATETIME.
- The STATUS value is Unscreened (3).
- The ENTRY_ID is assigned by the Clintrial software, and is the batch-load account associated with the protocol into which you are batch loading data.
- The ENTRY_DATETIME value is the date and time that the record was batch loaded.
- The CT_RECID is a one-part unique identifier generated from a sequence during the initial load by Oracle SQL Loader.
- The SUBJECT_ID is 0.
- The DB_ID is the identifier of your database instance.
- The CTS$REASON value is blank.

For descriptions of the system items, see the *Reference Guide* or the *Design* section in *Admin and Design*.

How system item assignment is changed

When you screen records, the following system items change for each record:

- The ENTRY_ID becomes the user account that screened the records.
- The MERGE_DATETIME becomes the date and time that the records were screened.
- The CT_RECID changes to the four-part identifier assigned by the Clintrial software.
- For panel types 1 through 4, the SUBJECT_ID becomes the value of the SUBJECT_ID that is associated with the subject in the enrollment panel. For Type 5 panels, it becomes a unique value in the enrollment panel.

The following example shows the values of system items for four batch-loaded records for which system items have not yet been updated:

STATUS	ENTRY-_ID	MERGE	CT_RECID	DB_ID	SUBJECT-_ID
3	CTSLOAD	10/1/99 12:31:12	1	1	0
3	CTSLOAD	10/1/99 12:31:12	2	1	0
3	CTSLOAD	10/1/99 12:31:12	3	1	0
3	CTSLOAD	10/1/99 12:31:12	4	1	0

The following example shows the values of the same four records after system items have been updated:

STATUS	ENTRY-_ID	MERGE	CT_RECID	DB_ID	SUBJECT-_ID
3	SMITH	10/3/99 14:00:06	1,SQLOAD.LL?Min001.001	1	10

STATUS	ENTRY-_ID	MERGE	CT_RECID	DB_ID	SUBJECT-_ID
3	SMITH	10/3/99 14:00:06	1,SQLOAD.LL?Min002.001	1	10
3	SMITH	10/3/99 14:00:06	1,SQLOAD.LL?Min003.001	1	10
3	SMITH	10/3/99 14:00:06	1,SQLOAD.LL?Min004.001	1	129

About grouping

Grouping is an automatic process performed during screening that collects repeating records into observations for batch-loaded records. An *observation* is a group of records in a page section that contains repeating items, or a group of records in a non-subject study book that has been configured for grouping. Grouping is only meaningful for records in a Type 0 panel (non-subject data), a Type 2 panel, where multiple records can exist for the same subject, or a Type 4 panel, where multiple records can exist for the same subject visit.

For example, suppose you batch load data for multiple adverse events observed during a subject visit. When the records are grouped, all the events become part of the same observation.

Grouping for Type 0 panels (non-subject data) uses the user-defined grouping keys and subset keys specified in Design, and optionally, the grouping key items for subject data.

Grouping for Type 1-5 panels (subject data) uses:

- Subject item
- Block key item
- Page key item
- Block repeat key item
- Page repeat key item
- Subset key item

CT_RECIDs and observations

The CT_RECID system item indicates whether records are part of the same observation. For records that are part of an observation, the base part of the CT_RECID, called the stem, is the same and the last three digits, called the observation sequence, are different.

The following example shows four records for the ADVERSE panel. Three of the records are for the same SUBJECT_ID, VISITNO, and PAGENO.

CT_RECID	SUBJECT_ID	VISITNO	PAGENO
1,SQLOAD.LL?Min001.001	10	2	1
1,SQLOAD.LL?Min002.001	10	2	1
1,SQLOAD.LL?Min003.001	10	2	1
1,SQLOAD.LL?Min004.001	10	3	1

Assuming that there are no block repeats or page repeats defined, the Clintrial software changes the CT_RECIDs of grouped records as part of the screening process to reflect that they are part of the same observation. In the following example, the records have been grouped based on SUBJECT_ID, VISITNO, and PAGENO. Thus, the three records that have the same SUBJECT_ID, VISITNO, and PAGENO are given a CT_RECID that is the same, except for the last three digits.

CT_RECID	SUBJECT_ID	VISITNO	PAGENO
1,SQLOAD.LL?Min001.001	10	2	1
1,SQLOAD.LL?Min001.002	10	2	1
1,SQLOAD.LL?Min001.003	10	2	1
1,SQLOAD.LL?Min004.001	10	3	1

About auditing

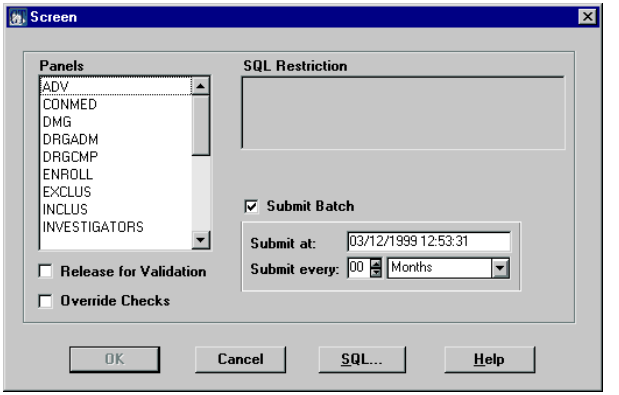
Records with the status Unscreened (3) and Screening Error (-3) are not eligible for auditing.

Oracle does not audit unscreened batch-loaded data because it does not meet the definition of electronic record per our interpretation of CFR Part 11. Screening process converts eligible database records into Clintrial electronic records. In order for a record to become the Clintrial record the data has to comply with our requirements, that is at the very least there has to be a unique constant identifier to track each record, which in case of Clintrial it is the CT_RECID field. This field is changed by screening process which makes any prior auditing of no value.

For a detailed description of what is happening during screening when the raw data you batch loaded is converted into the Clintrial electronic records, see "Loading the data" on page 58. During loading Oracle looks at nothing but datatypes, therefore data loaded could contain invalid keys (context items). That could also make freshly loaded records unsuitable for auditing because they do not comply with existing metadata definitions. If it is necessary to record every alteration to the data after it was loaded the process should be adjusted so that loading is immediately followed by screening.

How to begin

From the **Load** menu, select **Screen**. The Screen dialog box opens:



Select the panels for which you want to screen data.

How to restrict records

To restrict records based on a SQL restriction, click the SQL Restriction box, or click **SQL**. For more information on restricting records, see the *Reference Guide*.

How to perform screening as a batch job

You can perform screening either interactively or as a batch job. If you perform a task interactively, you cannot use Manage for other tasks until the current task is completed. For information about batch jobs, see the Manage Help.

How to release records for validation

If you check Release for Validation, then the status of records that pass screening will change to Verified (1), and the records will be eligible for validation. The status of the records that fail screening will change to Screening Error (-3).

If you clear Release for Validation, then the status of records that pass or fail screening will not change; therefore, the records will not be eligible for validation. However, errors in these records will be recorded in the Error Log.

Before releasing records for validation, you may want to ensure that all records will pass screening to avoid potential problems later. To do so:

1. Clear Release for Validation and screen the records.
2. Review the Error Log to determine which records failed screening.
3. Edit the records that failed screening.
4. Screen records again, with Release for Validation still cleared.
5. When all records pass screening, check Release for Validation and then screen the records.

How to override data-entry checks

If you check Override Checks, you can override the following checks for items:

- For an item with an attached checklist, the value must exist in the checklist.
- The value must be within any upper or lower bounds that have been defined for the item.

Eligibility

Records with the status Unscreened (3) or Screening Error (-3) are available for screening.

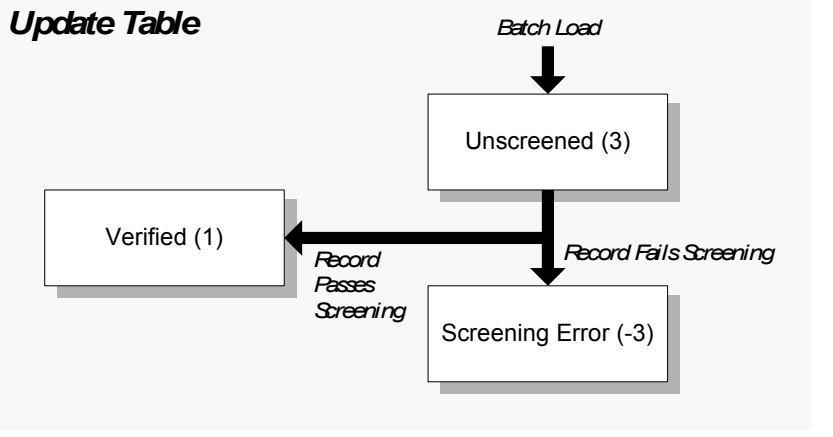
Effect on the record status

If a record passes screening and was released for validation (described on page 67), then the record status changes from Unscreened (3) to Verified (1).

If a record fails screening and was released for validation, then the record status changes from Unscreened (3) to Screening Error (-3).

If the record was not released for validation, then the record status does not change as a result of passing or failing screening. However, errors that occur during screening are recorded in the Error Log.

The following figure shows the possible status changes for batch-loaded records when Release for Validation is checked:



How errors appear in the Error Log

Errors that occur during screening are reported in the Error Log with the Error Type SCREEN.

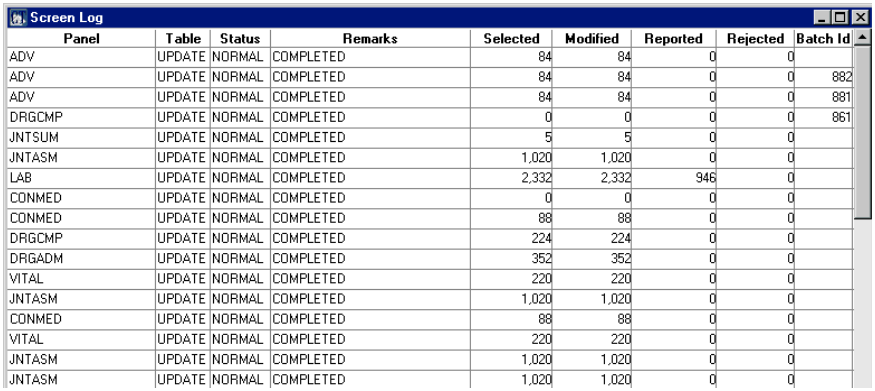
Screen Log

The *Screen Log* is a cumulative report that describes the screening results for the most recently screened panels.

From the **Reports** menu, select **Screen Log >> View**. The following table describes the information in the Screen Log:

Report column:	Description:
Panel	Source panel for which batch-loaded records were screened.
Table	Oracle table in which batch-loaded records were screened. This value will always be UPDATE, as screening is only performed on data in the UPDATE table.
Status	NORMAL indicates that screening completed successfully; ERROR indicates screening did not complete successfully.
Remarks	COMPLETED if status is NORMAL; an error message if status is ERROR.
Selected	Number of records for which screening was attempted.
Modified	Number of records that were screened successfully.
Reported	If you are overriding data checks during screening, then the number of data checks that failed, but passed screening because checks were overridden.
Rejected	Number of data checks that failed screening.
Batch Id	Oracle batch job queue ID, if screening was run as a batch job.
User Id	User account that submitted or ran the screening.
Start	Date and time that screening began.
End	Date and time that screening completed.
Restriction	SQL WHERE clause that was used to select records.

The following example shows a portion of the Screen Log:



Screen Log

Panel	Table	Status	Remarks	Selected	Modified	Reported	Rejected	Batch Id
ADV	UPDATE	NORMAL	COMPLETED	84	84	0	0	
ADV	UPDATE	NORMAL	COMPLETED	84	84	0	0	882
ADV	UPDATE	NORMAL	COMPLETED	84	84	0	0	881
DRGCMP	UPDATE	NORMAL	COMPLETED	0	0	0	0	861
JNTSUM	UPDATE	NORMAL	COMPLETED	5	5	0	0	
JNTASM	UPDATE	NORMAL	COMPLETED	1,020	1,020	0	0	
LAB	UPDATE	NORMAL	COMPLETED	2,332	2,332	946	0	
CONMED	UPDATE	NORMAL	COMPLETED	0	0	0	0	
CONMED	UPDATE	NORMAL	COMPLETED	88	88	0	0	
DRGCMP	UPDATE	NORMAL	COMPLETED	224	224	0	0	
DRGADM	UPDATE	NORMAL	COMPLETED	352	352	0	0	
VITAL	UPDATE	NORMAL	COMPLETED	220	220	0	0	
JNTASM	UPDATE	NORMAL	COMPLETED	1,020	1,020	0	0	
CONMED	UPDATE	NORMAL	COMPLETED	88	88	0	0	
VITAL	UPDATE	NORMAL	COMPLETED	220	220	0	0	
JNTASM	UPDATE	NORMAL	COMPLETED	1,020	1,020	0	0	
JNTASM	UPDATE	NORMAL	COMPLETED	1,020	1,020	0	0	

How to work with the Screen Log

You can view the Screen Log, purge all entries from it, or purge selected entries based on the following criteria:

- Panel name
- User account
- Type of database table (UPDATE or DATA)
- Status (NORMAL or ERROR)
- Range of the date and time that the screening started
- Range of the date and time that the screening ended

You can use the **View** menu to filter or sort a displayed Screen Log, and the **File** menu to save or print the log.

Editing unscreened records

When records fail screening, you should edit them and screen them again. You can also edit unscreened records.

Note: You can also edit unscreened records, or records that have failed screening, by performing a global modification as described in Chapter 7.

Eligibility

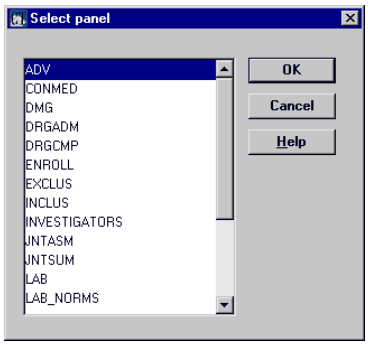
Records with the status Unscreened (3) or Screening Error (-3) are available for editing.

Effect on the record status

The record status does not change as a result of editing an unscreened record.

How to begin

From the **Load** menu, select **Unscreened Records >> Edit**. The Select panel dialog box opens:



After you select a panel and type of database table, the Edit Unscreened Records window opens. You can modify the value of any item except the system items.

If you modify the value of a grouping item, then the record will be regrouped as part of the rescreening process. This will prolong the rescreening process.

If you modify the value of a subject item or subject-related item, then the rescreening will be prolonged. The SUBJECT_ID system item is then updated during the rescreening process.

Deleting unscreened records

Screening batch-loaded records could potentially produce numerous errors. You may decide to edit the input file and rerun the batch-load process rather than editing all the records that produced an error. Before batch loading the data again, you should delete all unscreened, batch-loaded records for the panel.

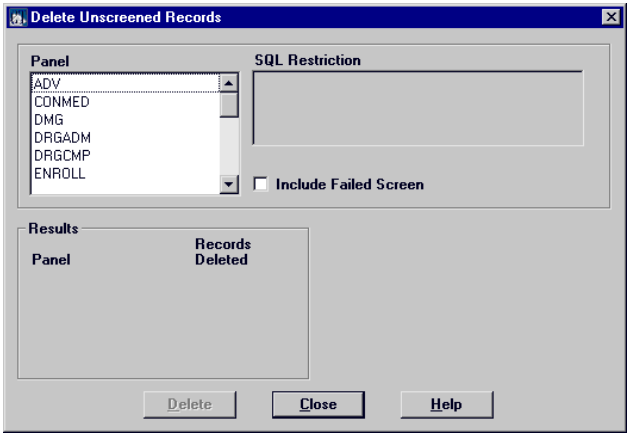
Note: You can also delete unscreened records, or records that have failed screening, by performing a global deletion as described in Chapter 7.

Eligibility

Records with the status Unscreened (3) or Screening Error (-3) are available for deletion.

How to begin

From the **Load** menu, select **Unscreened Records >> Delete**. The Delete Unscreened Records dialog box opens:



Select the panel in which the records were batch loaded.

How to include records that failed screening

If you check Include Failed Screen, then records with the status Screening Error (-3) are included in the deletion.

If you clear Include Failed Screen, then records with the status Screening Error (-3) are not included in the deletion.

How to restrict records

To restrict records based on a SQL restriction, click the SQL Restriction box. For example, you could use a SQL restriction to delete only records that were loaded during a particular time period. For more information on restricting records, see the *Reference Guide*.

4 Coding within Clintrial

Overview

Coding is the process of assigning a standard code from a coding thesaurus to a value that has been entered for an item. For example, an entered drug could be assigned a standard code from the WHODRL thesaurus. Coding provides the following benefits to clinical data management:

- It standardizes the use of terminology describing information, such as adverse events data, that is collected during clinical studies.
- It reduces the time and effort that is required to manually look up and select terms in a coding thesaurus.

The designer determines which items will be coded. Typical items to be coded are clinical events, drugs, or diseases.

What is verbatim text?

The text entered by the user is referred to as verbatim text. The *verbatim text* is the entered text for which you want to assign a standard code from a coding thesaurus. For example, the following verbatim text might be entered for clinical events:

	Clinical Event	**Onset Date**	**End Date**
Verbatim text	Pain in eye	3/1/99	3/6/99
	Patient had rash	3/12/99	4/28/99

Coding methods

There are two methods of coding:

- In *automatic coding*, the Clintrial software uses an algorithm to search the coding thesaurus for the term matching the verbatim text and assign an appropriate code to the verbatim text if the search is successful.
- In *interactive coding*, you can search the coding thesaurus in various ways, and manually assign an appropriate code to the verbatim text.

You must perform automatic coding, and then use interactive coding for items that were not successfully coded automatically.

Types of thesauruses

The Clintrial software provides a means to use industry-standard thesauruses, such as:

- International Classification of Diseases, 9th Revision (ICD-9-CM)
- World Health Organization Drug Reference List (WHODRL)
- World Health Organization Adverse Reaction Terminology (WHOART) dictionary
- Coding Symbols for a Thesaurus of Adverse Reaction Terminology (COSTART)
- Medical Dictionary for Drug Regulatory Affairs (MedDRA)

The Clintrial software also provides a means to use user-defined thesauruses, which the designer can set up in Design.

What is the TERMS panel?

The TERMS panel contains codes and terms. A *term* is a standard word or phrase that describes a clinical event, such as a disease or drug.

This chapter refers to the TERMS panel. A view onto the TERMS panel, rather than the panel itself, is used during coding. Also, this chapter assumes that the name of the panel is TERMS. If the TERMS panel is called something other than TERMS, then the view must still be called TERMS.

For example, the TERMS panel might contain the following code and term:

Code:	**Term:**
PYORRHEA	PERIODONTITIS

In some coding thesauruses (such as COSTART), codes are alphanumeric. In other coding thesauruses (such as WHOART), the codes are numeric.

The designer can set up a code to have from one to three parts. For example, the WHOART dictionary contains two-part codes like 568.01.

What is the SYNONYMS panel?

The SYNONYMS panel contains synonyms of terms in the TERMS panel.

Note: This chapter refers to the SYNONYMS panel. A view onto the SYNONYMS panel, rather than the panel itself, is used during coding. Also, this chapter assumes that the name of the panel is SYNONYMS. If the SYNONYMS panel is called something other than SYNONYMS, then the view must still be called SYNONYMS.

A row in the SYNONYMS panel corresponds to the associated row in the TERMS panel, with the exception of the value of the term.

For example, the SYNONYMS panel might contain the following two synonyms for the term PERIODONTITIS, which in the TERMS panel is associated with the code PYORRHEA:

Code:	**Term:**
PYORRHEA	GUM DISEASE
PYORRHEA	RECEDING GUMS

What is the STOPWORDS panel?

The STOPWORDS panel contains words that might commonly be part of verbatim text, but that do not have medical meaning that must be preserved. Examples are articles and prepositions, such as “the” or “she,” and words, such as “subject” or “complained.”

Note: This chapter refers to the STOPWORDS panel, although a view onto the STOPWORDS panel, instead of the panel itself, is used during coding. Also, this chapter assumes that the panel name is STOPWORDS. If the STOPWORDS panel is called something other than STOPWORDS, then the view must still be called STOPWORDS.

The TERMS, SYNONYMS, and STOPWORDS panels exist in the thesaurus protocol.

Coding-related items

The panel in the clinical data protocol that contains the verbatim text must also contain the following items:

- An item to store the code
- A workflow item

The designer may have set up a panel to include other optional coding- related items, such as:

- The second and third part of a 3-part code.
- The number of matches found during automatic coding.
- The name of the user account that performed coding.
- The date that coding was performed.
- The confidence level, that is, the step of the thesaurus algorithm that resulted in a code being assigned during automatic coding.
- An item to store normalized text. That is, the verbatim text at the point that the thesaurus algorithm finishes; either by successfully coding, or by completing all steps without successfully coding. This is only relevant to automatic coding.

What is the workflow item?

Each item to be coded must have an associated *workflow item*, which identifies the type of coding that was performed. When coding occurs, the workflow item receives one of the following values:

- AUTO — If automatic coding was performed and was successful. If the system parameter AUTOCODE_SET_FAIL is set to No and automatic coding fails, then the workflow item receives the value AUTO.
- FAIL — If the system parameter AUTOCODE_SET_FAIL is set to Yes and automatic coding fails, then the workflow item receives the value FAIL.
- INT — If interactive coding was performed and was successful.

What is the number of matches found?

Each item to be coded may have an associated item to store the number of matches found during automatic coding. The system parameter AUTO_FULL_CNT determines the value that will be stored for this item if multiple matches are found:

- If AUTO_FULL_CNT is set to Yes, then the actual number of matches found is stored.
- If AUTO_FULL_CNT is set to No, then”>1” is stored as the number of matches found.

  Note: Automatic coding will be performed faster if this parameter is set to No.

The number of matches found per item is only relevant to automatic coding.

What is the confidence level?

Each item to be coded may have an associated item to store the confidence level, which identifies the step number of the thesaurus algorithm that resulted in a code being assigned. The confidence level item is only relevant to automatic coding.

For more information, see "How the thesaurus algorithm works" on page 84.

Normalized Text

The text remaining after the thesaurus algorithm completes, either by successfully coding or by unsuccessfully coding, will be stored in this item. The normalized text item is only relevant to automatic coding.

Coding setup

To use interactive or automatic coding, you must set up the thesaurus protocol and the clinical data protocol. You then batch load and prepare your thesaurus data.

Setting up the thesaurus protocol

To set up the thesaurus protocol for use with the default thesaurus algorithm, you must minimally perform the following tasks in Design:

1. Have the thesaurus data files available for batch loading, or be prepared to define your own thesaurus data.
2. Create the thesaurus protocol.
3. Create three specialized Type 0 panels to receive the thesaurus data:
   a. TERMS
   b. SYNONYMS
   c. STOPWORDS

   Note: If you use a customized thesaurus algorithm, then it is not required that you set up the TERMS, SYNONYMS, AND STOPWORDS panels.
4. Create specialized items within the panels:
   a. TERMS:

- An item to store the code. You can create up to three items if the code contains multiple parts.
- An item to store the term that is language-specific. You must create an item to store the English term. The name of the item must contain the string ENGLISH. You must create one item for each language that you want to support, with the language string included in the item name.

b. SYNONYMS:

- An item to store the code. You can create more than one item if the code contains multiple parts. The number of items, as well as the size and type of the items, must correspond to the associated items and their sizes and types in the TERMS panel.
- An item to store the synonym that is language-specific. You must create an item to store the English synonym. The name of the item must contain the string ENGLISH. You must create one item for each language that you want to support, with the language string included in the item name.

c. STOPWORDS:

- An item to store the stopword that is language-specific. You must create an item to store the English stopword. The name of the item must contain the string ENGLISH. You must create one item for each language that you want to support, with the language string included in the item name.

5. Create thesaurus languages for each national language that you want the thesaurus to support.
6. Install the panels.
7. Create a thesaurus view for each panel:
   a. TERMS
   b. SYNONYMS
   c. STOPWORDS
8. Optionally create a customized thesaurus algorithm.

For more information on setting up thesaurus protocols, see the *Design* section in *Admin and Design*.

Setting up the clinical data protocol

To set up the clinical data protocol, you must perform the following steps in Design:

1. Create the clinical data protocol.
2. Create panels and items.
3. Create three coding-related items of type TEXT for each item to be coded:

a. An item to store the verbatim text that will be coded.
b. An item to store the code that is sufficiently large enough to store the largest expected code.
c. An item to store the workflow value.

4. Optionally create an item for:
   a. The name of the user.
   b. The date the item was coded.
   c. The confidence level of coding.
   d. The number of matches found by automatic coding.
   e. The multiple parts of a code.
   f. Normalized text.
5. Set the thesaurus attribute on the code item defined in Step 3.
6. Set up a coding target to associate items in the thesaurus protocol with the coding-related items in the clinical data protocol.
   a. Indicate the thesaurus algorithm that you want to use, if you are not using the default algorithm.
7. Install the panels.

For more information on setting up clinical data protocols, see the *Design* section in *Admin and Design*.

Batch loading and preparing thesaurus data

When you have completed the necessary thesaurus protocol and clinical data protocol setup, you can batch load and prepare your thesaurus data.

Oracle does not provide thesaurus data. You must obtain the raw thesaurus data files from a regulatory authority or third-party vendor. You then batch load the thesaurus data into the thesaurus protocol using Manage. You can also create your own site-specific thesaurus data through interactive data entry using Enter.

Other coding setup checks

Additionally, you must ensure that the following conditions have been met for automatic and interactive coding to function properly:

1. The thesaurus data must be in uppercase letters, unless you are using a custom thesaurus algorithm without the Comprehensive Normalization

option checked. In this case, interactive coding will be more difficult to perform.

2. The thesaurus data must be screened, validated, and merged from the update table to the data table. Only data in the DATA table is searched during coding.
3. The verbatim text item field length in the clinical data protocol should be no longer than the term item field length in the thesaurus protocol.
4. When the number of coded items does not match in the clinical data protocol and the thesaurus protocol, the length of the field receiving the concatenated data must be as long as the sum of the corresponding fields in the thesaurus protocol.
5. The thesaurus attribute must be set on the code1 item, and not the verbatim text item.

For more information on batch loading, see Chapter 3.

Performing automatic coding

Automatic coding is the process by which the Clintrial software automatically assigns codes to verbatim text.

When you run automatic coding, the Clintrial software tries to match the verbatim text to terms (or synonyms) in the coding thesaurus:

- If one match is found, then the Clintrial software assigns the associated code.
- If there are no matching terms (or synonyms), then no code is assigned.
- If there are multiple matching terms (or synonyms), then no code is assigned because the Clintrial software does not know which code is the most appropriate.

For records for which no matches or multiple matches are found, you may want to perform interactive coding, or you may want to review the data, create an appropriate synonym, and then run automatic coding again.

How the thesaurus algorithm works

During automatic coding, the Clintrial software uses a *thesaurus algorithm* to determine the most appropriate code for the verbatim text. The Clintrial software supplies a default thesaurus algorithm, as described in the *Design* section in *Admin and Design.* You can also define a custom thesaurus algorithm to use.

Before beginning to process data using the default thesaurus algorithm, the Clintrial software converts the verbatim text to uppercase, discards extra spaces between words, and discards punctuation (as identified for each language by the designer). The seven steps of the default thesaurus algorithm are as follows:

Step Number:	Step Description:
1	The Clintrial software looks in the TERMS panel for a term that is an exact match to the verbatim text: • If exactly one match is found, then the Clintrial software returns the code, records the number of matches as "1", and records the confidence level as "1". The algorithm ends. • If multiple matches are found, then the Clintrial software returns no code and records the number of matches as ">1" or the actual number of matches, depending on the setting of the system parameter AUTO_FULL_CNT. The algorithm ends. • If no match is found, then the Clintrial software goes to Step 2.
2	The Clintrial software looks in the SYNONYMS panel for a synonym that is an exact match to the verbatim text: • If exactly one match is found, then the Clintrial software returns the code, records the number of matches as "1", and returns the confidence level as "2". The algorithm ends. • If multiple matches are found, then the Clintrial software returns no code and records the number of matches as ">1" or the actual number of matches, depending on the setting of the system parameter AUTO_FULL_CNT. The algorithm ends. • If no match is found, then the Clintrial software goes to Step 3.
3	The Clintrial software removes any word that is an exact match to a stopword defined in the STOPWORDS panel from verbatim text, creating a filtered text string. The Clintrial software also breaks up the verbatim filtered text string into an array of words. The Clintrial software goes to Step 4.

Step Number:	Step Description:
4	The Clintrial software looks in the TERMS panel for a term that is an exact match to the filtered text string: • If exactly one match is found, then the Clintrial software returns the code, records the number of matches as "1", and returns the confidence level as "4". The algorithm ends. • If multiple matches are found, then the Clintrial software returns no code and records the number of matches as ">1" or the actual number of matches, depending on the setting of the system parameter AUTO_FULL_CNT. The algorithm ends. • If no match is found, then the Clintrial software goes to Step 5.
5	The Clintrial software looks in the SYNONYMS panel for a synonym that is an exact match to the filtered text string: • If exactly one match is found, then the Clintrial software returns the code, records the number of matches as "1", and returns the confidence level as "5". The algorithm ends. • If multiple matches are found, then the Clintrial software returns no code and records the number of matches as ">1" or the actual number of matches, depending on the setting of the system parameter AUTO_FULL_CNT. The algorithm ends. • If no match is found, then the Clintrial software goes to Step 6.
6	The Clintrial software looks in the TERMS panel for a term that contains each word of the array in any order: • If exactly one match is found, then the Clintrial software returns the code, records the number of matches as "1", and returns the confidence level as "6". The algorithm ends. • If multiple matches are found, then the Clintrial software returns no code and records the number of matches as ">1" or the actual number of matches, depending on the setting of the system parameter AUTO_FULL_CNT. The algorithm ends. • If no matches are found, then the Clintrial software goes to Step 7. ***Note**:* The term may contain additional words. However, the term must contain all words in the verbatim text array.

Step Number:	Step Description:
7	The Clintrial software looks in the SYNONYMS panel for a synonym that contains every word in the array in any order: • If exactly one match is found, then the Clintrial software returns the code, records the number of matches as "1", and returns the confidence level as "7". • If multiple matches are found, then the Clintrial software returns no code and records the number of matches as ">1" or the actual number of matches, depending on the setting of the system parameter AUTO_FULL_CNT. • If no matches are found, then the Clintrial software returns no code, records the number of matches as "0", and records the confidence level as "8".

What is recoding?

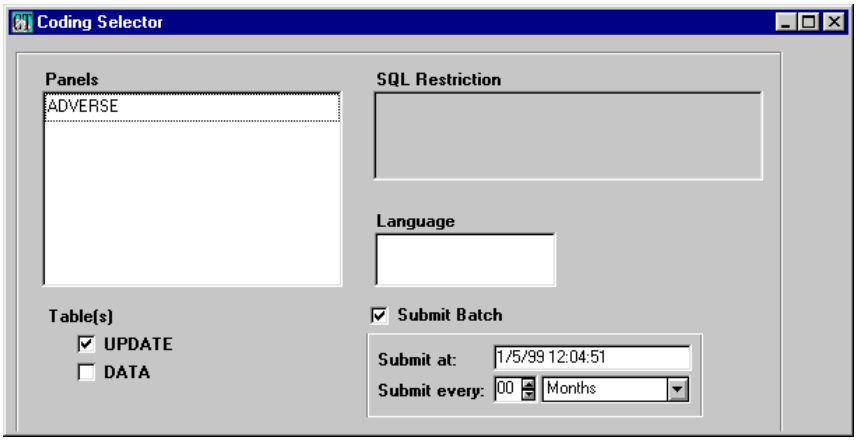
When an item has been successfully coded, its associated workflow item contains the value AUTO or INT. You can recode the items for which the workflow item is not Null. *Recoding* the item replaces the current code with a different code. For example, suppose that an item was coded interactively to have the code 568.01. If the item is recoded using automatic coding, then the automatic coding process will assign a different code to the item if changes have been made to data in the thesaurus. You could also recode the item using interactive coding.

The following table shows whether an item is recoded during automatic coding, based on a combination of the setting of the system parameter AUTOCODE_RECODE_ALL and the setting of the Override Coding attribute set up in Design for the protocol:

	AUTOCODE_RECODE _ALL=YES		**AUTOCODE_RECODE _ALL=NO**	
Workflow item	Override Coding=Y	Override Coding=N	Override Coding=Y	Override Coding=N
AUTO	Recode	Recode	Do not recode	Do not recode
FAIL	Recode	Recode	Do not recode	Do not recode
INT	Recode	Do not recode	Do not recode	Do not recode

How to begin

From the **Manage** menu, select **Code >> Automatic**. The Coding Selector window opens:



You can perform automatic coding on a specific coding target in a panel, or on all coding targets in a panel.

To perform coding on a specific coding target in a panel, select Selected Coded Item for a Panel. You must then select a panel and coded item on which to perform automatic coding. You can only select one coded item.

To perform automatic coding on all coding targets on a panel, select Panel. You must then select the panels for which you want to automatically code data. Only panels containing items set up for coding are available in the list. All items that are set up for coding in each selected panel will be automatically coded.

Note: If a panel's coding procedure in the clinical data protocol or any of the necessary views for a panel in the thesaurus protocol is invalid, then the panel is unavailable for selection in the window. This ensures that you do not attempt to code items in a panel with an invalid coding setup.

Select the types of database tables for which you want to automatically code. You can select the update table, the data table, or both.

How to restrict records

To restrict records based on a SQL restriction, click the SQL Restriction box. For more information on restricting records, see the *Reference Guide*.

How to select a language

If more than one language is available, then select the language in which you want to code. When the Clintrial software searches the coding thesaurus, matching terms are retrieved in the selected language.

How to specify the job type

You can perform automatic coding either interactively or as a batch job. If you perform a task interactively, then you will not be able to use Manage for other tasks until the current task is completed. For information about batch jobs, see the Manage Help.

Automatic Coding Log

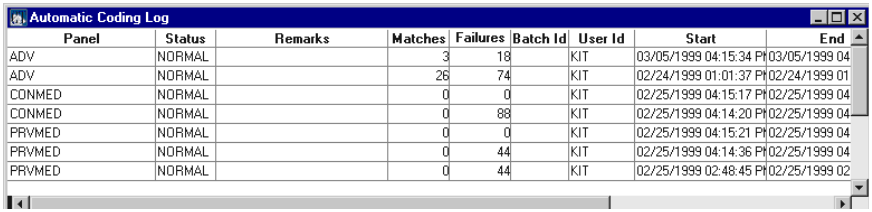
The *Automatic Coding Log* is a cumulative report that provides general information about the number of records that were coded during automatic coding.

From the **Reports** menu, select **Coding Log >> View**. The following table describes the information in the Automatic Coding Log:

Report column:	**Description:**
Panel	Name of the panel in which records were automatically coded.
Status	NORMAL if automatic coding completed successfully; ERROR if automatic coding did not complete successfully.
Remarks	COMPLETED if status is NORMAL; an error message if status is ERROR.
Matches	Number of records in which items were coded.
Failures	Number of records for which matches were not found.
Batch Id	Oracle batch job queue ID, if the automatic coding was run as a batch job.

Report column:	Description:
User Id	User account that submitted or ran the automatic coding.
Start	Date and time that automatic coding began.
End	Date and time that automatic coding completed.
Restriction	SQL WHERE clause used to select records that was built automatically from the specified selection criteria.
Table	Type of database table (UPDATE or DATA) in which automatic coding occurred.

The following example shows a portion of the Automatic Coding Log:


Automatic Coding Log

Panel	Status	Remarks	Matches	Failures	Batch Id	User Id	Start	End
ADV	NORMAL		3	18		KIT	03/05/1999 04:15:34 PM	03/05/1999 04
ADV	NORMAL		26	74		KIT	02/24/1999 01:01:37 PM	02/24/1999 01
CONMED	NORMAL		0	0		KIT	02/25/1999 04:15:17 PM	02/25/1999 04
CONMED	NORMAL		0	88		KIT	02/25/1999 04:14:20 PM	02/25/1999 04
PRVMED	NORMAL		0	0		KIT	02/25/1999 04:15:21 PM	02/25/1999 04
PRVMED	NORMAL		0	44		KIT	02/25/1999 04:14:36 PM	02/25/1999 04
PRVMED	NORMAL		0	44		KIT	02/25/1999 02:48:45 PM	02/25/1999 02

How to work with the Automatic Coding Log

You can view the Automatic Coding Log, purge all entries from it, or purge selected entries from it based on the following criteria:

- Panel name
- User account
- Type of database table (UPDATE or DATA)
- Status (NORMAL or ERROR)
- Range for the date and time that the automatic coding started
- Range for the date and time that the automatic coding completed

You can use the **View** menu to filter or sort a displayed Automatic Coding Log, and the **File** menu to save or print the log.

Performing interactive coding

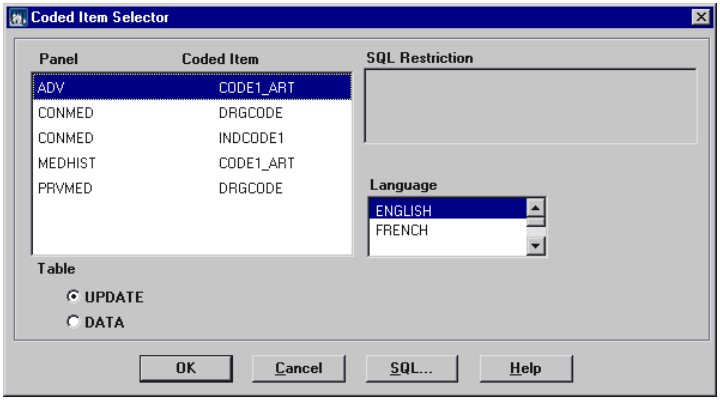
Interactive coding provides a means to search the coding thesaurus manually, and then select an appropriate code for the verbatim text. You can use interactive coding to:

- Assign codes to items that failed automatic coding.
- Change or clear codes that were previously assigned.

  Note: Changing or clearing codes is dependent upon the protocol attribute Override Coding. For more information on this attribute, see the *Design* section in *Admin and Design*.
- Assign codes to items that have not yet been coded.

How to begin

From the **Manage** menu, select **Code >> Interactive**. The Coded Item Selector dialog box opens:



Select the panel and item for which you want to code interactively. Only panels containing items set up for coding are available in the list.

Note: If a panel's coding procedure in the clinical data protocol or any of the necessary views in the thesaurus protocol for a panel is invalid, then the panel is unavailable for selection in the window. This ensures that you do not attempt to code items in a panel with an invalid coding setup.

Select the type of database table for which you want to code interactively. You can select either the update table or the data table.

How to restrict records

To restrict records based on a SQL restriction, click the SQL Restriction box. Your restriction will replace the restriction normally placed on the data selected for interactive coding. For more information on restricting records, see the *Reference Guide*.

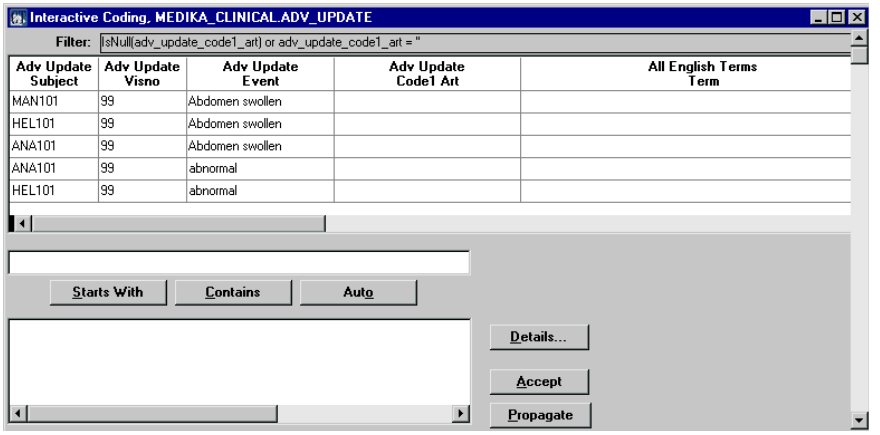
If you do not use a restriction, only records that have failed the automatic coding process will be displayed. That is, records with a NOT NULL workflow value will be displayed.

How to select a language

If more than one language is available, then select the language in which you want to code. When the Clintrial software searches the coding thesaurus, matching terms are retrieved in the selected language.

How to continue

When you click **OK** in the Coded Item Selector dialog box, the Interactive Coding window opens:



How to filter records

The Clintrial software automatically retrieves all records with a workflow value from the database. You can view a subset of the selected records by using the Filter field.

In the Interactive Coding window, click the text in the Filter field. The Specify Filter dialog box opens, where you can change or remove the default filter, or add your own.

For more information on entering filters, see the *Reference Guide*.

How to select a record to code

The list of records includes all records for which the workflow item is AUTO, FAIL, or INT. If the workflow item is Null, then the record is not included in the list by default. To code items for which the workflow item is Null, you must remove the default SQL restriction and implement your own filter.

When you select the record that you want to code, the verbatim text displays in the search text field below the list. This is the text that the Clintrial software will attempt to match.

How to select a matching method

There are three methods by which you can search the coding thesaurus. The results of the search are listed below the search text field.

Button:	**Search method:**
Starts With	List terms and synonyms that begin with the search text.
Contains	Lists terms and synonyms that contain the search text.
Auto	Lists terms that would be found by the thesaurus algorithm that is used for automatic coding. This search method is useful if more than one match was found during automatic coding and you need to select one appropriate term.

Note: If you are using a user-defined thesaurus, then the thesaurus data must be in uppercase letters. If the data is in lowercase letters, then no matches will be found when using the search methods.

When you click **Starts With** or **Contains** and you are using a customized thesaurus algorithm, the preferred TERMS view is used to search the thesaurus. You specify the preferred TERMS view in Design when you create a customized thesaurus algorithm. You can set the preferred view to the TERMS or to the SYNONYMS panel.

If you are using the default algorithm, then the TERMS view is used to search the thesaurus.

How to assign a code

Select a code and term from the list, then do one of the following:

- Click **Details** to get additional information on the code.
- Click **Accept** to accept the selected code. The associated code is assigned to the verbatim text.
- Click **Propagate** to assign the selected code to all records that have the same verbatim text as the selected record.

The list of records in the window is updated to reflect the selected code. When you are satisfied with the code, from the **File** menu, select **Save**.

Using the Edit menu

The **Edit** menu becomes available when the Interactive Coding window opens. The following table describes the **Edit** menu commands:

Command:	**Description:**
Propose Code	Enables you to propose a known code for verbatim text instead of searching for a match on the term.
Clear	Clears the coding target fields in the selected record. ***Note**:* Changing or clearing codes is dependent upon the protocol attribute Override Coding. For more information on this attribute, see the *Design* section in *Admin and Design*.
Propagate Clear	Clears the coding target fields in all records that have the same verbatim text as the selected record.

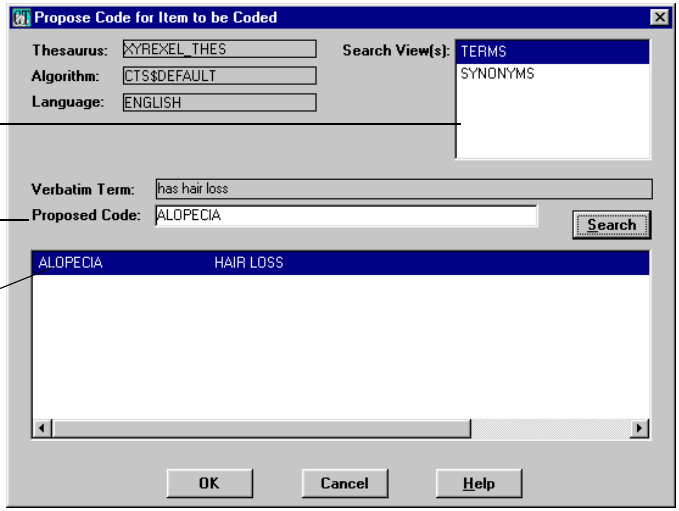
Using the Propose Code command

The Propose Code dialog box allows you to propose a known code for the verbatim text in the selected record. For example, to associate a specific code with the verbatim text "hair loss", from the **Edit** menu, select **Propose Code**. The Propose Code for Item to be Coded dialog box opens:

Select one or more search views. This field provides a list of views that are referenced in the thesaurus algorithm.

*Enter a proposed code, then click **Search**.*

*Select a code, then click **OK**. The code "ALOPECIA" is now associated with the verbatim text "HAIR LOSS".*



If you select more than one search view, then the time required to search for possible matches will significantly increase. It is also possible that too many matches will be found.

You can use multiple wildcards in the Proposed Code field to refine your search. For example, if you enter ALOPEC%, the Clintrial software will find fewer matches.

Note: If more than sixty matches are found, you are prompted to further refine your search.

The code that you propose will only apply to the selected record in the Interactive Coding window. Once the association is made, you can propagate the change to other records by clicking **Propagate** in the Interactive Coding window.

Coding with MedDRA

The Clintrial software provides a means to use the Medical Dictionary for Drug Regulatory Activities (MedDRA) during automatic and interactive coding. *MedDRA* is a mixed-case, hierarchical thesaurus that contains terminology applicable to all phases of drug development, and to the health effects of devices. The MedDRA terminology categories include:

- Symptoms
- Signs
- Diseases
- Diagnoses
- Therapeutic indications
- Investigations
- Surgical or medical procedures
- Medical, social, or family history characteristics

You perform automatic and interactive coding with MedDRA as you would perform coding with any other thesaurus. Using Manage, you can perform coding against the Preferred Terms (PT), or against the Lowest Level Terms (LLT). You set up a thesaurus protocol and a clinical data protocol using the steps on page 81 as you would for other industry-standard thesauruses.

What are the Preferred Terms?

The *Preferred Terms* (PT) are distinct descriptors for the MedDRA terminology categories. PTs are hierarchically located above LLTs, and are used to group together equivalent LLTs.

If you perform coding against the PT panel, then the Clintrial software searches the PT panel, and then optionally the LLT panel for a matching term.

What are the Lowest Level Terms?

The *Lowest Level Terms* (LLT) are the lowest hierarchical level of terms in the MedDRA dictionary. Each LLT is linked to only one PT that is its preferred descriptor in the terminology.

If you perform coding against the LLT panel, then the Clintrial software searches the LLT panel for a matching term.

Other Hierarchy Levels

The following table describes the other MedDRA hierarchy levels:

Name:	Full Name:	Description:
HLT	High Level Terms	Used solely for data retrieval purposes.
HLGT	High Level Group Terms	Used to group together HLTs, and for data retrieval purposes.
SOC	System Organ Class	The highest level of the MedDRA hierarchy that provides the broadest concept for data retrieval.

CT_MEDDRA protocol

The CT_MEDDRA protocol is a sample thesaurus protocol provided with the Clintrial software that is specifically structured for the MedDRA dictionary. CT_MEDDRA includes the following predefined objects:

- Panels
- Items
- Page sections
- Page templates
- Thesaurus views
- Thesaurus algorithms
- Derivations
- Translation functions

The protocol contains one panel for each MedDRA table.

CT_MEDDRA is intended as an example to assist you in setting up a thesaurus protocol for MedDRA. CT_MEDDRA is set up to perform coding on panels in the MEDIKA_CLINICAL Sample Study. However, you can also use CT_MEDDRA to perform coding on your own clinical data protocol.

Caution: If you choose to use CT_MEDDRA with your own clinical data protocol, do not modify or delete panels or items. If you modify or delete panels or items, the predefined Retrieve queries provided with the Clintrial software will not function properly.

To use CT_MEDDRA, you must first import the protocol, and ensure that you name the protocol CT_MEDDRA. You then batch load the MedDRA dictionary into the CT_MEDDRA protocol.

After you import CT_MEDDRA, you must execute scripts that create MedDRA translation functions and indexes on CT_MEDDRA panels. For more information on executing the scripts, see *Getting Started*.

For more information on importing the CT_MEDDRA protocol, see the *Sample Study* section in *Getting Started*.

Note: Oracle does not supply the MedDRA dictionary. You must purchase the most recent version of the MedDRA dictionary from a regulatory authority or third-party vendor.

Batch loading MedDRA

Sample control files are provided with the Clintrial software to help you batch load the MedDRA dictionary into CT_MEDDRA. You can also modify the control files as necessary to batch load the MedDRA dictionary into your own thesaurus protocol.

For more information on batch loading data, see Chapter 3.

MEDIKA_CLINICAL protocol

You use the CT_MEDDRA protocol in conjunction with the MEDIKA_CLINICAL Sample Study. You perform coding against the ADV_LLT and ADV_PT panels in MEDIKA_CLINICAL.

MEDIKA_CLINICAL also includes several predefined queries to use with Ad Hoc Query in Retrieve. By default, the PT and LLT terms are returned during coding. The queries provide a means to derive additional terminology from the other levels in the MedDRA dictionary without any additional setup or recoding. The queries capture terms from the following hierarchical levels, as associated with the PT and LLT returned during coding:

- HLT
- HLGT
- SOC

For more information on the Retrieve queries, see the *Retrieve* section in *Enter, Resolve, and Retrieve*.

Coded Item Report

The *Coded Item Report* is a cumulative report that provides detailed information about each item that was coded.

From the **Reports** menu, select **Coded Items**. Select the panel for which you want to view coded items.

Select the type of database table for which you want to view coded items. You can select the update table, the data table, or both.

If more than one language is available, then select the language in which you want to view the report.

The following table describes the information in the Coded Item Report:

Report column:	**Description:**
Panel Name	Name of the panel containing the item.
Item Name	Name of the item that contains the code (or the first part of a multipart code); the value of this item is the Code1 Item for each entry.
Subject Item	Subject identifier of the record containing the item.
Block Item	Block key value of the record containing the item.
Block Repeat Item	Block repeat key value of the record containing the item.
Page Item	Page key value of the record containing the item.
Page Repeat Item	Page repeat key value of the record containing the item.
Encoded Item	Verbatim text.
Term Used	Search text; that is, the term that was used to search the coding thesaurus. For automatic coding, this is the same as the verbatim text. For interactive coding, this may or may not be the same as the verbatim text.
Confidence	In automatic coding, the step number of the thesaurus algorithm that resulted in a code being assigned.

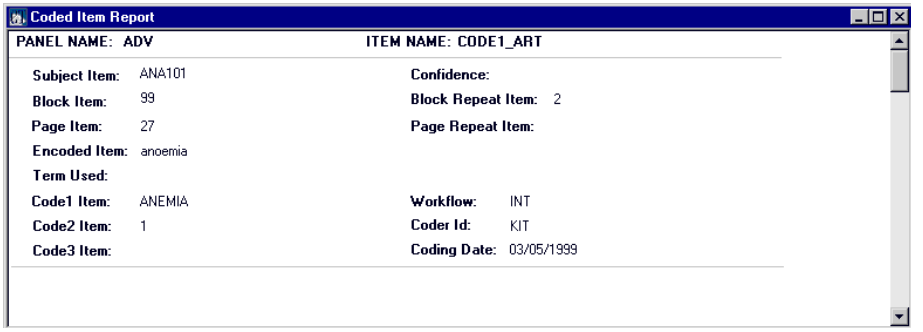
Report column:	Description:
Code1 Item	Code for the first part of a multipart code.
Code2 Item	Code for the second part of a multipart code. This is optional.
Code3 Item	Code for the third part of a multipart code. This is optional.
Workflow	AUTO for automatic coding; INT for interactive coding.
Coder Id	User account that coded the item. This is optional.
Coding Date	Date and time that coding was run. This is optional.

Note: The designer determines if the Code2, Code3, Coder Id, and Coding Date items will have values on the report.

How to work with the Coded Item Report

You can review the Coded Item Report, print the report, and save the report to a file.

The following example shows a Coded Item Report for records that have been interactively coded in the ADV panel:



You can use the **View** menu to filter or sort a displayed Coded Item Report, and the **File** menu to save or print the report.

5 Using Manage & Central Coding to code data

Overview

Coding is the process of assigning a standard code from a coding dictionary to a value that has been entered for an item as verbatim text. For example, a drug could be assigned a standard code from the WHO-DD dictionary. If the verbatim text entry for the drug a subject took to treat a headache during the study was entered as “Tylenol”, then from the WHODD dictionary, it could be coded as “002144.01.008”, with the Trade Name “Tylenol aches and strains medication” and the Preferred Name “Parafon”.

Coding provides the following benefits to clinical data management:

- It standardizes the use of terminology describing information, such as adverse events data, that is collected during clinical studies.
- It reduces the time and effort that is required to manually look up and select terms in a coding dictionary.

The decision as to which coding utility will be used is made in the Admin and Design modules, either as a system-wide parameter for all protocols, or on an individual protocol basis using a protocol parameter.

The protocol designer determines which items will be coded. This is done in the Clintrial Design module. Typical items to be coded are clinical events, drugs, or diseases.

What is a coding dictionary?

A *coding dictionary* is a dictionary thesaurus that contains standard codes for a particular type of clinical data. There are two types of dictionaries: industry-standard and user-defined.

Contact Oracle for a list of supported dictionary versions.

What is verbatim text?

The text entered by the user is referred to as verbatim text. The *verbatim text* is the entered text for which you want to assign a standard code from a coding dictionary. For example, the following verbatim text might be entered for clinical events:

	Clinical Event	Onset Date	End Date
Verbatim text	Pain in eye	3/1/09	3/6/09
	Patient had rash	3/12/09	4/28/09

Why use coding dictionaries?

You use coding dictionaries to:

- Provide standardization for statistical analysis.
- Summarize terms by grouping verbatim terms into standardized terms.
- Create a standard language that is comparable across all therapeutic teams.
- Reduce the time needed to reach a final format, which leads to faster regulatory approval.

Which coding utility should I use?

In order to match clinical data (verbatim text) against standard dictionary codes, you may either:

- Use Clintrial Manage module, and optionally, the Clintrial Classify extended module, or
- Use the Oracle Central Coding application.

The decision to use either approach may be made on a protocol basis. For example, existing protocols may continue to use the Manage and the Classify modules for coding, while new protocols may use the Central Coding application. Of course, existing protocols may be updated to use the Central Coding application if you want to use it as a standard within your organization.

The Central Coding application is a web-based application that integrates with both the Oracle InForm application and the Oracle Clintrial application to provide centralized coding for studies within an organization.

Because the Central Coding software works independently from the Clintrial and InForm software, you can have parallel work paths for the clinical study teams. As a result, coding can happen earlier in the study cycle, providing valuable data visibility for study managers who review and assess study safety concerns.

When you use the Central Coding software for coding, you are not limited to three-part coding as you are with the Clintrial software.

Note: The instructions contained in this chapter for setting up the Clintrial application to send coding requests to Central Coding assume that all Central Coding tasks have been performed to support Clintrial, and that the Clintrial Design module has been setup to identify which protocols, panels and target items should be coded using the Central Coding application.

For information on Central Coding setup, see the Central Coding *User Guide*. For more information on setting up Clintrial's Design module to use the Oracle Central Coding application, see the Clintrial *Admin and Design* guide.

Types of dictionaries

You can obtain the raw dictionary data files for the Central Coding application from a regulatory authority or third-party vendor. The Clintrial software provides a means to use industry-standard dictionaries, such as:

- World Health Organization Drug Dictionary (WHO-DD)
- World Health Organization Drug Dictionary C Format (WHO-DD C) (which may be used to autocode a Preferred Term or Trade Name)
- Coding Symbols for a Thesaurus of Adverse Reaction Terminology (COSTART)
- Medical Dictionary for Drug Regulatory Activities (MedDRA and MedDRAJ)
- Data File for Ethical Drugs (Coding Table) from Iyaku-Joho-Kenkyujo, Inc. (JDrug)

The Central Coding software also provides a means to use custom dictionaries.

How automatic coding relates to interactive coding

At data entry, the data-entry operator enters the verbatim text for the item to be coded. Central Coding provides two methods of determining the correct code for an entered item that has been set up as a coded item:

- Automatic coding

  If a single match is found on the verbatim text using the specified coding algorithm, the Central Coding software selects a code for the verbatim text item to be coded. The Central Coding software supplies a default coding algorithm, or you can create your own customized coding algorithms.

- Interactive coding

  In Central Coding, the data manager selects a code from a scrolling list of similar matching terms, each of which has an associated code.

The Clintrial data manager sets up which panel items will be coded by specific Central Coding dictionaries in the Design module, and actually sends them to Central Coding using the Manage module. The requests may be batch loaded or sent immediately to be coded in Central Coding. Depending on how the Central Coding application is setup, the items will be designated for Automatic Coding first if possible. The uncoded verbatims are then reviewed and coded via interactive coding, also in Central Coding.

For more information on automatic and interactive coding, see the *Central Coding Users Guide*.

Performing coding in Central Coding

Automatic coding is the process by which the Oracle Central Coding software automatically assigns codes to verbatim text. All actual coding is performed in the Central Coding application.

When you run automatic coding, the Central Coding software tries to match the verbatim text to terms (or synonyms) in the coding dictionary:

- If one match is found, then the Central Coding software assigns the associated code.
- If there are no matching terms (or synonyms), then no code is assigned.
- If there are multiple matching terms (or synonyms), then no code is assigned because the Central Coding software does not know which code is the most appropriate.

For records for which no matches or multiple matches are found, you may want to perform interactive coding in the Central Coding software, or you may want to review the data, create an appropriate synonym, and then run automatic coding again.

For more information on automatic coding as performed by the Central Coding application, see the *Central Coding User Guide*.

Using Clintrial Manage to send Coding requests to Central Coding

Steps in setting up Clintrial to work with Central Coding

To set up the Clintrial software to use a Central Coding dictionary, you must do the following:

1. Ensure network or Internet access to the Central Coding Server. (See the *Clintrial Getting Started* guide for more information.)
2. Configure the CC_HOST parameter with the HTTP address of the Central Coding interface. This may be set in Admin as a System or Protocol parameter. (See "Design system parameters" in Chapter 5 of the *Clintrial Admin & Design* manual.)
3. Set the parameter USE_CENTRAL_CODING to Yes for the target protocol. This may be set in Admin as a System or protocol parameter.
4. Create a dictionary definition. (See “Setting up a dictionary in Clintrial for use with Central Coding” in Chapter 5 of the *Clintrial Admin & Design* manual.)
5. Define labels for the dictionary definition. (See "Setting up Label Types and Label Names in Clintrial Central Coding Dictionaries" in Chapter 5 of the *Clintrial Admin & Design* manual.)
6. Select a dictionary definition for an item in a panel. See "Select a dictionary definition for an item in a panel" in Chapter 5 of the *Clintrial Admin & Design* manual.)
7. Create a Central Coding encoding target. See "How to create a Central Coding Encoding Target" in Chapter 5 of the *Clintrial Admin & Design* manual.)
8. Map the target items with the defined labels. (See "Mapping a defined label with a Coding target" in Chapter 5 of the *Clintrial Admin & Design* manual.)
9. Use the Manage module to send coding requests to Central Coding. (This chapter.)
10. Check the Automatic Coding Log to see the status of the Coding requests sent to Central Coding. (This chapter.)

When setup is complete in the Central Coding application, and you have completed the necessary dictionary and encoding target setup in the Design module, you can either send the requests for coding to the Central Coding application immediately, or batch load the coding requests.

Either way, the actual coding is performed in the Central Coding application, and the Clintrial application simply sends the requests, asks the Central Coding application for requests that have been coded, and receives the data back after the coding is performed. If you send the coding requests immediately, the Manage module will not perform other functions until all the requests are sent.

The items that need to be coded are sent to Central Coding using the Manage Coding Selector dialog box.

Central Coding performs the coding requests, then loads the dictionary data into its own database. The data is sent back to Manage when Clintrial sends a request to Central Coding to send back coded verbatims. Replies with coding information are saved in Clintrial's protocol database.

Verbatims to be coded in the Central Coding application are contained within requests; one verbatim per request. When the Central Coding application receives a coding request from the Clintrial Manage module, the assignment rules determine whether the request is to be automatically or interactively coded, and which coding dictionary to use.

Note: All communication between the Clintrial application and the Central Coding application is initiated from the Clintrial application.

To autocode the request, the Central Coding application attempts to find an unambiguous response using a predefined set of steps in a coding algorithm. If autocoding succeeds, the Central Coding application stores the information in the Central Coding database. When a new coding request is received from the Clintrial application, Central Coding returns the coded information to the Clintrial application. If autocoding fails, a coder must interactively code the request, and nothing is sent to Clintrial until interactive coding is successful.

An administrator can configure the Central Coding application so that successfully autocoded requests can be automatically approved, or so that all requests require manual approval by an approver. An administrator can also configure the application so that autocoding results require review by a coder.

When interactive coding is successful, the application stores the configured elements from the dictionary. An administrator can configure the Central Coding application so that, like autocoded requests, interactively coded requests can be

automatically approved or so that they require manual approval by an approver. Approvers may approve or disapprove a coding request, or indicate that more information is required to code the request.

As coding requests move through the steps in the Central Coding workflow, their status is tracked and automatically updated to reflect their state of completion.

After a coding request is successfully coded and approved, it is available for delivery to the Clintrial application. The Central Coding job queue forwards it to Clintrial when Clintrial asks for requests that are ready for delivery. This happens when the Receive Responses checkbox is checked on the Coding Selector window.

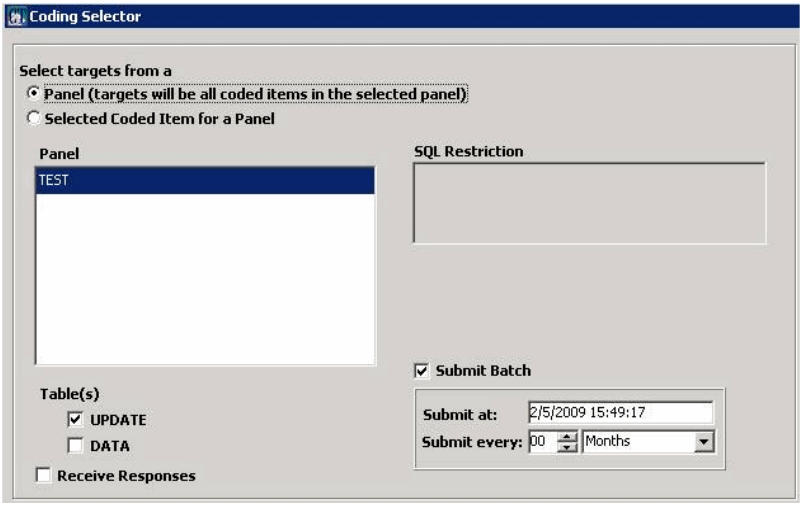
When a response is received from Central Coding, the Clintrial data is updated with the information sent. When responses are received, the following special cases apply:

- If the verbatim text has changed or the values of any associated items have changed since the request was made, the response is ignored and a new request with the new text is sent the next time requests are sent, if necessary.
- If the Clintrial record was deleted, a request is sent to Central Coding to delete the corresponding coding request.
- If a second response for the same record is received, the new values overwrite the previous ones.
- If you are using Multisite Replication, and the ownership of the record has changed since the request was sent, the request cannot be processed.
- When using Global Delete, if requests have been sent to Central Coding, but responses have not yet been received, requests are sent to Central Coding to delete the corresponding coding request.

Note: When problems arise at the Central Coding server (for example, running out of tablespace in the database), the Automatic Coding log in Clintrial may return a non-specific message for the failure. If unexpected errors occur while the Central Coding jobs are running, you should check the Central Coding server Event Viewer for application-specific problems, or consult the Database Analyst (DBA) responsible for the Central Coding server.

How to begin

From the **Manage** menu, select **Code > Automatic**. The Coding Selector window opens:



How to select coding targets

You may designate a specific coding target in a panel, or all coding targets in a panel for coding by Central Coding. The coding targets displayed will only be those defined in Design for Central Coding.

To designate a specific coding target in a panel, choose **Selected Coded Item for a Panel**. You must then select a panel and an item for coding. You can only select one coded item and it must have been set up for Central Coding in Design.

To designate all coding targets on a panel, select **Panel**. You must then select the panels for which you want to have Central Coding code data. Only panels containing items set up for Central Coding in Design are available in the list. All items that are set up for coding in each selected panel will be sent to Central Coding for coding.

Note: If a panel's coding procedure in the clinical data protocol is invalid, then the panel is unavailable for selection in the window. This ensures that you do not attempt to code items in a panel with an invalid coding setup.

How to specify the types of database tables to update

Select the types of database tables for which you want to send requests. You can select the UPDATE table, the DATA table, or both.

How to receive responses from Central Coding after targets are coded

Select the Receive Responses checkbox to receive coding responses. The responses may update the UPDATE table, the DATA table, or both.

How to restrict records

To restrict records based on a SQL restriction, click the SQL Restriction box. Your restriction will replace the restriction normally placed on the data. For more information on restricting records, see the *Reference Guide*.

If you do not use a restriction, then coding requests will be sent for all records with a value for the verbatim text, but which have not yet been coded (Workflow value is null).

Note: The restriction applies only to new requests. Any available responses will be processed.

For more information on restricting records, see the Clintrial *Reference Guide*.

Note: When you export then import a protocol where requests have been sent to Central Coding, but not yet received back (workflow item values are SENT) the verbatims will not be coded in the imported protocol. To send requests for the imported protocol, set the protocol parameter AUTOCODE_RECODE_ALL to YES. To avoid recoding items that were coded previously in the exported protocol set the coding SQL restriction to <workflow_item>= 'SENT'.

How to specify the job type

The coding requests may be batch loaded or sent immediately to be coded in Central Coding. Check the box **Submit Batch** to have the coding requests sent to Central coding as a batch job. If you send the coding requests immediately, the Manage module will not perform other functions until all the requests are sent.

For more information about batch jobs, see the Manage Help.

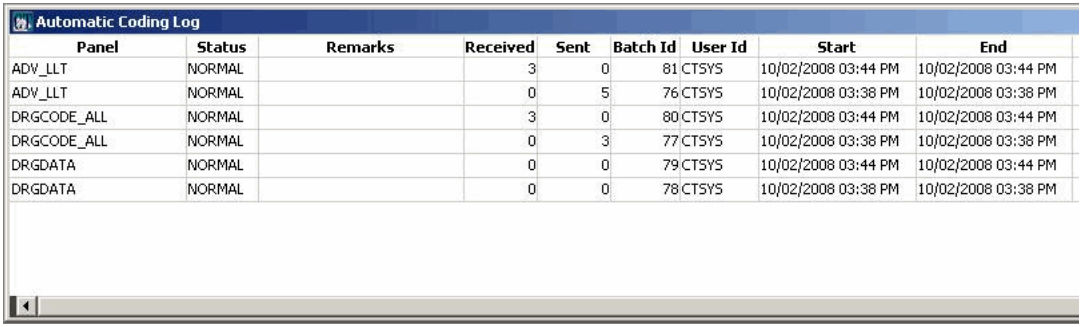
Automatic Coding Log

The *Automatic Coding Log* is a cumulative report that provides general information about the number of records that were sent to Central Coding to be coded.

From the **Reports** menu, select **Coding Log > View**. The following table describes the information in the Automatic Coding Log:

Report column:	Description:
Panel	Name of the panel in which records were automatically coded.
Status	NORMAL if automatic coding completed successfully; ERROR if automatic coding did not complete successfully.
Remarks	COMPLETED if status is NORMAL; an error message if status is ERROR.
Received	Number of responses delivered from Central Coding.
Sent	Number of new requests sent to Central Coding.
Batch Id	Oracle batch job queue ID, if the automatic coding was run as a batch job.
User Id	User account that submitted or ran the automatic coding.
Start	Date and Time the batch job began.
End	Date and Time the batch job ended.
Restriction	SQL WHERE clause used to select records that was built automatically from the specified selection criteria.
Table	Type of database table (UPDATE or DATA) for which requests were sent. This column may also show RECV, which indicates that responses have been received from Central Coding.

The following example shows a portion of the Automatic Coding Log:



Automatic Coding Log

Panel	Status	Remarks	Received	Sent	Batch Id	User Id	Start	End
ADV_LLT	NORMAL		3	0	81	CTSYS	10/02/2008 03:44 PM	10/02/2008 03:44 PM
ADV_LLT	NORMAL		0	5	76	CTSYS	10/02/2008 03:38 PM	10/02/2008 03:38 PM
DRGCODE_ALL	NORMAL		3	0	80	CTSYS	10/02/2008 03:44 PM	10/02/2008 03:44 PM
DRGCODE_ALL	NORMAL		0	3	77	CTSYS	10/02/2008 03:38 PM	10/02/2008 03:38 PM
DRGDATA	NORMAL		0	0	79	CTSYS	10/02/2008 03:44 PM	10/02/2008 03:44 PM
DRGDATA	NORMAL		0	0	78	CTSYS	10/02/2008 03:38 PM	10/02/2008 03:38 PM

How to work with the Automatic Coding Log

You can view the Automatic Coding Log, purge all entries from it, or purge selected entries from it based on the following criteria:

- Panel name
- User account
- Type of database table (UPDATE or DATA) or RECV, indicating responses received from Central Coding.
- Status (NORMAL or ERROR)
- Range for the date and time that records were sent to Central Coding.
- Range for the date and time that records were received from Central Coding.

You can use the **View** menu to filter or sort a displayed Automatic Coding Log, and the **File** menu to save or print the log.

Note: Regardless of which table you chose in the Coding Selector window (the Update table, the Data table, or both), the Coding Log will list which table was actually updated with the coded forms.

Note: When problems arise at the Central Coding server (for example, running out of tablespace in the database), the Automatic Coding log in Clintrial may return a non-speciifc message for the failure. If unexpected errors occur while the Central Coding jobs are running, you should check the Central Coding server Event Viewer for application-specific problems, or consult the Database Analyst (DBA) resposible for the Central Coding server.

What is recoding?

When an item has been successfully coded, its associated workflow item contains the value CODED. You can recode the items for which the workflow item is not Null. *Recoding* the item replaces the current code with a different code. For example, suppose that an item was coded interactively to have the code 568.01. If the item is recoded using automatic coding, then the automatic coding process will assign a different code to the item if changes have been made to data in the thesaurus. You could also recode the item using interactive coding.

The following table shows whether an item is recoded during automatic coding, based on a combination of the setting of the system parameter AUTOCODE_RECODE_ALL and the setting of the Override Coding attribute set up in Design for the protocol:

	AUTOCODE_RECODE _ALL=YES		**AUTOCODE_RECODE _ALL=NO**	
Workflow item	Override Coding=Y	Override Coding=N	Override Coding=Y	Override Coding=N
SENT	Recode	Recode	Do not recode	Do not recode
CODED	Recode	Recode	Do not recode	Do not recode

Note: Oracle recommends that if you are planning to use Central Coding on existing protocols which were formerly setup to use Clintrial coding, before you export a protocol for import after upgrading, you set the protocol parameter AUTOCODE_RECODE_ALL to **No**.

The original reason for allowing AUTOCODE_RECODE_ALL was to allow you to recode everything if the coding dictionary underwent updates or changes. With Central Coding, that is no longer necessary, because if the Dictionary used by Central Coding changes, it will detect which requests need to be recoded, and perform the work on only those requests. To see the impact of an update to a dictionary, you may choose run an Impact Analysis in Central Coding.

For more information about importing protocols into Clintrial when AUTOCODE_RECODE_ALL is set to **Yes**, see the *Clintrial Getting Started* guide.

6 Validating Data

Overview

Validation is a process that performs the following:

- Calculates any derived items set up by the designer.
- Cleans clinical data by applying the logic and consistency rules that were set up by the designer.

You can validate records in the update table or in the data table. You must validate records in the update table before you can merge them from the update table to the data table.

You can validate records in more than one panel at a time.

Note: Depending on the setting of the system parameter ALLOW-_MERGE_TO_VALIDATE, you may validate records as part of the merge process, which is described in Chapter 8.

What is a validation procedure?

During validation, the Clintrial software applies to data the *validation procedure* attached to the panel. A validation procedure is a PL/SQL procedure that is built automatically from derivations and rules associated with a panel. There is one validation procedure for each panel.

What is a derivation?

A *derivation* is a PL/SQL statement or series of statements that calculates the value of an item or a temporary variable during validation. For example, a derivation might calculate the AGE item from the BIRTH_DATE and CONSENT_DATE items.

***Caution*:** Data-entry checks (for example, checks against upper and lower bounds) are not applied to derived values.

When a derived value is stored in the database, the change may be reflected in the Audit Report, depending on the setting of the audit start point.

What is a rule?

A rule is part of a PL/SQL statement that evaluates to True or False. For example, a rule might be "DOSAGE is not Null and DRUGNAME is not Null." If the DOSAGE item is not Null, and DRUGNAME item is not Null, then the rule evaluates to True.

Each rule has an associated rule action:

- If a rule with the rule action REPORT evaluates to False, then the record is considered to have passed the rule, and the record passes validation. However, the evaluation of the rule to False generates an entry in the Error Log. The use of rules with the rule action REPORT is intended for rules that are significant, but that are not crucial to data cleaning.
- If a rule with the rule action REJECT evaluates to False, then the record is considered to have failed the rule. The failed rule generates an entry in the Error Log, and the record fails validation.

Passing or failing validation

A record can pass or fail validation:

- A record passes validation only if it passes all rules attached to the panel.
- A record fails validation if it fails one or more rules attached to the panel.

Note: Records that fail a rule with the rule action REPORT are considered to have passed the rule.

How flags and rules work

If a flag is attached to a rule, then the following occurs during validation (regardless of whether the rule action is REPORT or REJECT, and regardless of whether the record is released for merge):

When one or more rules evaluate to:	**Result:**
TRUE	The flag associated with the rule is removed, if it was already attached to the record.
FALSE	The flag associated with the rule is automatically attached to the record. The text in the rule message (in Design) is used as the flag comment.

Validating data

The eligibility of update table records for validation depends on whether verification (reentry of data) is required for the panel:

- If a panel has been set up to require verification, then only records with the status Verified (1), Validated (0), or Validation Error (-1) are available for validation.
- If a panel does not require verification, then records with the status Unverified (2), Verified (1), Validated (0), or Validation Error (-1) are available for validation.

Note: If you do not release records for merge, then you can also validate records with the status Verification Error (-2). For more information, see "How to release records for merge" on page 123.

All data table records are available for validation, since all data table records have the status Validated (0).

Note: You can validate records as many times as necessary. For example, if you have validated records and then the designer changes the rules and derivations attached to a panel, then you must validate the records again.

Effect on the record status

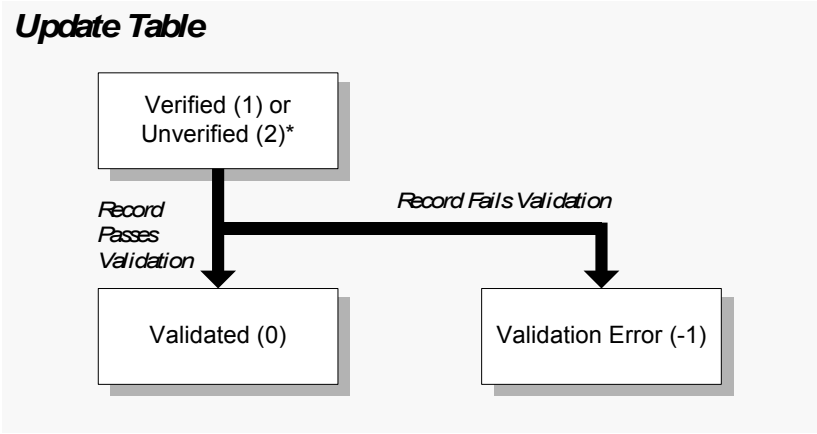
When an update table record is validated and released for merge:

- If the record passes validation, then its status becomes Validated (0).
- If the record fails validation, then its status becomes Validation Error (-1).

If a record in the update table passes or fails validation but has not been released for merge, then its status does not change.

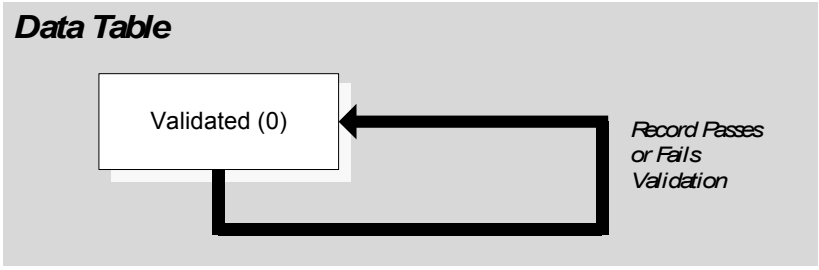
If a record in the data table passes or fails validation, then its status remains Validated (0).

The following figure shows changes in record status as a result of validation of records in the update table:

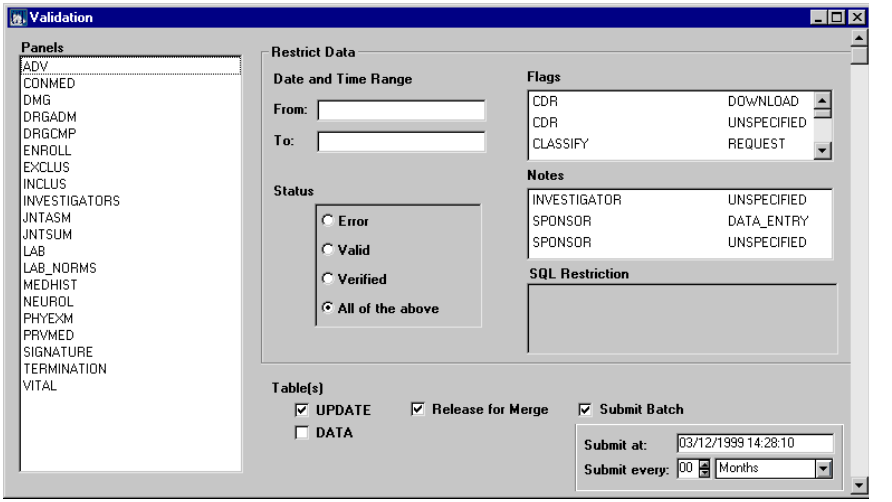


* An Unverified record can be validated only if the panel is not set up in Design to require verification.

The following figure shows how the record status does not change as a result of validation of records in the data table:



From the **Manage** menu, select **Validate**. The Validation window opens:



The system parameter and user preference SELECT_BY_PAGE determines whether records are selected by panel or by page for validation. The default setting of the parameter is No, where records are selected by panel. To change the user preference, from the **File** menu, select **Preferences**. Set the preference to either Yes or No.

If the user preference SELECT_BY_PAGE is set to No, then the Validation window lists all panels in the current protocol. Select the panels for which you want to validate data. To select all panels, from the **Edit** menu, select **Select Panels >> All.** The order in which data in the selected panels is validated is determined by the designer in Design.

Caution: Do not validate the Resolve panels:

- VCT_ERRORSTATUS_UPDATE
- VCT_ERRORITEM_UPDATE

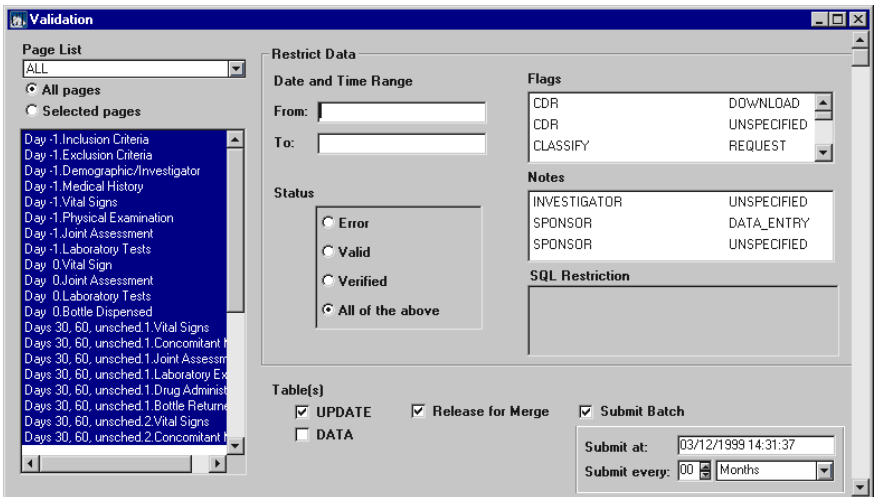
Resolve only uses the update tables. Validating and merging these panels will make Resolve discrepancies unavailable.

Select the types of database tables for which you want to validate data. You can select the update table, the data table, or both types of database tables.

Note: You can validate the records in an observation either individually or as a group. However, all records in an observation are merged at the same time. If the merge fails for one record in the observation, then the merge fails for all records in the observation. Thus, all records in an observation must pass validation before you can merge the records in the observation.

Validation by study page

If the SELECT_BY_PAGE user preference is set to Yes, then the Validation window lists all study pages in the selected page list for the current study book, as shown in the following example:



You can then:

- Click **All pages** to validate records on all pages that appear in the list.
- Click **Selected pages** and select specific pages with records to be validated.

Note: The Validation window only specifies which records are selected for validation, and does not guarantee that all records on a page are validated as a group.

Using Page Lists

If the SELECT_BY_PAGE user preference is set to Yes, then the **List** menu commands become available. You can use the **List** menu commands to create, edit, or delete a page list. You can then select a page list from the **Page List** drop-down list.

Page lists are used in Manage and Enter. Therefore, any changes that you make to a page list in Manage also affect Enter.

Note: In Manage, you cannot work with subject lists, as you can in Enter. You can only work with page lists.

For more information on page lists, see the Manage Help.

How to restrict records

You can optionally restrict records based on:

- Date and time.
- Flags and notes.
- A SQL restriction. Click the SQL Restriction box, or, from the **Edit** menu, select **SQL Restriction**.
- Record status.

Note: You can clear the restrictions you set. From the **Edit** menu, select **Clear Restrictions**.

For information on restricting records based on date and time, flags and notes, or a SQL restriction, see the *Reference Guide* or the Manage Help.

To restrict records based on record status, click one of the following:

If you click:	The validation includes:
Error	Records with the status Validation Error (-1).
Valid	Records with the status Validated (0).
Verified	Records with the status Verified (1); if verification is not required, also records with the status Unverified (2).
Failed verify	Records with the status Verification Error (-2). This command is only available if you do not check Release for Merge.
All of the above	Records with the status -1, 0, 1, and 2. If you do not check Release for Merge, then this option also includes records with the status Verification Error (-2).

How to release records for merge

The Release for Merge check box applies to records in the update table.

If you check Release for Merge, the status of records that pass validation changes to Validated (0), and the records are eligible for merging.

If you clear Release for Merge, the status of records that pass validation does not change, and the records are not eligible for merging. Before releasing records for merge, you can ensure that all the records will pass validation. To do so:

1. Clear Release for Merge and validate the records.
2. Review the Error Log to determine which records failed validation.
3. Edit the records that failed validation.
4. Validate records again, with Release for Merge still cleared.
5. When all records pass validation, check Release for Merge and validate the records.

The Release for Merge option enables you to review the results of validation before you release the records for merge.

How to specify the job type

You can perform validation either interactively or as a batch job. If you perform validation as a batch job, you may not be able to use your computer for other tasks until the batch job is completed. For more information on batch jobs, see the Manage Help.

How to begin

To begin validation by panel or by page, from the **File** menu, select **Run**.

How errors appear in the Error Log

When a rule with the rule action REPORT evaluates to False during validation, it is recorded as an entry in the Error Log with the error type VALIDATE and the Error Action REPORT.

When a rule with the rule action REJECT evaluates to False during validation, it is recorded as an entry in the Error Log with the error type VALIDATE and the Error Action REJECT.

For information about the Error Log, see Chapter 9.

Summary of statuses and derived values

The following table summarizes how record statuses and derived values behave during validation:

If the record is:	and it passes validation: (that is, passes all rules)	or it fails validation: (that is, fails one or more rules)
In the update table, not released for merge	• The record status does not change. • Derived values are stored.	• The record status does not change. • Derived values are stored.
In the update table, released for merge	• The record status becomes Validated (0). • Derived values are stored.	• The record status becomes Validation Error (-1). • Derived values are stored.
In the data table	• The record status does not change. • Derived values are stored.	• The record status does not change. • Derived values are not stored.

Validation Log

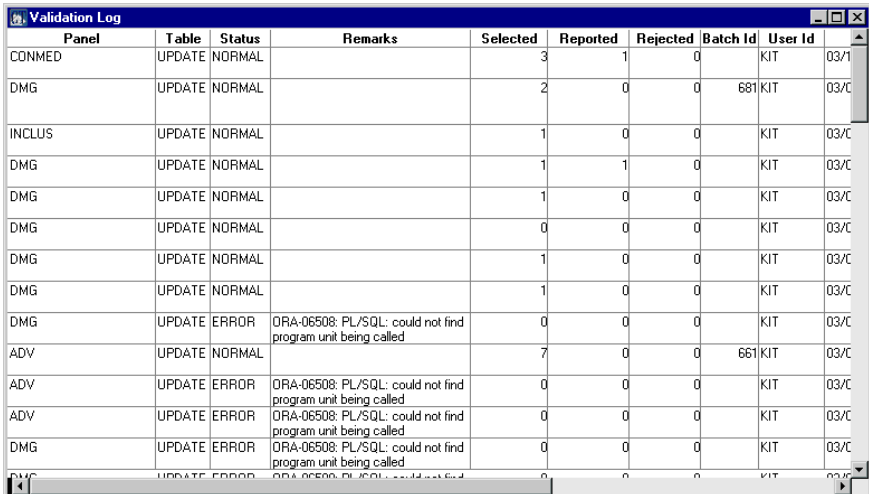
The *Validation Log* is a cumulative log of validation results. There is one Validation Log for each protocol.

From the **Reports** menu, select **Validation Log >> View**. The following table describes the information in the Validation Log:

Report column:	Description:
Panel	Name of the panel in which records were validated.
Table	Type of database table (UPDATE or DATA) in which records were validated.

Report column:	Description:
Status	NORMAL if the validation completed successfully; ERROR if the validation did not complete successfully.
Remarks	COMPLETED if the validation completed successfully; an error message if the validation did not complete successfully.
Selected	Number of records for which validation was attempted.
Reported	Number of rules with the rule action REPORT that evaluated to False.
Rejected	Number of rules with the rule action REJECT that evaluated to False.
Batch Id	Oracle batch job queue ID, if the validation was submitted as a batch job.
User Id	User account that validated records.
Start	Date and time that the validation began.
End	Date and time that the validation completed.
Restriction	SQL WHERE clause used to select records.

The following example shows a portion of a Validation Log:



Validation Log

Panel	Table	Status	Remarks	Selected	Reported	Rejected	Batch Id	User Id	
CONMED	UPDATE	NORMAL		3	1	0		KIT	03/1
DMG	UPDATE	NORMAL		2	0	0	681	KIT	03/0
INCLUS	UPDATE	NORMAL		1	0	0		KIT	03/0
DMG	UPDATE	NORMAL		1	1	0		KIT	03/0
DMG	UPDATE	NORMAL		1	0	0		KIT	03/0
DMG	UPDATE	NORMAL		0	0	0		KIT	03/0
DMG	UPDATE	NORMAL		1	0	0		KIT	03/0
DMG	UPDATE	NORMAL		1	0	0		KIT	03/0
DMG	UPDATE	ERROR	ORA-06508: PL/SQL: could not find program unit being called	0	0	0		KIT	03/0
ADV	UPDATE	NORMAL		7	0	0	661	KIT	03/0
ADV	UPDATE	ERROR	ORA-06508: PL/SQL: could not find program unit being called	0	0	0		KIT	03/0
ADV	UPDATE	ERROR	ORA-06508: PL/SQL: could not find program unit being called	0	0	0		KIT	03/0
DMG	UPDATE	ERROR	ORA-06508: PL/SQL: could not find program unit being called	0	0	0		KIT	03/0

How to work with the Validation Log

You can view the Validation Log, purge all entries from it, or purge selected entries from it based on the following criteria:

- Panel name
- User account
- Type of database table (UPDATE or DATA)
- Status (NORMAL or ERROR)
- Range for the date and time that the validation began
- Range for the date and time that the validation completed

You can use the **View** menu to filter or sort a displayed Validation Log, and the **File** menu to save or print the log.

Automatic revalidation

When a record that previously underwent the validation process is changed, the Clintrial software automatically revalidates the record. A record has previously undergone the validation process if it has the status Validated (0) or Validation Error (-1). As with the initial validation, a record can pass or fail automatic revalidation.

If a record in the update table fails revalidation, then you can save the changes. As with the initial validation, the evaluation of a rule to False during revalidation generates an entry in the Error Log. If a record in the data table fails revalidation, then you cannot save the changes.

As with the initial validation, the Clintrial software may calculate and store derived values as a result of revalidation, and the Clintrial software may attach flags to data or remove flags from data.

How revalidation works

The following table describes how revalidation works. Derived values are stored as a result of revalidation except for data table records that fail revalidation.

If the record is in the:	**And the status is:**	**During automatic revalidation:**
Update table	Validated (0)	If the record passes revalidation, then the change is saved and the record status remains 0. If the record fails revalidation, then the change is saved, and the record status changes to -1.
Update table	Validation error (-1)	If the record passes revalidation, then the change is saved and the record status changes to 0. If the record fails revalidation, then the change is saved and the record status remains -1.
Data table	Validated (0)	If the record passes validation, then the change is saved and the record status remains 0. If the record fails revalidation, then the change is not saved, and the record status remains 0.

7 Globally Changing or Deleting Data

Overview

Global change is the process of changing the value of one or more items in multiple records. Once you have specified a global change, you can preview the changes to records before modifying the records.

What is global deletion?

Global deletion is the process of deleting multiple records. Once you have specified a global deletion, you can preview the effects of the deletions before actually deleting the records.

Caution: You can delete all of a subject's records, including those in the enrollment panel, through global deletion.

Enrollment data

The only way to change or to delete data in the data table for the enrollment panel is to perform a global change or global deletion.

Caution: The changes that you make to enrollment data can affect records in multiple panels. For example, if you change the subject item, then records in all panels will be changed to have the new subject item value.

Globally changing or deleting data

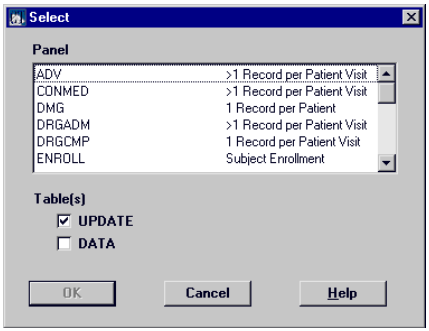
All records, regardless of status, are available for global change or deletion.

Effect on the record status

The record status does not change as a result of global change or deletion, except as a result of revalidation as described in "Revalidation" on page 136.

How to begin

From the **Manage** menu, select **Global Change** or **Global Delete**. The Select dialog box opens:



Select the panels in which to make the global change or deletion.

Global change restrictions

If you are making a global change, then you must consider the following restrictions:

- To change Type 0 panel data, you must select only the Type 0 panel.
- To change any subject-type context items, with the exception of the subject item, you must select only the enrollment panel.
- To change the subject item value you can either select the enrollment panel (then the change propagates to every Type 1-4 panel) or you can select Type 1-4 panel.

  Note: If possible, the subject item value should be changed in the enrollment panel to preserve the audit history. If subject item is changed for Type 1-4 panel, the software deletes the record and inserts a new one with a different ct_recid. As a result the audit trail of the newly created record does not contain the audit history of the original record.
- To change other context item values, select all panels that you want to change, excluding the enrollment panel and any Type 0 panels.
- To change Type 1-4 panel data, you can select the panels individually or in groups. If you select the panels individually, then all nonsystem items in the panel will be listed, with the exception of subject-related context items. If you select the panels in groups, then all non-subject type context items will be listed.

  Note*:* You cannot directly change any derived item values.

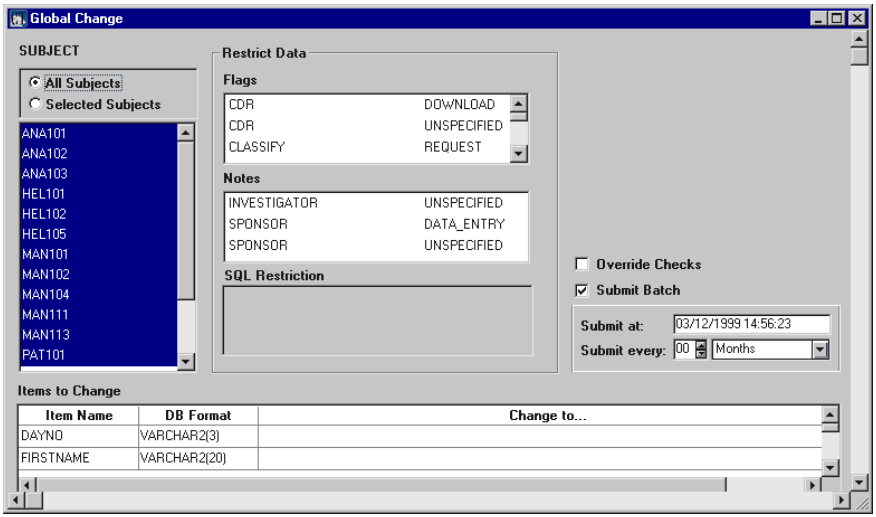
Global deletion restrictions

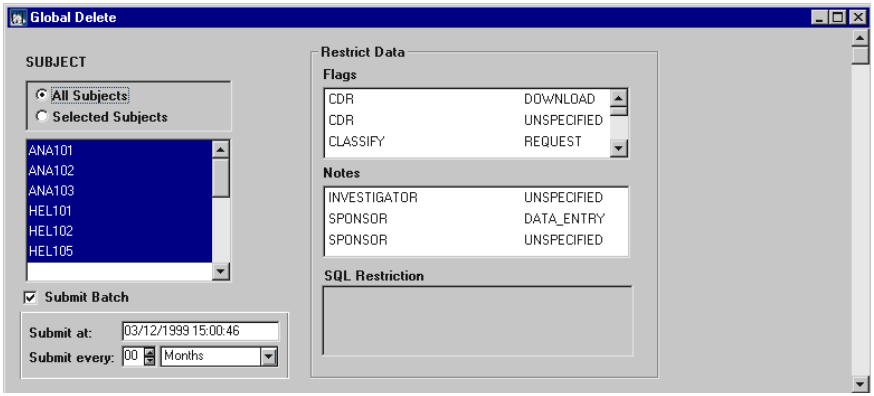
If you are making a global deletion, then you must consider the following restrictions:

- To delete Type 0 panel data, you must select only the Type 0 panel.
- To delete Type 1-4 panel data, you must select all panels for which you want to delete data, excluding the enrollment panel and any Type 0 panels.
- If you select only the enrollment panel, then all data for each subject selected will be deleted from Type 1-5 panels in the protocol. The subject's enrollment panel record will also be deleted.
- To delete Type 1-4 panel data, you can select the panels individually or in groups. If you select multiple panels, then you can delete some or all of the records from the panels. The subject's enrollment panel record will not be deleted. Therefore, the subject will still be enrolled.

Select the type of database table in which you want to make the global change or deletion. You can select the update table, the data table, or both types of database tables.

When you click **OK** in the Select dialog box, the Global Change window or the Global Delete window opens:





How to select subjects

In the Global Change window or the Global Delete window:

- If you click **All Subjects**, the change or deletion that you specify will be made for all subjects' records in the selected panels.
- If you click **Selected Subjects**, and then select subjects from the list, then the change or deletion that you specify will be made for only the selected subjects' records in the selected panels.

How to specify the job type

You can perform global change or global deletion either interactively or as a batch job. If you perform this task interactively, then you will not be able to use Manage for other tasks until the current task is completed. For more information on batch jobs, see the Manage Help.

How to restrict records

You can optionally restrict records based on:

- A SQL restriction. Click the SQL Restriction box, or, from the **Edit** menu, select **SQL Restriction**.
- Flags and notes.

For more information on restricting records, see the *Reference Guide* or the Manage Help.

How to specify a change

In the Global Change window, select each item that you want to change.

In the Change to... field, enter the value to which you want to change the item:

- The new value must match the DB Format (database format) of the item.
- For the TEXT data type, you must enclose the new value in single quotation marks.
- For any data type, the new value can be a constant or a calculated value, which can refer to other items in the panel.
- To specify a calculated value, specify a SQL expression that is a valid UPDATE statement. The SQL expression can contain any valid Oracle function or operator.

Note: If the item selected for change is a context key or a grouping item, the modified record is deleted and a new record with a different ct_recid is created. As a result the audit trail of the newly created record does not contain the audit history of the original (deleted) record. The change to the context item and all changes prior remain in the audit trail of the deleted record.

The following examples show the ways in which you can specify new values:

Item name:	Database format:	New value:
AGE	NUMBER(2)	25
VISIT	VARCHAR2(5)	'BASELINE'
VISIT_DATE	DATE	‘01-feb-1999‘ or TO_DATE (‘01-feb-1999’,’DD-MON-YYYY’) ***Note***: Use the date format that has been set up for your Oracle database, or use the TO_DATE() function to override it.
BPDIA	NUMBER(2)	BPDIA+10
TOTAL	NUMBER(2)	ITEM_1 + ITEM_2

How to override data-entry checks

When you make a global change, the Clintrial software applies the same checks that are applied during interactive data entry. These checks are:

- Confirming that subjects are enrolled.
- Confirming that subject, block, and page keys are defined.
- Confirming that block repeat and page repeat keys are defined, if they will be used.
- Confirming that subset keys (if used) are defined.
- Confirming that a master record exists for a detail record.
- Confirming that the master key is unique.
- Confirming that grouping items have values, if grouping items are defined for Type 0 panels. Confirms that default grouping items have values for Type 2 and Type 4 panels.
- Confirming that values are provided for mandatory items.
- Confirming that a code for an item with an attached codelist exists in the codelist.
- Applying the range checks (upper and lower limits) that are defined for items.
- Confirming that a value exists in the checklist for an item with an attached checklist.

If you check Override Checks in the Global Change window, you can override the following checks for items:

- For an item with an attached checklist, the value must exist in the checklist.
- The value must be within any upper or lower bounds that have been defined for the item.

Revalidation

When you change and try to save a record with the status Validated (0) or Validation Error (-1), the Clintrial software automatically attempts to revalidate the record.

If a record in the update table fails revalidation, then you can save the changes. As with the initial validation, the evaluation of a rule to False during revalidation generates an entry in the Error Log.

If a record in the data table fails revalidation, then you cannot save the changes.

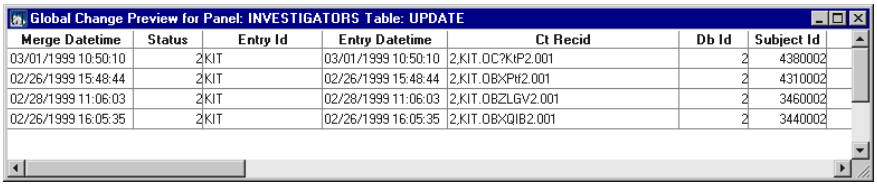
For more information about revalidation, see "Automatic revalidation" on page 126.

Coding

If the protocol parameter ENCODE_CLEAR_ITEMS is set to Yes, then coding-related items are cleared when verbatim text is changed. However, during global change, if you explicitly specify a coding-related item, the item receives the explicitly assigned value.

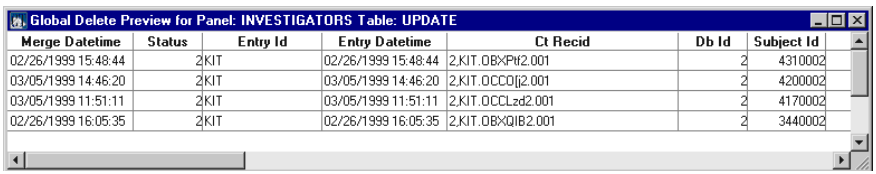
How to preview

Before you globally change or delete records, it is recommended that you preview the records that will be affected. To preview a global change or deletion, from the **View** menu, select **Preview**. The Global Change Preview window or the Global Delete Preview window opens, listing records that meet the selection criteria:



Global Change Preview for Panel: INVESTIGATORS Table: UPDATE

Merge Datetime	Status	Entry Id	Entry Datetime	Ct Recid	Db Id	Subject Id
03/01/1999 10:50:10	2	KIT	03/01/1999 10:50:10	2,KIT.OC?KtP2.001	2	4380002
02/26/1999 15:48:44	2	KIT	02/26/1999 15:48:44	2,KIT.OBXPtf2.001	2	4310002
02/28/1999 11:06:03	2	KIT	02/28/1999 11:06:03	2,KIT.OBZLGV2.001	2	3460002
02/26/1999 16:05:35	2	KIT	02/26/1999 16:05:35	2,KIT.OBXQIB2.001	2	3440002



Global Delete Preview for Panel: INVESTIGATORS Table: UPDATE

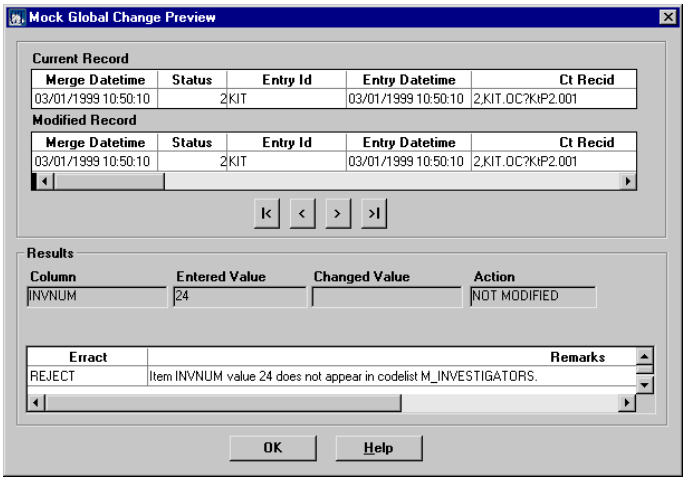
Merge Datetime	Status	Entry Id	Entry Datetime	Ct Recid	Db Id	Subject Id
02/26/1999 15:48:44	2	KIT	02/26/1999 15:48:44	2,KIT.OBXPtf2.001	2	4310002
03/05/1999 14:46:20	2	KIT	03/05/1999 14:46:20	2,KIT.OCCO[j2.001	2	4200002
03/05/1999 11:51:11	2	KIT	03/05/1999 11:51:11	2,KIT.OCCLzd2.001	2	4170002
02/26/1999 16:05:35	2	KIT	02/26/1999 16:05:35	2,KIT.OBXQIB2.001	2	3440002

The Global Change Preview window and the Global Delete Preview window display the records in one panel and one type of database table at a time. The window title indicates the panel and the table with which you are currently working. If you are working with more than one panel or table type, you can view and select all available records by using:

- The **View** menu's **First Table**, **Prior Table**, **Next Table**, and **Last Table** commands.
- The arrow buttons on the Task toolbar.

If you are globally deleting records, then when you have confirmed that the appropriate records will be deleted, you must return to the Global Delete window. To run the global deletion, from the **File** menu, select **Run**. All records listed in the Global Delete Preview window are deleted.

If you are globally changing records, then in the Global Change Preview window, select the records for which you want to preview the global change. Then, from the **View** menu, select **Preview Change**. The Mock Global Change Preview dialog box opens:



The Current Record is the current record in the database. The Modified Record is the way the record will look in the database if you make the global change.

You can use the arrow buttons to scroll through the list of records, if multiple records were selected.

In the Results section of the window:

- The Column field is the name of the item being changed.
- The Entered Value field is the value you entered in the Change to field of the Global Change dialog box.
- The Changed Value field shows the value that the item will have if you make the global change.
- If the change passes data-entry checks and revalidation, then the Action field is MODIFIED; otherwise, the Action field is NOT MODIFIED.

If the change is to the subject item in the enrollment panel, only the enrollment panel record will be previewed. Records in panels to be changed are not previewed.

After previewing the records, return to the Global Change window. To run the actual global change, from the **File** menu, select **Run**. All records listed in the Global Change Preview window are modified, even if you did not preview the changes for all of them.

Reason for change

If auditing is in effect for any records that you globally changed or deleted, then the Reason for Change dialog box opens. If the AUDIT_REASON_REQD system parameter is set to Yes, then you must specify a reason for the change or deletion. The same reason applies to all records that are included in the global change or deletion.

The Clintrial software stores the reason for change in the CTS$REASON system item of each record.

How errors appear in the Error Log

If a record fails a data-entry check during global change (and the check is not overridden) then an entry is made in the Error Log with the error action REJECT and one of the following error types:

- GLOBCH if the error was during running of the actual global change.
- MGLOBCH if the error was during previewing of the global change.

If an error occurs during global deletion, then an entry is made in the Error Log with the error action REJECT and the error type GLOBAL_DEL.

For more information about the Error Log, see Chapter 9.

Global Change Log

The *Global Change Log* is a cumulative report that contains the results of global changes. There is one Global Change Log for each protocol.

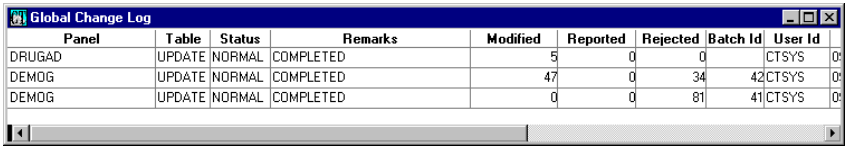
From the **Reports** menu, select **Global Change Log >> View**. The following table describes the information in the Global Change Log:

Report column:	**Description:**
Panel	Name of the panel in which the global change was made.
Table	Type of database table (UPDATE, DATA, or BOTH) in which the global change was made.

Report column:	Description:
Status	NORMAL if the global change completed successfully; ERROR if the global change did not complete successfully.
Remarks	COMPLETED if status is NORMAL; an error message if status is ERROR.
Selected	Number of records for which the global change was attempted.
Modified	Number of records in which values were changed. If you change enrollment data, the log shows only one record as modified for each subject selected even though records in other panels are changed.
Reported	Number of items that failed data checks, but passed because the checks were overridden.
Rejected	Number of records that failed the global change.
Batch Id	Oracle batch job queue ID, if the global change was submitted as a batch job.
User Id	User account that made the global change.
Start	Date and time that the global change began.
End	Date and time that the global change completed.
Restriction	SQL WHERE clause used to select records.

Note: Each panel and table combination is listed in the Global Change Log as a separate process.

The following example shows a portion of a Global Change Log:



Panel	Table	Status	Remarks	Modified	Reported	Rejected	Batch Id	User Id
DRUGAD	UPDATE	NORMAL	COMPLETED	5	0	0		CTSYS
DEMOG	UPDATE	NORMAL	COMPLETED	47	0	34	42	CTSYS
DEMOG	UPDATE	NORMAL	COMPLETED	0	0	81	41	CTSYS

How to work with the Global Change Log

You can view the Global Change Log, purge all entries from it, or purge selected entries from it based on the following criteria:

- Panel name
- User account
- Type of database table (UPDATE or DATA)
- Status (NORMAL or ERROR)
- Range for the date and time that the global change started
- Range for the date and time that the global change completed

You can use the **View** menu to filter or sort a displayed Global Change Log, and the **File** menu to save or print the log.

Global Delete Log

The *Global Delete Log* is a cumulative log of the results of global deletions. There is one Global Delete Log for each protocol.

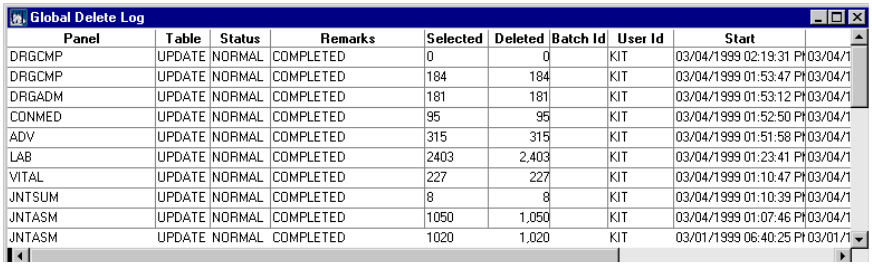
Note: Each panel and table combination is listed in the Global Delete Log as a separate process.

From the **Reports** menu, select **Global Delete Log >> View**. The following table describes the information in the Global Delete Log:

Report column:	**Description:**
Panel	Name of the panel for which the global deletion was made.
Table	Type of database tables (UPDATE or DATA) in which the global deletion was made.
Status	NORMAL if the global deletion completed successfully; ERROR if the global deletion did not complete successfully.
Remarks	COMPLETED if status is NORMAL; an error message if status is ERROR.
Selected	Number of records for which the global deletion was attempted.

Report column:	Description:
Deleted	Number of records deleted.
Batch Id	Oracle batch job queue ID, if the global deletion was submitted as a batch job.
User Id	User account that made the global deletion.
Start	Date and time that the global deletion started.
End	Date and time that the global deletion ended.
Restriction	SQL WHERE clause used to select records.

The following example shows a portion of a Global Delete Log:



Global Delete Log

Panel	Table	Status	Remarks	Selected	Deleted	Batch Id	User Id	Start	
DRGCMP	UPDATE	NORMAL	COMPLETED	0	0		KIT	03/04/1999 02:19:31 PM	03/04/1
DRGCMP	UPDATE	NORMAL	COMPLETED	184	184		KIT	03/04/1999 01:53:47 PM	03/04/1
DRGADM	UPDATE	NORMAL	COMPLETED	181	181		KIT	03/04/1999 01:53:12 PM	03/04/1
CONMED	UPDATE	NORMAL	COMPLETED	95	95		KIT	03/04/1999 01:52:50 PM	03/04/1
ADV	UPDATE	NORMAL	COMPLETED	315	315		KIT	03/04/1999 01:51:58 PM	03/04/1
LAB	UPDATE	NORMAL	COMPLETED	2403	2,403		KIT	03/04/1999 01:23:41 PM	03/04/1
VITAL	UPDATE	NORMAL	COMPLETED	227	227		KIT	03/04/1999 01:10:47 PM	03/04/1
JNTSUM	UPDATE	NORMAL	COMPLETED	8	8		KIT	03/04/1999 01:10:39 PM	03/04/1
JNTASM	UPDATE	NORMAL	COMPLETED	1050	1,050		KIT	03/04/1999 01:07:46 PM	03/04/1
JNTASM	UPDATE	NORMAL	COMPLETED	1020	1,020		KIT	03/01/1999 06:40:25 PM	03/01/1

How to work with the Global Delete Log

You can view the Global Delete Log, purge all entries from it, or purge selected entries from it based on the following criteria:

- Panel name
- User account
- Type of database table (UPDATE or DATA)
- Status (NORMAL or ERROR)
- Range for the date and time that the global deletion began
- Range for the date and time that the global deletion completed

You can use the **View** menu to filter or sort a displayed Global Delete Log, and the **File** menu to save or print the log.

8 Merging Data

Overview

Merging is the process of moving validated data from the update table to the data table. You can only merge data that has passed validation.

Note: Depending on the setting of the system parameter ALLOW-_MERGE_TO_VALIDATE, you may be able to validate records as part of the merge process.

Duplicate records

A *duplicate record* is a record for which a record already exists for the same subject or subject visit, and the same panel. When you merge records, the Clintrial software checks for duplicate records.

Merging data

Only records that are in the update table and have the status Validated (0) are available for merging.

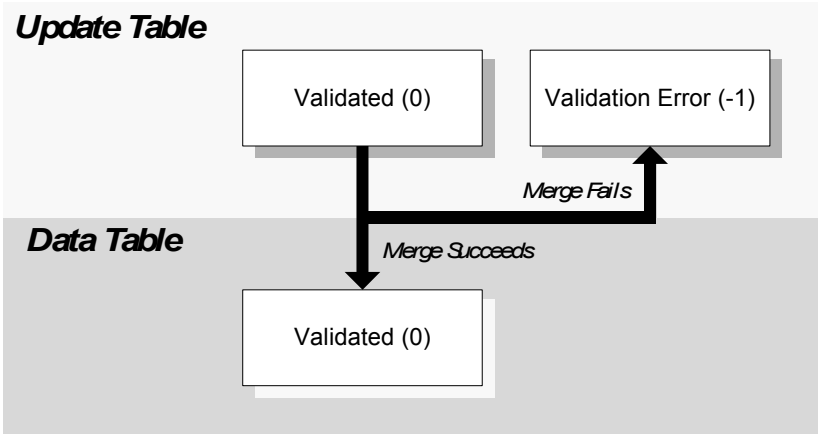
All records must be validated before you can merge them, even if the panel has no attached derivations or rules.

Effect on the record status

If the merge succeeds, then the Clintrial software moves the record from the update table to the data table. The status of the record remains Validated (0).

If the merge fails, then the record remains in the update table. The record status becomes Validation Error (-1).

The following figure shows changes in record status as a result of merging:

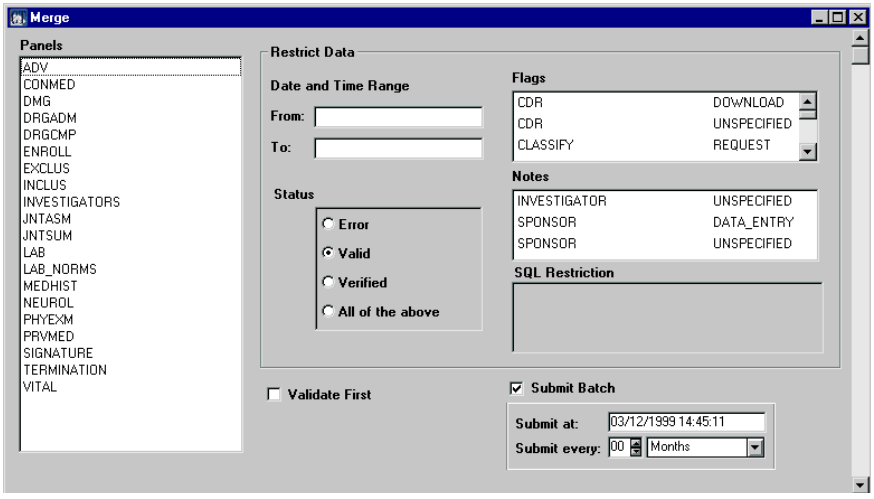


About panel keys

It is recommended that you set up panel keys for the Type 0, Type 2, and Type 4 panels into which you will merge data. The items referenced by the panel key definition must be defined as required items.

How to begin

From the **Manage** menu, select **Merge**. The Merge window opens:



The system parameter and user preference SELECT_BY_PAGE determines whether records are selected by panel or by page for merge. The default setting of the parameter is No. To change the user preference, from the **File** menu, select **Preferences**. Set the preference to either Yes or No.

If the user preference SELECT_BY_PAGE is set to No, then the Merge window lists all panels in the current protocol.

Caution: Do not merge the Resolve panels:

- VCT_ERRORSTATUS_UPDATE
- VCT_ERRORITEM_UPDATE

Resolve only uses the update tables. Merging these panels will make Resolve discrepancies unavailable.

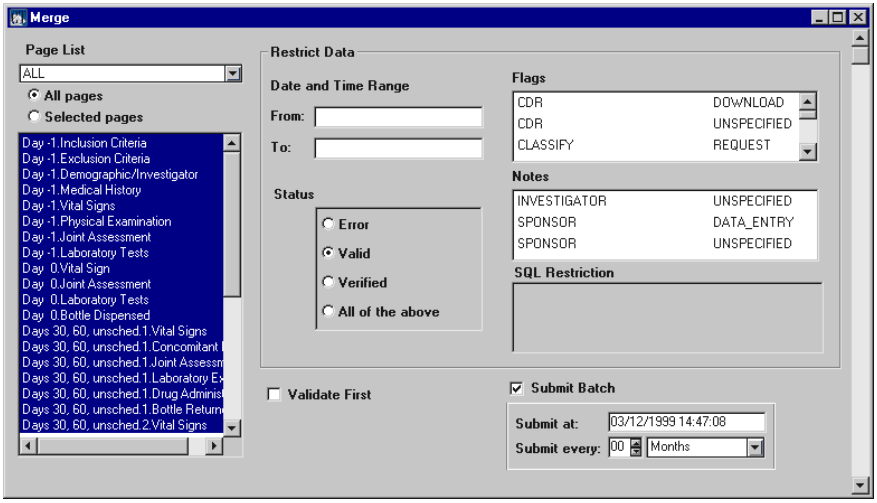
Select the panels for which you want to merge data. To select all panels, from the **Edit** menu, select **Select Panels >> All**.

Panels with invalid validation procedures are unavailable for selection in the Merge window. If you need to merge records in a panel that is listed but is unavailable, check with the designer to determine whether the panel's validation procedure has been compiled properly.

Note: All records that are part of an observation are merged at the same time. If the merge fails for one record that is part of the observation, then the merge fails for all records that are part of the observation.

Merge by study page

If the SELECT_BY_PAGE user preference is set to Yes, the Merge window lists all study pages in the selected page list for the current study book, as shown in the following example:



You can then:

- Click **All pages** to merge records in all pages that appear in the list.
- Click **Selected pages** and select specific pages with records to be merged.

Note: The Merge window only specifies which records are selected for merge, and does not guarantee that all records on a page are merged as a group.

Using Page Lists

If the SELECT_BY_PAGE user preference is set to Yes, then the **List** menu commands become available. You can use the List menu commands to create, edit, or delete a page list. You can then select a page list from the Page List drop-down listbox.

Page lists are used in Manage and Enter. Therefore, any changes that you make to a page list in Manage also affect Enter.

Note: In Manage, you cannot work with subject lists, as you can in Enter. You can only work with page lists.

For more information on page lists, see the Enter Help.

How to restrict records

You can optionally restrict records based on:

- Date and time
- Flags and notes
- A SQL restriction. Click the SQL Restriction box, or, from the **Edit** menu, select **SQL Restriction**.

For more information on restricting records, see the *Reference Guide* or the Manage Help.

If you are validating records as part of the merge, you can also restrict records on the basis of status. Only records of the specified status will be validated.

For more information about status restrictions during validation, see "How to restrict records" on page 122.

How to validate first

If the Validate First check box is available, you can check it to validate the records as part of the merge. If a record fails validation, then an entry is made in the Error Log and the record is not merged.

If the Validate First check box is unavailable, or if you do not check the Validate First check box, then you must have previously validated the records.

How to specify the job type

You can perform merging either interactively or as a batch job. If you perform a task interactively, you may not be able to use Manage for other tasks until the current task is completed. For information about batch jobs, see the Manage Help.

How to begin

To run the merge process, from the **File** menu, select **Run**.

How errors appear in the Error Log

If an error occurs during merging, it is recorded as an entry in the Error Log with the error type MERGE. For information about the Error Log, see Chapter 9.

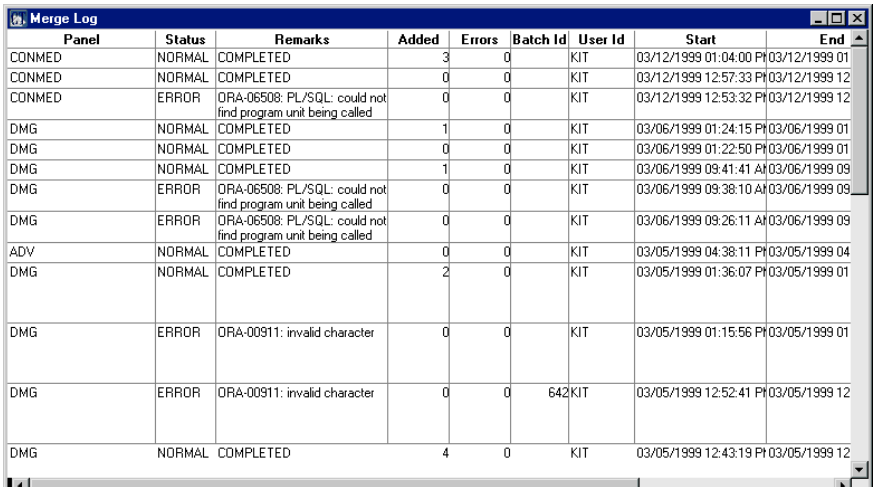
Merge Log

The *Merge Log* is a cumulative log that contains general information about the number of records added to the data table during merging. There is one Merge Log for each protocol.

From the **Reports** menu, select **Merge Log >> View**. The following table describes the information in the Merge Log:

Report column:	**Description:**
Panel	Name of the panel in which records were merged.
Status	NORMAL if the merge completed successfully; ERROR if the merge did not complete successfully.
Remarks	COMPLETED if status is NORMAL; an error message if status is ERROR.
Added	Number of records added (merged) to the data table.
Errors	Number of errors that occurred during merging.
Batch Id	Oracle batch job queue ID, if the merge was submitted as a batch job.
User Id	User account that submitted or ran the merge.
Start	Date and time that merging started.
End	Date and time that merging ended.
Restriction	SQL WHERE clause used to select records.

The following example shows a portion of a Merge Log:



Merge Log

Panel	Status	Remarks	Added	Errors	Batch Id	User Id	Start	End
CONMED	NORMAL	COMPLETED	3	0		KIT	03/12/1999 01:04:00 PM	03/12/1999 01
CONMED	NORMAL	COMPLETED	0	0		KIT	03/12/1999 12:57:33 PM	03/12/1999 12
CONMED	ERROR	ORA-06508: PL/SQL: could not find program unit being called	0	0		KIT	03/12/1999 12:53:32 PM	03/12/1999 12
DMG	NORMAL	COMPLETED	1	0		KIT	03/06/1999 01:24:15 PM	03/06/1999 01
DMG	NORMAL	COMPLETED	0	0		KIT	03/06/1999 01:22:50 PM	03/06/1999 01
DMG	NORMAL	COMPLETED	1	0		KIT	03/06/1999 09:41:41 AM	03/06/1999 09
DMG	ERROR	ORA-06508: PL/SQL: could not find program unit being called	0	0		KIT	03/06/1999 09:38:10 AM	03/06/1999 09
DMG	ERROR	ORA-06508: PL/SQL: could not find program unit being called	0	0		KIT	03/06/1999 09:26:11 AM	03/06/1999 09
ADV	NORMAL	COMPLETED	0	0		KIT	03/05/1999 04:38:11 PM	03/05/1999 04
DMG	NORMAL	COMPLETED	2	0		KIT	03/05/1999 01:36:07 PM	03/05/1999 01
DMG	ERROR	ORA-00911: invalid character	0	0		KIT	03/05/1999 01:15:56 PM	03/05/1999 01
DMG	ERROR	ORA-00911: invalid character	0	0	642	KIT	03/05/1999 12:52:41 PM	03/05/1999 12
DMG	NORMAL	COMPLETED	4	0		KIT	03/05/1999 12:43:19 PM	03/05/1999 12

How to work with the Merge Log

You can view the Merge Log, purge all entries from it, or purge selected entries from it based on the following criteria:

- Panel name
- User account
- Type of database table (UPDATE or DATA)
- Status (NORMAL or ERROR)
- Range for the date and time that the merge started
- Range for the date and time that the merge ended

You can use the **View** menu to filter or sort a displayed Merge Log, and the **File** menu to save or print the log.

9 Working with the Error Log

Viewing the Error Log

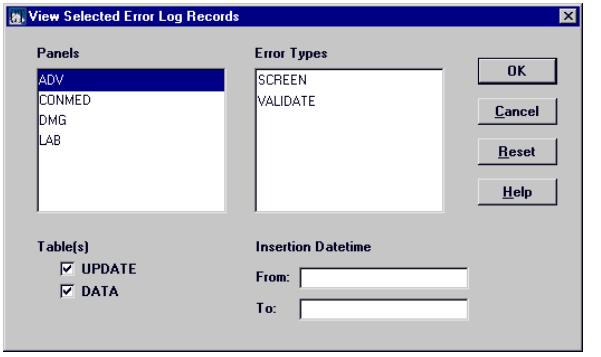
The *Error Log* is a cumulative log of errors that occurred during screening, validation, merge, global change, and global deletion in Manage. The Error Log is also a cumulative log of errors that occurred during screening, validation, and transfer in Lab Loader. You use the Error Log to view and correct records that failed these processes. There is one Error Log for each protocol.

How to begin

To view the Error Log for all panels in a protocol, from the **Reports** menu, select **Error Log >> View All**.

To view the Error Log for selected panels, from the **Reports** menu, select **Error Log >> View by Panel**.

The View Selected Error Log Records dialog box opens:

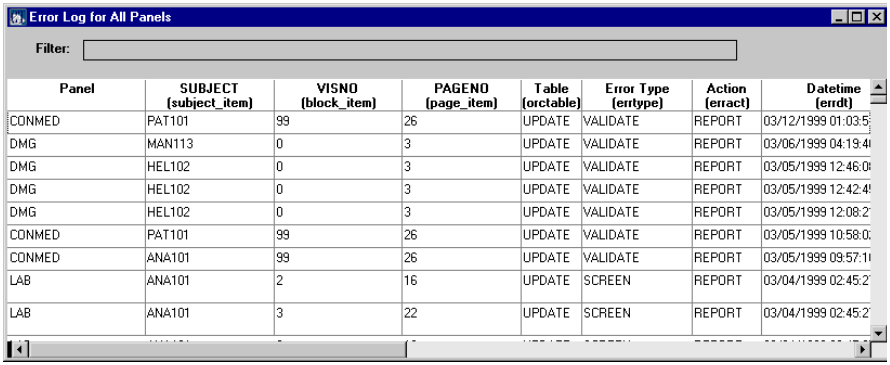


Select the panels for which to view the Error Log. Then, select the error types for which you want records to be displayed on the Error Log. If you do not select an error type, then records containing all error types will display on the log.

Select the type of database table for which you want to display the Error Log. You can select the update table, the data table, or both types of database tables.

You can further restrict the records that appear in the log by entering a range of dates and times that the records were generated.

The following example shows the Error Log:



If you are working with more than one page of records, you can view records by page using:

- The **View** menu's **First Page**, **Prior Page**, **Next Page**, and **Last Page** commands.
- The arrow buttons on the Task toolbar.

You can view the Error Log, purge all entries from it, or purge selected entries from it based on the following criteria:

- Panel
- Error type
- Type of database table (UPDATE or DATA)
- Date and time the entries were added to the log
- SQL Restriction

You can use the **View** menu to filter or sort a displayed Error Log, and the **File** menu to save or print the log.

Error Log contents

The following table describes the information in the Error Log:

Report column:	**Description:**
Panel	If you selected the **View All** submenu command, name of the panel containing the record with the error.

Report column:	Description:
Error	The name of the error.
Subject item	For Type 1 through Type 5 panels. The column heading is the subject item. The value in the column is the value of the record's subject item.
Block key item	For Type 1 through Type 4 panels. The column heading is the block item. The value in the column is the value of the record's block item.
Block repeat key item	For Type 1 through Type 4 panels. The value of the block repeat key item (if the context panel for the protocol has a block repeat key item).
Page key item	For Type 1 through Type 4 panels. The column heading is the page item. The value in the column is the value of the record's page item.
Page repeat key item	For Type 1 through Type 4 panels. The value of the page repeat key item (if the context panel for the protocol has a page repeat key item).
Table	Type of database table (UPDATE or DATA) containing the record.
Error Type	The Clintrial task during which the error occurred: • GLOBCH —Global change • MGLOBCH — Previewing of a global change (a temporary entry that appears only during the preview) • GLOBDEL — Global deletion • MERGE — Merge • SCREEN — Screening • VALIDATE — Validation For error type TRANSFER, see the *Lab Loader* section in *Manage, Classify, and Lab Loader.*

Report column:	Description:
Action	For error types GLOBCH, MGLOBCH, or SCREEN: • REPORT — The record did not pass data-entry checks, but the checks were overridden. • REJECT — The record did not pass data-entry checks, and the checks were not overridden. For error type VALIDATE: • REPORT — A rule with the error action REPORT evaluated to FALSE. • REJECT —A rule with the error action REJECT evaluated to FALSE. For error type SCREEN: • REPORT — There is an error with the study book. For example, a page is not defined for a visit. Or, the record did not pass data-entry checks. • REJECT — There is an error with the data. For example, the subject is not enrolled. Or, the record did not pass data-entry checks. For error type MERGE: • REJECT — There is a duplicate record. For more information on screen checks, see "Screening batch-loaded data" on page 61.
Datetime	Date and time that the error occurred.
Remarks	Description of the error, as determined by the error type.
Rule Name	For error type VALIDATE, name of the rule that evaluated to False. For error types SCREEN, GLOBCH, or MGLOBCH, the name of the item that failed a screen check. For example, if the error is that there was no subject identifier for a record you tried to screen, this value is SUBJECT_ID.
Ct Recid	Value of the CT_RECID system item for the record.

Additional item

With the user preference ERRLOG_DISPLAY_ITEM, you can specify an additional item to appear in the Error Log for Type 0 panels. The item only displays on the Error Log when you use the **View By Panel** submenu command.

Editing records from the Error Log

When a record fails a process in Manage, you may need to edit the record and repeat the process. For example, if a record fails validation, you may need to edit the record and validate it again. You can edit records directly from the Error Log if you have to correct Enter access rights. You do not need to use Enter to edit the records.

You can use the Error Log to edit records that have an error reported against them if you have the required access rights and if your designer has defined a study page and study book for the panel that contains the record that you want to edit.

When you select a record in the Error Log, a study page opens in which you can edit the records and save the new values to the database.

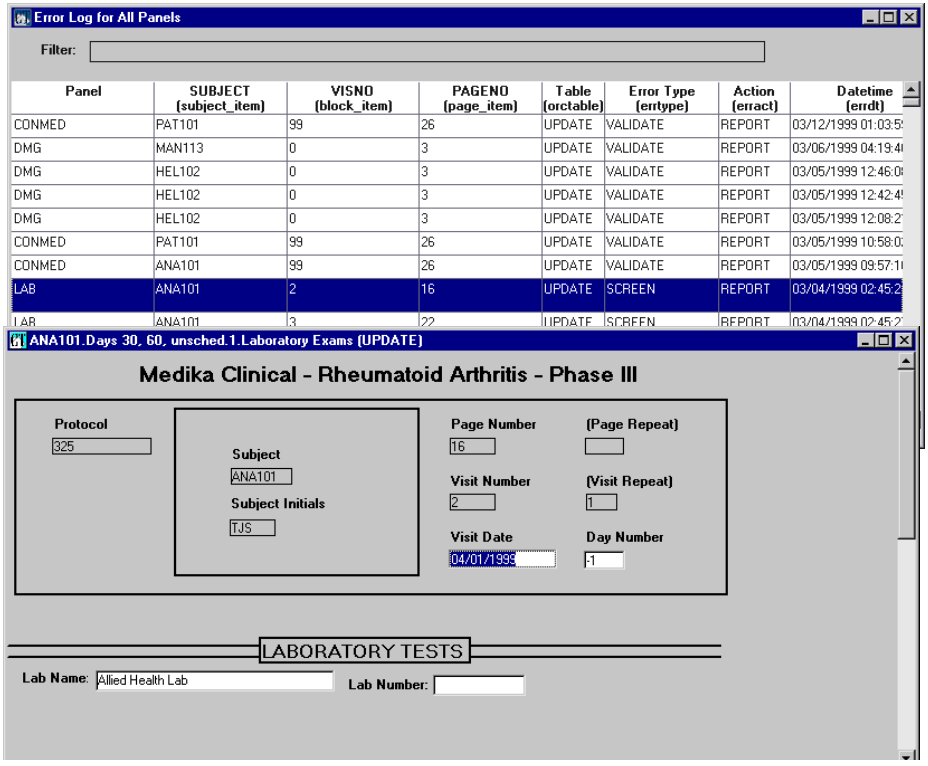
You can also:

- Supply a reason for change.
- Attach flags and notes to records.
- Work with discrepancies.

Note: You must set the study book to use when editing from the Error Log. From the **File** menu, select **Set Study Book**. A dialog box opens in which you can select the study book.

How to edit from the Error Log

To select a record in the Error Log for editing, double-click the record. The Clintrial software opens the study page that contains the record. The following example shows a portion of the study page that opens for a record from the LAB panel of the MEDIKA_CLINICAL protocol that was selected in the Error Log:



You edit the record in the same way that you enter or edit records in a study page in Enter. However, you can perform only some of the editing and navigation functions available in Enter. For example:

- You can edit only one study page at a time; you cannot navigate to other study pages in the study book.
- You cannot add or insert repeating items.
- You cannot delete any records.

Using the Error Log with discrepancies

If the protocol is set up for Resolve, then you can also use the Error Log to show, create, and delete discrepancies. A *discrepancy* is either an actual or a potential data problem, such as missing values or variations from an expected range, or inconsistencies among data values entered over time for different panels. Discrepancies are created automatically in Manage when the protocol is set up for Resolve and:

- A record fails merging.
- A rule evaluated to FALSE during validation.

For example, if during merging two records have the same subject, page, and block key values, then both records generate a REJECT error on the Error Log, and both records generate discrepancies.

For more information about editing records or discrepancies from the Error Log, see the Manage Help.

For more information on resolving discrepancies, see the *Resolve* section in *Enter, Resolve, and Retrieve*.

Revalidation

When you change and attempt to save a record with the status Validated (0) or Validation Error (-1), the Clintrial software automatically attempts to revalidate the record.

If a record in the update table fails revalidation, you can save the changes. As with the initial validation, the evaluation of a rule to False during revalidation generates an entry in the Error Log.

If a record in the data table fails revalidation, you cannot save the changes.

For more information, see "Automatic revalidation" on page 126.

Reason for change

If auditing is in effect for the record that you edited, then the Reason for Change dialog box opens. If the AUDIT_REASON_REQD system parameter is set to Yes, then you must specify a reason for the change. Otherwise, specifying a reason for change is optional.

The Clintrial software stores the reason for change in the CTS$REASON system item.

10 Auditing Data and Notes

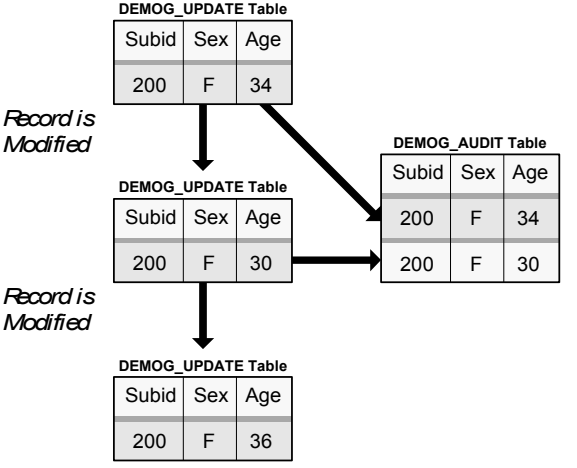
Overview

Auditing is the process of tracking changes made to clinical data, and of tracking notes associated with clinical data. The designer determines which Clintrial software panels and tasks are audited, and whether notes are audited.

What is the audit table?

When a record is changed or deleted, a copy of the record as it was before the change or deletion is stored in the audit table for the panel. There is one audit table for each installed panel.

The following figure shows how, as the value for AGE is changed twice in the DEMOG_UPDATE table, a copy of the record before the change is stored in the DEMOG_AUDIT table if auditing is in effect:



What is the audit tags table?

If auditing of notes has been set up for a protocol and auditing is in effect, then a copy of a note that is attached to a record that is eligible for auditing is stored in the audit table when it is changed. The audit table stores a copy of the note before it was changed.

What is the audit start point?

The *audit start point* is the data management activity after which auditing begins. Depending on where auditing is set to begin, auditing can track changes to records or notes in the update table, data table, or both.

The designer determines when auditing begins. There is a default audit start point for the database, and there may be protocol-specific or panel-specific audit start points.

The following table summarizes possible audit start points:

Audit start point:	Database table:	Description:
ENTRY	Update table	Auditing begins after the record is entered interactively.
VERIFICATION	Update table	If a record is entered interactively, auditing begins after the record has been verified. If a record is entered by batch loading, auditing begins after the record has passed screening. Records with the status 3 (Unscreened) or -3 (Screening Error) are not eligible for auditing.
VALIDATION	Update table	Auditing begins after the record has been validated, regardless of whether it passed or failed validation.
VALIDITY	Update table	Auditing begins after the record has passed validation.
MERGE	Data table	Auditing begins after the record is merged successfully.

Audit report

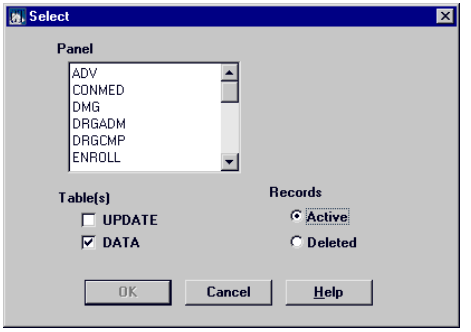
The *audit report* shows differences between the record before and after it was modified. It also shows records that have been deleted from the update table or data table.

If auditing is in effect when values are changed in any way for the items (including system items) that make up a record, then an entry for the record is made in the audit report.

Note: If a derived value changes as a result of validation, an entry is made in the audit report. If the status of the record changes because the record was processed, then an entry is made in the audit report. For example, if a record is validated, then an entry is generated for the report.

How to begin

From the **Reports** menu, select **Audit Records**. The Select dialog box opens:



Select the panel for which you want to display the audit report.

Select the type of database table for which you want to display the audit report. You can select the update table, data table, or both types of database tables.

To work with only records that are currently in the update table or data table, click Active. To work with only records that have been deleted from the update table or data table, click Deleted.

Note: If Global Change has been used to modify a context key of panel record, only changes that took place after modification of the context key will be included into the Active Records report. The modification to the context key and all changes prior to key modification will be included into Deleted Records report.

Example 1. If you modify a record three times, and then change the value of a context key, the Clintrial software deletes the modified record and inserts the record into the panel that is being modified. All four changes are now stored in the audit trail of the deleted record under the old context key. If you run a report for the active record, you will not see the details for the changes you made. You may or may not see the audit trail of the new record; it depends on a Audit Start parameter. These details are included in the Deleted Record report.

Example 2. If you change a record three times, and then change the value of a context key, the Clintrial software deletes the modified record and inserts the record into the panel that is being modified. If two more changes to non-context items are made, these two changes are stored in the audit trail of the NEW record with the new ct_recid. If you run a report for active records, the last two changes that took place after the context item was modified appear in the Active Records report. The Deleted Records report shows modifications to the context item and all modifications prior the context key change.

How to select records

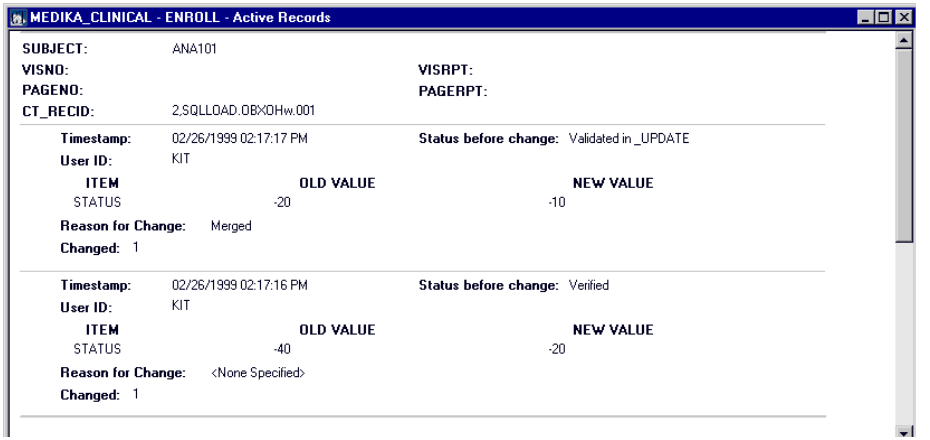
When you click **OK** in the Select dialog box, the Select for Audit window opens, listing records that meet the selection criteria.

You can use the **View** menu to filter or sort the list of records.

How to run the audit report

To run the audit report, select one or more records from the Select for Audit window, and from the **File** menu, select **Run**.

The Clintrial software creates an audit report that includes any existing audit records for the records that you specified. The following example shows an entry in the audit report for a record in the ENROLL panel:



You can use the **View** menu's **First Page**, **Prior Page**, **Next Page**, and **Last Page** commands to view different pages of the audit report, and the **File** menu to save or print the report.

Audit Report contents

The following table describes the information in the Audit Report for each modified record:

Report column:	**Description:**
Subject item	For Type 1 through Type 5 panels. The field name is the subject item. The value in the field is the value of the record's subject item.
Block key item	For Type 1 through Type 4 panels. The field name is the block item. The value in the field is the value of the record's block item.
Block repeat key item	For Type 1 through Type 4 panels. The value of the block repeat key item (if the context panel for the protocol has a block repeat key item).

Report column:	Description:
Page key item	For Type 1 through Type 4 panels. The field name is the page item. The value in the field is the value of the record's page item.
Page repeat key item	For Type 1 through Type 4 panels. The value of the page repeat key item (if the context panel for the protocol has a page repeat key item).
CT_RECID	Value of the CT_RECID system item.
Timestamp	Date and time the record was modified or deleted.
Status before change	Status of the record before the record was modified.
User ID	User account that modified or deleted the record.
ITEM	Name of the item for which a value was modified. ***Note:*** The Status item may appear in this column. This is a system item for internal Clintrial software purposes only.
OLD VALUE	Value of the item before the modification.
NEW VALUE	Value of the item after the modification.
Reason for Change	The reason that the user specified for the change or deletion.
Changed	The number of items that were changed in the record.

Additional context item

With the user preference AUDIT_ITEM_LIST, you can specify one additional context item to appear in the audit report.

Audit Notes Report

The Audit Notes Report shows notes that have been modified or added. The designer determines whether investigator notes, sponsor notes, or both are audited for a protocol. Additionally, to audit notes, auditing must be in effect for the record that the note refers to, as determined by the audit start point.

If auditing is in effect for notes, then modifications of notes attached to an observation, record, or item generate an entry in the Audit Notes Report. The Audit Notes Report does not show deletions of notes attached to clinical data.

How to run the Audit Notes Report

From the **Reports** menu, select **Audit Notes**. Select the panel for which you want to display the report.

The following table describes the information in the Audit Notes Report:

Report column:	**Description:**
Subject	Subject identifier of the record to which the note is attached.
Record	The CT_RECID of the record to which the note is attached. (For an observation-level note, this is the first record in the observation.)
Database Table	Update table or data table, depending on the type of database table to which the note is attached.
Entry Date	Value of the system item ENTRY_DATETIME for the record to which the note is attached.
Item note	Item note, record note, or observation note, depending on the level of data to which the note is attached.
Entry Id	User account that modified the note.

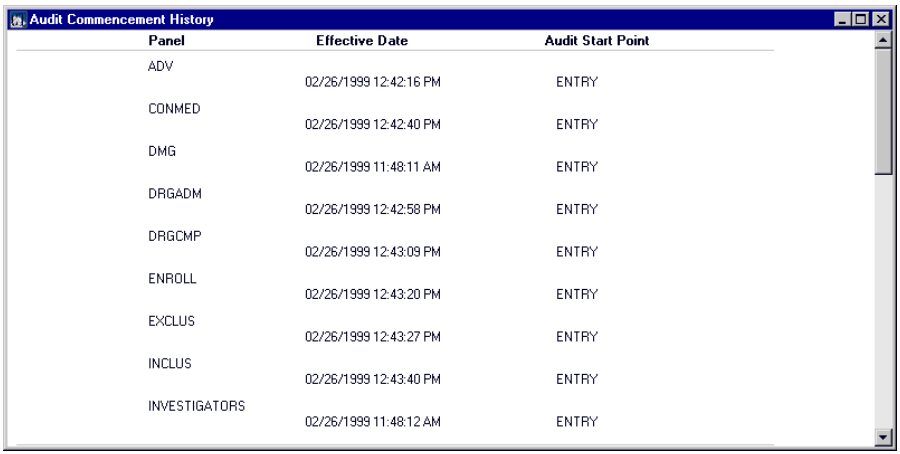
You can use the **View** menu to filter or sort a displayed Audit Notes Report, and the **File** menu to save or print the report.

Audit History Report

The *Audit History Report* shows the audit start point of panels, and any changes that are made to the audit start point for the panels in a protocol. You can view and print the Audit History Report.

How to run the Audit History Report

From the **Reports** menu, select **Audit History**. The Audit Commencement History report opens:



You can use the **View** menu's **First Page**, **Prior Page**, **Next Page**, and **Last Page** commands to view different pages of the Audit History Report, and the **File** menu to save or print the report.

The following table describes the information in the Audit Commencement History report:

Report column:	Description:
Panel	Name of the panel to which the audit start point applies.
Effective Date	Date on which the audit start point was set or changed.
Audit Start Point	Processing event at which the audit start point is set to begin; for possible values, see "What is the audit start point?" on page 163.

Subject Audit Report

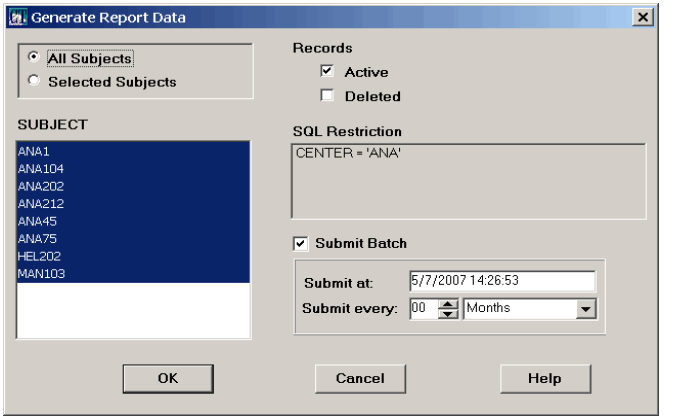
The *Subject Audit Report* shows any changes that are made to the subjects in a protocol, including data for all panels/pages. You can view and print the report. The *Subject Audit Report* is available under the **Reports** menu in Manage.

In order to obtain this report, you must

1. Generate a data set for the report.
   - Choose subjects for which data should be gathered.
   - Data is saved as of the time the report data is generated. If the report generation is submitted as a batch job, then the data is saved as of the time the job runs.
   - To generate and purge report data, you must have an access level of **Full** for the Access Right of **Other** in the **Manage** module.
2. Use the generated data to create a report.
   - The report may contain a subset of the subjects and pages/panels.
   - To create and print report data, you must have an access level of **Read** for the Access Right of **Other** in the **Manage** module.

How to generate data for the Subject Audit Report

From the **Reports** menu, select **Audit Subjects**. You can then choose between **Generate Data...** or **Create Report...**. The initial step is to generate data. When you choose this option, the **Generate Report Data** screen opens:



Select the **All Subjects** or the **Selected Subjects** for which you want to display the audit report. If **Selected Subjects** is chosen, one or more subjects in the list may be selected. If **All Subjects** is chosen, then you will be warned about the performance impact after hitting the **OK** button.

To work with subjects that are currently enrolled, click **Active**. To work with subjects that have been deleted, click **Deleted**. Both may be selected.

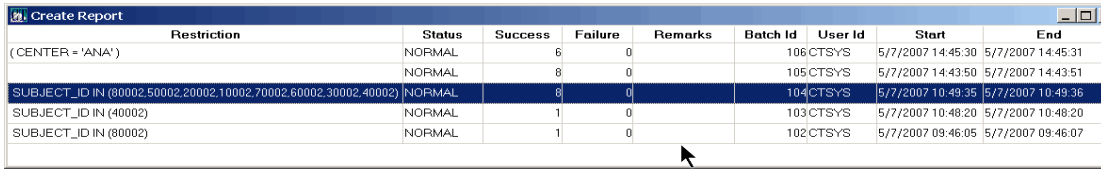
You can create a **SQL Restriction** in the clause builder to further specify the data reported. The subject list does not change, but the restriction is passed to the batch job.

Submit Batch is selected by default. If **Submit Batch** is deselected, you will be warned that the operation may be time consuming. If you wish to continue anyway, the report data will be generated, and you will be taken directly to the **Create Report** window.

If the **Submit Batch** is selected, you may make this a recurring batch job by specifying how often the job should be run. When you hit the **OK** button, you will be informed that the job has been submitted, and to see the menu item **Reports\Audit Subjects\Create Report...** for the job status.

Batch jobs may be managed via the existing **Tools\Batch Job Queue** menu items, just as for other jobs. **Modify**, **Delete** and **Run** options are available as for other batch jobs.

To access the data generated, go to **Reports\Audit Subjects\Create Report...** A browser window appears with summary information for each data set that has been generated.

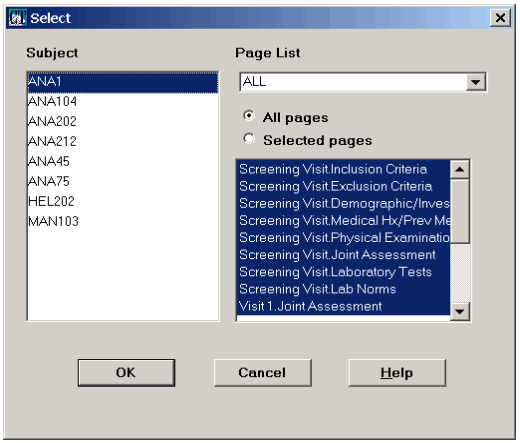


To delete all generated data for a dataset, select a row in the browser and use **Edit\Delete**.

How to create and view the Subject Audit Report

The actual report is created by selecting a row in the browser and using **File\Run**.

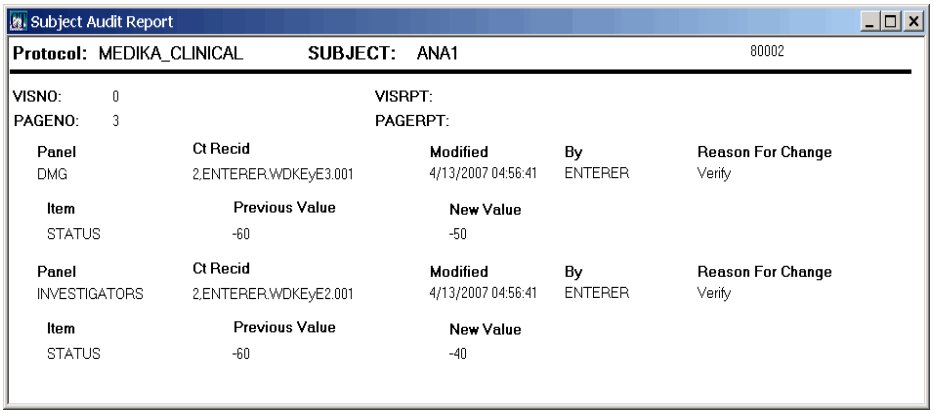
A dialog box appears which allows you to further limit the contents of the report.



The **Subject** list includes only those subjects actually included in the data set.

The **Page List** or **Panel List** varies depending on your preference setting for **SELECT_BY_PAGE**. If **Yes**, a list of pages is shown, allowing either all pages or one or more selected pages. If **No**, a list of panels is shown, allowing either all or one or more selected panels. Protected panels for which you do not have access do not appear. The **Page** or **Panel** lists otherwise includes all available in the protocol, and not just those for which data was actually included in the dataset.

Clicking **OK** causes the actual Subject Audit Report to appear.



Data in Protected Panels, for which you do not have access is excluded from the created report.

You can use the **View** menu's **First Page**, **Prior Page**, **Next Page**, and **Last Page** commands to view different pages of the Subject Audit Report, and the **File** menu to save or print the report. Standard printing options are available.

The following table describes the information in the Subject Audit Report:

Report column:	**Description:**
Panel	Name of the panel.
Ct Recid	Value of the CT_RECID system item.
Modified	Date on which the modification was made.
By	User account that modified or deleted the record.
Reason For Change	The reason the item was modified.
Item	Name of the item for which a value was modified.
Previous Value	Value of the item before the modification.
New Value	Value of the item after the modification.

11 Metadata Reports

Panel reports

There are two panel reports in Manage:

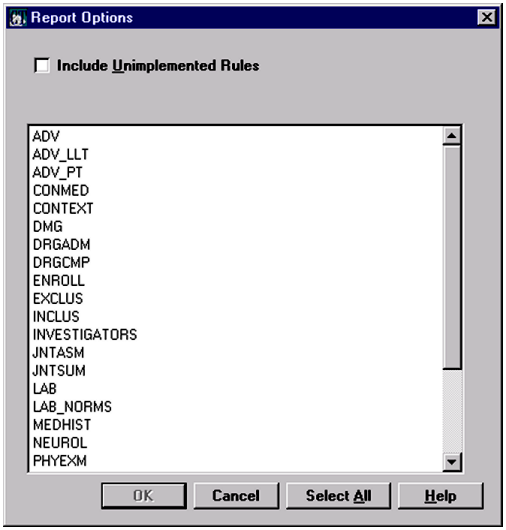
- Rules
- Derivations

The panel reports provide information on rules and derivations in the current protocol. You can print the reports, and then file the reports in archives when a study is complete, or you can use the reports for reference when you perform validation.

Rule Report

The Rule Report contains information on the rules associated with each panel in the current protocol. The Rule Report also optionally contains information on unimplemented rules. *Unimplemented rules* are rules that have been modified within a panel that is marked for revision. The rules are unimplemented if the revisions to the panel have not yet been implemented.

From the **Reports** menu, select **Panels >> Rules**. The Report Options dialog box opens:



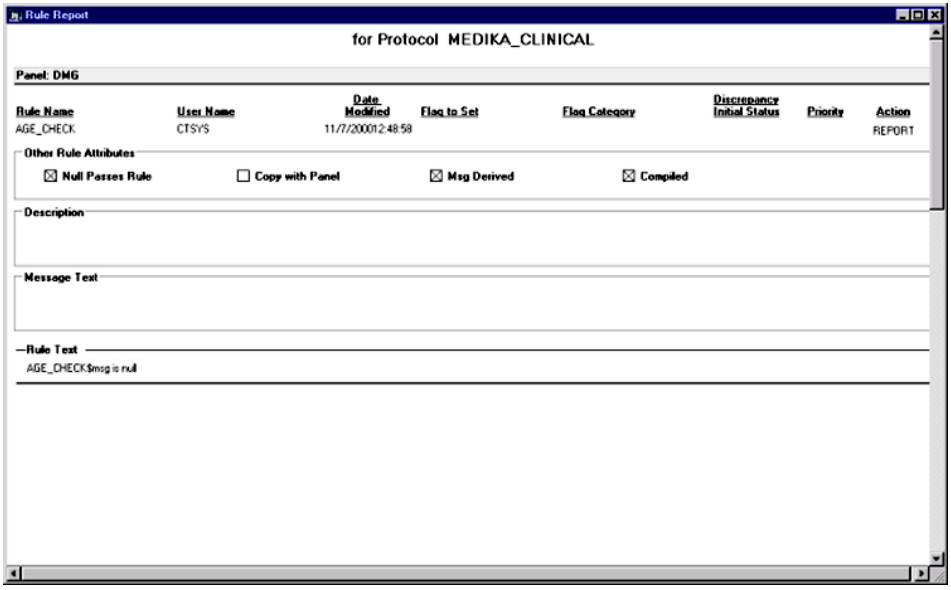
If you check Include Unimplemented Rules, then revisions to rules that have been modified within a panel marked for revision are included, instead of the original version of the rule.

If you clear Include Unimplemented Rules, then only the original versions of the rules are included in the report.

Select the panels for which you want to display rules, and then click **OK**. You can select more than one panel, or you can select all panels by clicking **Select All**.

The information that appears in the Rule Report is based on the rules in the panels that you select. For more information on the rule fields, see the *Design* section in *Admin and Design*.

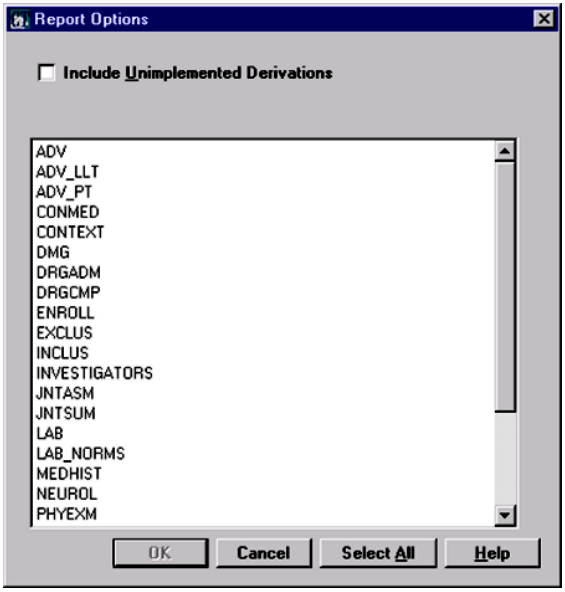
The following example shows a Rule Report:



Derivation Report

The Derivation Report contains information on the derivations associated with each panel in the current protocol. The Derivation Report also optionally contains information on unimplemented derivations. *Unimplemented derivations* are derivations that have been modified within a panel that is marked for revision. The derivations are unimplemented if the revisions to the panel have not yet been implemented.

From the **Reports** menu, select **Panels >> Derivations**. The Report Options dialog box opens:



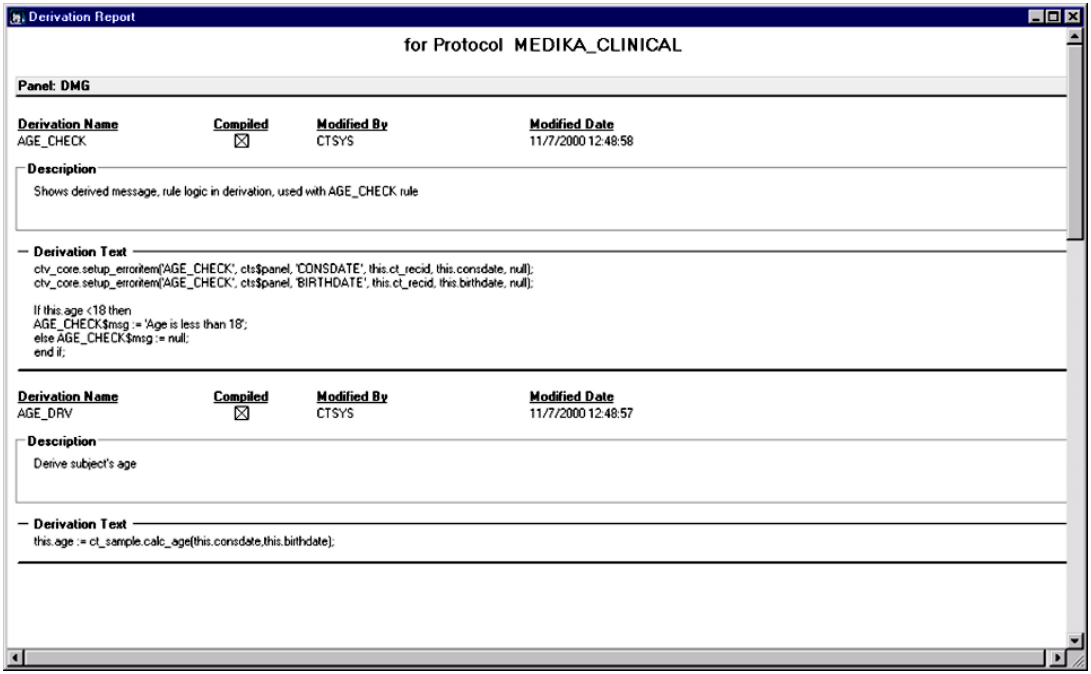
If you check Include Unimplemented Derivations, then revisions to derivations that have been modified within a panel marked for revision are included, instead of the original version of the derivation.

If you clear Include Unimplemented Derivations, then only the original versions of the derivations are included in the report.

Select the panels for which you want to display derivations, and then click **OK**. You can select more than one panel, or you can select all panels by clicking **Select All**.

The information that appears in the Derivation Report is based on the derivations in the panels that you select. For more information on the derivation fields, see the *Design* section in *Admin and Design*.

The following example shows a Derivation Report:



Display Object reports

There are two display object reports in Manage:

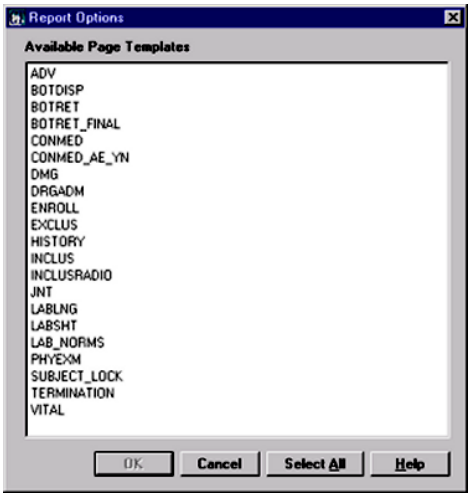
- Page Template Summary
- Study Books

The display object reports provide information on page templates and study books in the current protocol. You can print the reports, and then file the reports in archives when a study is complete, or you can use the reports for reference during Manage activities.

Page Template Summary Report

The Page Template Summary Report contains information on the page sections that appear on each page template.

From the **Reports** menu, select **Display Objects >> Page Template Summary**. The Report Options dialog box opens:



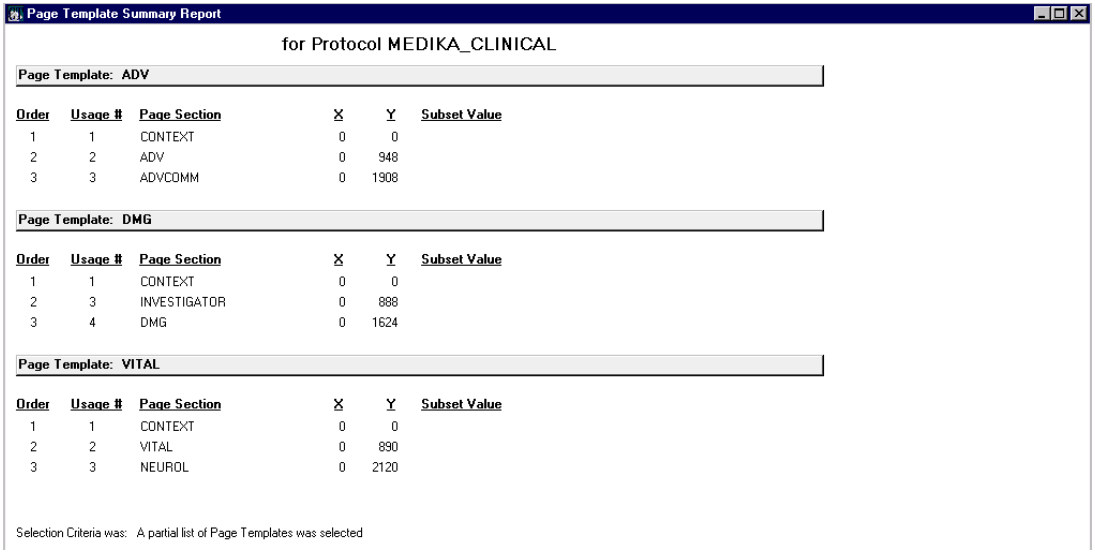
Select the panels for which you want to display page template information, and then click **OK**. You can select more than one panel, or you can select all panels by clicking **Select All**.

The following table describes the information in the Page Template Summary Report:

Report Column:	**Description:**
Order	Order of the page section on the page template, from the top of the page template to the bottom.
Usage #	Number that uniquely identifies each page section in the page template.
Page Section	Name of the page section on the page template.
X	Horizontal (X) coordinate of the page section on the page template.
Y	Vertical (Y) coordinate of the page section on the page template.
Subset Value	If the page section is a subset page section, then the subset key value.

Selection Criteria	If all panels are selected, then value is All Page Templates were selected. If specific panels are selected, then value is A partial list of Page Templates was selected.

The following example shows a Page Template Summary Report:



Page Template Summary Report

for Protocol MEDIKA_CLINICAL

Page Template: ADV

Order	Usage #	Page Section	X	Y	Subset Value
1	1	CONTEXT	0	0	
2	2	ADV	0	948	
3	3	ADVCOMM	0	1908	

Page Template: DMG

Order	Usage #	Page Section	X	Y	Subset Value
1	1	CONTEXT	0	0	
2	3	INVESTIGATOR	0	888	
3	4	DMG	0	1624	

Page Template: VITAL

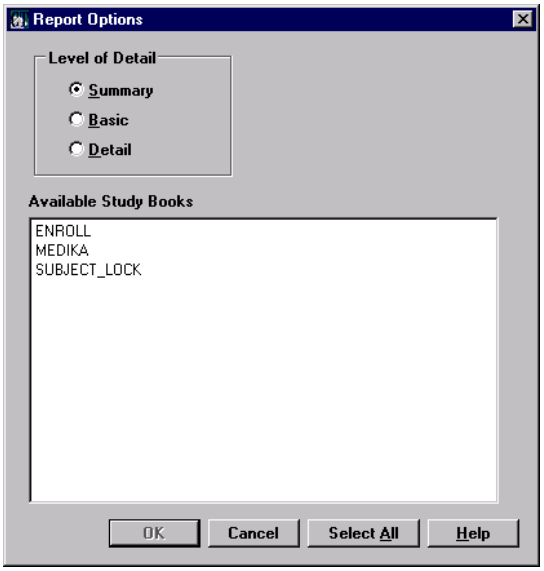
Order	Usage #	Page Section	X	Y	Subset Value
1	1	CONTEXT	0	0	
2	2	VITAL	0	890	
3	3	NEUROL	0	2120	

Selection Criteria was: A partial list of Page Templates was selected

Study Book Report

The Study Book Report contains information on study books within the current protocol, and optionally, contains information on the blocks and study pages within the study book. You can choose to print the report in three levels of varying detail.

From the **Reports** menu, select **Display Objects >> Study Books**. The Report Options dialog box opens:



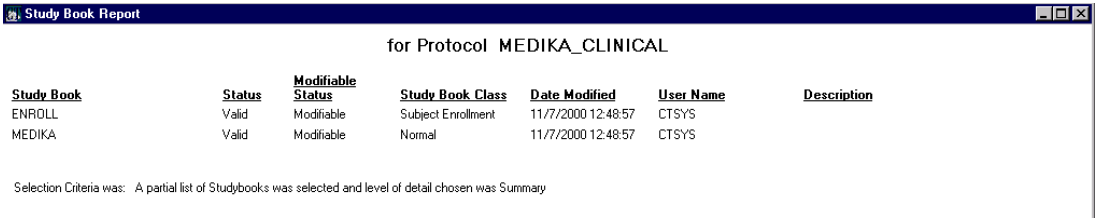
You can select one of three levels of detail in which the report will print:

- Summary — Prints only the study book attributes.
- Basic — Prints study book attributes and block attributes.
- Detail — Prints study book attributes, block attributes, and study page attributes.

Select the study books for which you want to display study book information, and then click **OK**. You can select more than one study book, or you can select all study books by clicking **Select All**.

The information that appears in the Study Book Report is based on the study books that you select. For more information on the fields that appear on the report, see the *Design* section in *Admin and Design*.

The following example shows a Study Book Report, in Summary format:



12 Manage and Multisite

Overview

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

- General information
- 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

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.

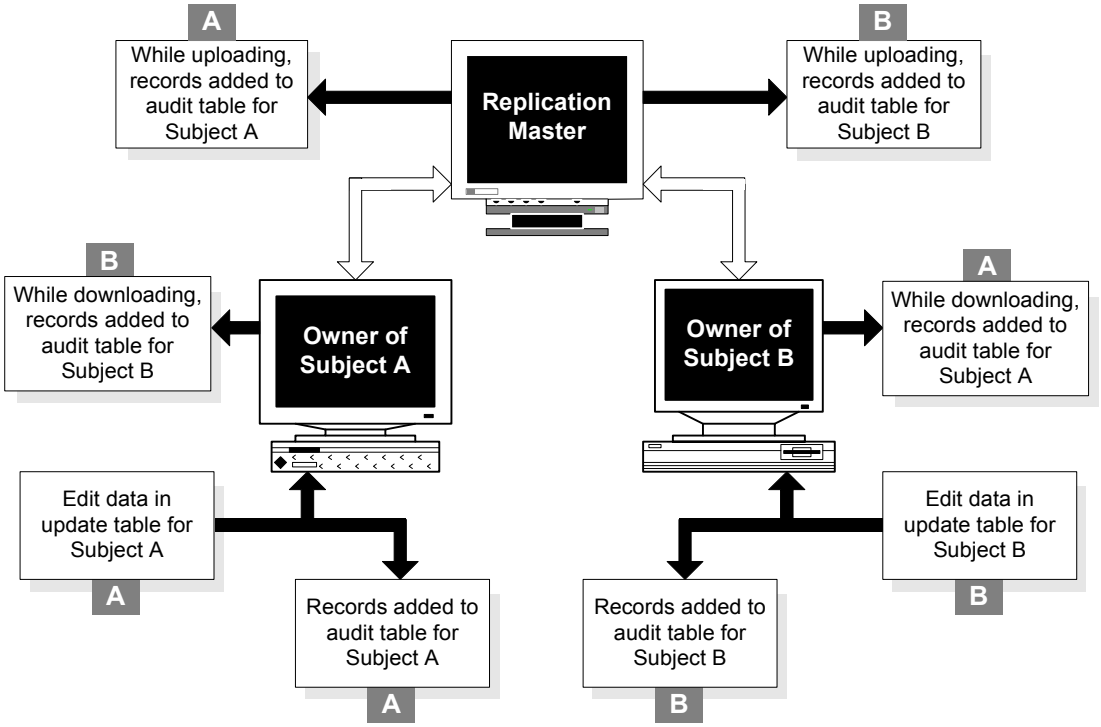
Auditing data in a replication environment

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. Trusted data is stored at the Replication Master site; therefore, 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.)



Auditing in a replication environment

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.
- Use Oracle Central Coding.

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

Coding in a replication environment

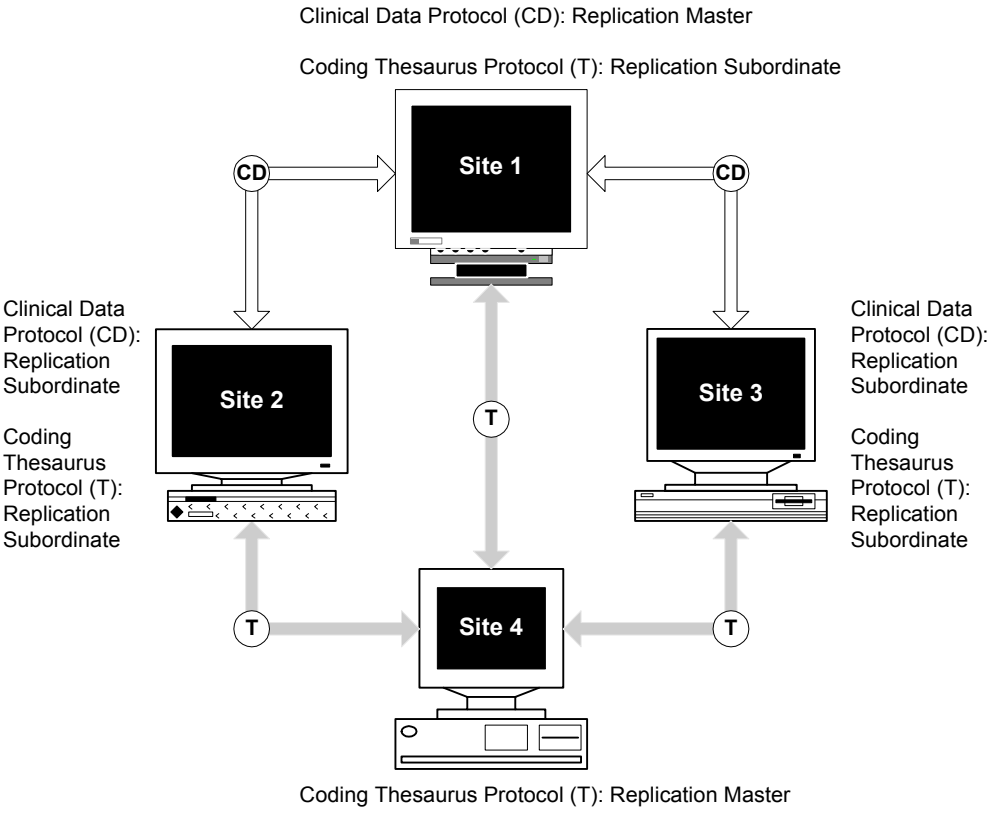
You can only code clinical data for subjects owned by the current site. To ensure that clinical data for subjects owned by different sites is coded consistently, you must create a replication environment for the coding thesaurus protocol that overlaps the replication environment for the clinical data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

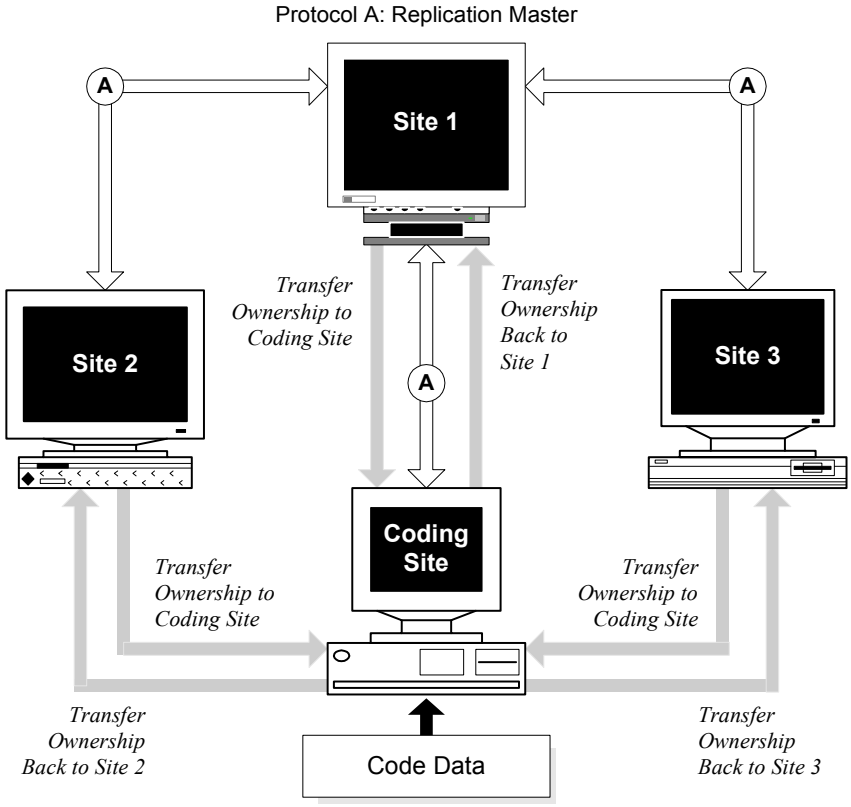
Coding at a central coding center

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. In this example, there is no need for the coding thesaurus protocol to be in replication, because it is used only at the Coding Site.



Replication environment with a central coding center

Classify

13 Introduction to Classify

Overview

This chapter provides an overview of the Classify's features and functions. It introduces terms and concepts used throughout this guide, and suggests how you might incorporate this module into your work.

This chapter also provides information on preparing to use Classify. It includes descriptions of the access right and access level assignments that users need to work in Classify, and recommended system parameter settings.

For step-by-step instructions on any tasks described in this chapter, see the Help.

Classify in the Clintrial software workflow

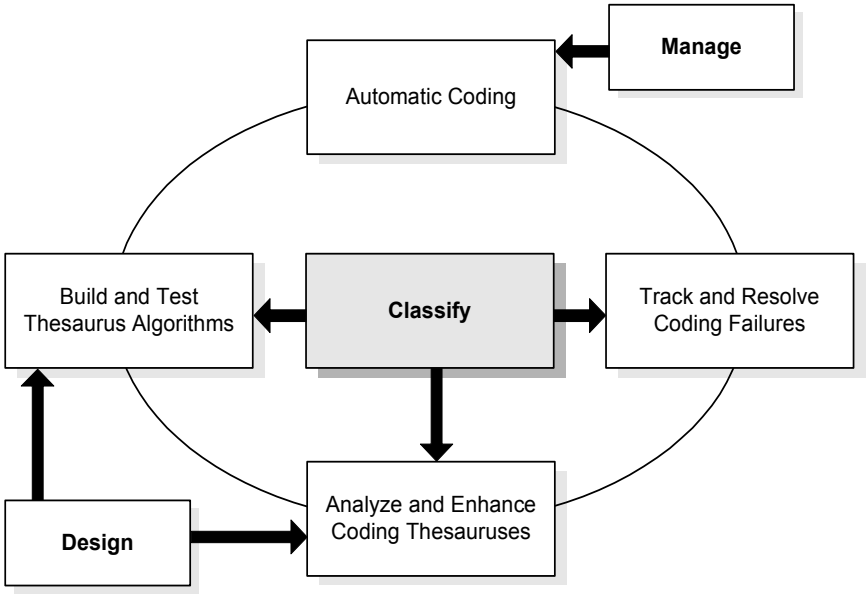
What does Classify do?

The Clintrial software Classify module is a Clintrial software extended module that helps coding experts and dictionary managers:

- Track, review, and find solutions for values that fail automatic coding.
- Examine the contents of a coding thesaurus protocol, and compare different coding thesaurus protocols.
- Build and test effective thesaurus algorithms.

These specialists can use different Classify features before and after automatic coding runs in Manage, and before and after creating or modifying coding thesaurus protocols and thesaurus algorithms in Design.

The following figure shows Classify's role in the Clintrial software workflow for coding:



When Classify is installed with the core Clintrial software modules, coding specialists can improve the accuracy, consistency, and efficiency of automatic coding.

Classify's objects

In Classify, you can work with three different *objects*: omission, thesaurus, and algorithm. Each Classify object corresponds to a branch of automatic coding, as follows:

- Omission — Helps you track, review, and find solutions for records that fail automatic coding.
- Thesaurus — Helps you examine and compare the contents of coding thesaurus protocols.
- Algorithm — Helps you build and test thesaurus algorithms.

Each of these Classify objects is introduced in this chapter.

Classify and coding omissions

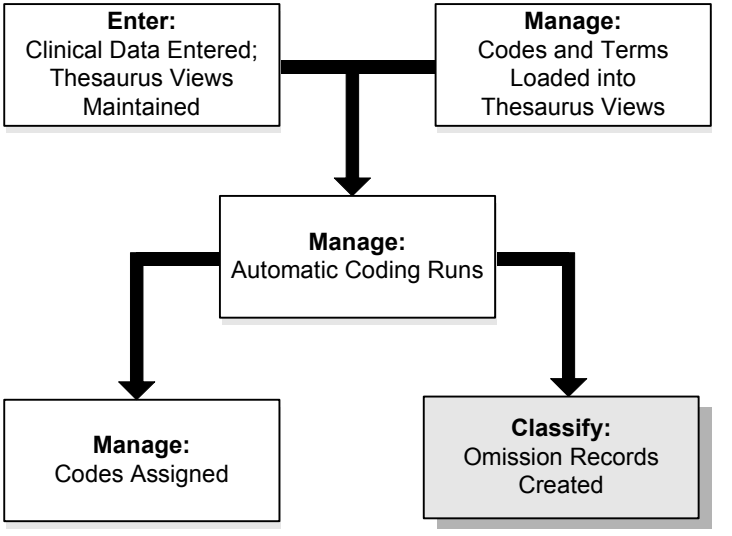
After you create coding thesaurus protocols in Design, you prepare for automatic coding by batch loading codes and terms into the thesaurus's views in Manage. You can enter additional codes and terms for a coding thesaurus protocol in Enter, which is also the module used to enter clinical data, including values in verbatim text item fields.

When automatic coding runs in Manage, the Clintrial software attempts to match the values in verbatim text item fields to the terms and synonyms in thesaurus views. If the value matches a single term or synonym, a corresponding code is assigned to the verbatim text automatically.

However, automatic coding can result in two other situations:

- A value does not match any terms.
- A value matches several different terms.

In these situations, the values fail to code automatically. In Classify, an *omission record* is created for each value that fails automatic coding. The following figure shows this process:



For more information on omissions and omission records, see Chapter 14.

Usage scenario

After automatic coding runs in Manage, omission records are created for future review by a coding expert. As omission records undergo review, a coding expert may propose solutions for them.

For example, suppose that an omission record is created for an adverse event field with a value of PHERENGYTIS. To solve this coding problem, any one of the following solutions could be proposed:

- Change the value of the verbatim text to PHARYNGITIS to correct its spelling.
- Request more information from the data-entry operator or investigational site.
- Add PHERENGYTIS to the appropriate thesaurus view as a synonym for PHARYNGITIS.

After you propose the solution for an omission record, the solution is reviewed and then accepted. Before it is accepted, a solution can be edited or, if necessary, cleared completely and replaced with a different type of solution.

When you accept a solution, you initiate one of the following processes:

- Create a new synonym record in a thesaurus view.
- Change the verbatim text in a clinical data record.
- Request information by flagging an item or creating a discrepancy record for it in Resolve.

You can apply both proposed and accepted solutions to other omission records, as appropriate. The ability to reuse an existing solution minimizes redundancy, and speeds the coding omission management workflow.

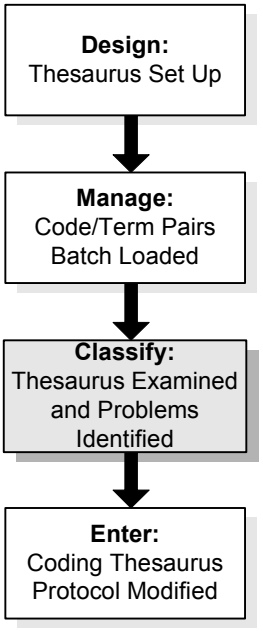
Classify and coding thesaurus protocols

In Design, you set up coding thesaurus protocols and thesaurus views, designate coding targets in clinical data protocols, and perform other tasks required for automatic coding. You then use Manage to batch load codes and their corresponding terms into the thesaurus's views.

Classify enhances automatic coding by helping you examine the codes and terms in a coding thesaurus protocol. It allows you to:

- Search for any code or text in a coding thesaurus protocol.
- Produce a report of terms that are included in a coding thesaurus protocol more than once; that is, the same term is present with different codes or is included in different views.
- Produce a report that compares the terms in two different coding thesaurus protocols, and also displays either terms that are found in both thesauruses or that are found in only one of them.

Before a coding thesaurus protocol is used for automatic coding, Classify allows you to identify terms or codes that may result in coding problems, and then make any necessary modifications in Enter. The following figure shows this process:



Classify and thesaurus algorithms

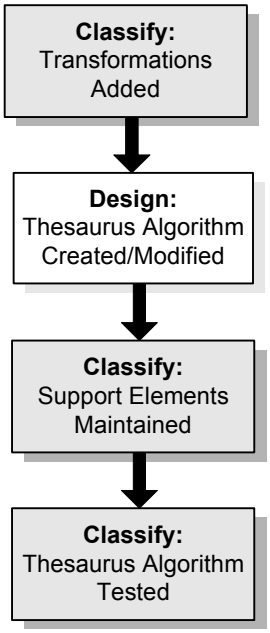
In Design, you create thesaurus algorithms by selecting a series of *transformations*, which make a specific change to a verbatim value, and *lookup steps*, which attempt matches to a term in a thesaurus view. Thesaurus algorithms are used during automatic coding to increase the likelihood of a match between the value entered by a user in Enter and a term that exists in the coding thesaurus protocol.

To enhance the effectiveness of your thesaurus algorithms, Classify provides 16 additional transformations. When you set up a thesaurus algorithm in Design, you can choose any of the Classify transformations, in addition to the standard Clintrial software transformation and lookup steps.

Some of Classify's transformations require a list of support elements. For example, if you use the Replace Words transformation in a thesaurus algorithm, you also need to define the words that you want to replace and their replacements. You maintain these transformation support elements in Classify.

After you create a thesaurus algorithm, you can use Classify to test it.

The following figure shows this process:



Required access rights and access levels for Classify

What are access rights and access levels?

An *access right* is a predefined set of Clintrial software activities that can be associated with a usergroup or a user. An *access level* determines what type of access the user has to the activities defined by an access right. Classify is installed with a complete set of access rights and access levels.

What are the Classify access rights?

Your system administrator can assign Classify access rights to the coding experts and dictionary managers who perform activities supported by this module. The Classify access rights are as follows:

- Propose is a non-protocol access right that gives users access to Classify's omission records, and allows users to propose solutions for them.
- Accept is a non-protocol access right that gives users access to Classify's omission records, and allows users to accept solutions for them.
- Thesaurus is a protocol access right that gives users access to specific coding thesaurus protocols and their thesaurus algorithms in Classify.
- Enter/Merged is a protocol access right that, when applied to a thesaurus protocol, allows users to modify or delete synonyms.

In addition, Design's System non-protocol access right is required to give users access to Classify's thesaurus and algorithm objects.

System administrators make access assignments in Admin.

Types of Classify access rights and access levels

Users who are assigned an access level of Full or Read for a Classify access right can perform specific tasks in Classify. The following table lists the privileges corresponding to each Classify access right and access level:

Access right:	Access level:	User can:
Propose	Full	• Review omission records. • Propose solutions. • Edit proposed solutions. • Clear proposed solutions. • Reuse solutions.
	Read	Review omission records.
Accept	Full	• Review omission records. • Accept proposed solutions. • Purge solved and obsolete omission records.
	NoDel	• Review omission records. • Accept proposed solutions.
	Read	Review omission records.
Thesaurus	Full	• Search for terms or codes in a coding thesaurus protocol. • Run thesaurus reports. • Test thesaurus algorithms. • Edit support elements for transformations. • Use **Configuration** menu commands.
	Read	• Search for terms or codes in a coding thesaurus protocol. • Run thesaurus reports. • Test thesaurus algorithms.
Enter/Merged	Full	• Modify synonyms. • Delete synonyms. • Create thesaurus synonym solutions. • Propose synonym solutions. • Accept synonym solutions.
	NoDel	• Propose synonym solutions. • Accept synonym solutions.
	Read	• Propose synonym solutions.

To prevent access to Classify's functions, your system administrator can assign users an access level of "-" or null for all Classify access rights. This is the default access level for all Classify access rights.

Assigning an additional access right in Design

Before a user can access Classify's thesaurus and algorithm objects, Design's non-protocol System access right must be assigned with an access level of Read or Full. Only users with this access right can review coding thesaurus protocols and thesaurus algorithms in Classify.

To perform any additional processing in Classify for a coding thesaurus protocol or its thesaurus algorithms, Classify's Thesaurus access right must also be assigned with the Full or Read access level. This access right is protocol-specific.

For more information on access rights and access levels, see the *Admin* section of *Admin and Design*.

Parameters for automatic coding

How the Classify parameters work

Three Classify-specific system parameters, which system administrators set in Admin, how you work in Classify, as follows:

- CTG_ALLOW_CHANGEVERB determines whether the **Propose Solution >> Change Verbatim** menu item is enabled. The default is Yes. If you reset it to No, this command will be suppressed, and coding experts will be unable to propose Verbatim solutions.
- CTG_AUTOACCEPT determines whether the system automatically accepts proposals defined by any user whose access level is Full for the Propose access right, and either Full or No Delete for the Accept access right. The default is No. If you reset it to Yes, you will speed the omission resolution process, but forfeit the chance to review proposals before you finalize them.
- CTG_EDIT_SYNTEXT determines whether coding experts can edit normalized text strings before saving them as synonyms. The default is No. If you reset it to Yes, some Synonym solution omission records may fail to code successfully.

The following eight user preferences can be set by the user:

- CTG_PANEL_RESTRICT restricts the omissions displayed in the Omission Browser to those from a specified list of panels. The list of panels is entered into the preferences field and panel names must be separated by commas. The resulting SQL clause restricting the panels appears in the Server Restriction field in the Omission Browser.
- CTG_PROT_RESTRICT restricts the omissions displayed in the Omission Browser to those from a specified list of protocols. The list of protocols is entered into the preferences field and protocol names must be separated by commas. The resulting SQL clause restricting the protocols appears in the Server Restriction field in the Omission Browser.
- CTG_THES_RESTRICT restricts the omissions displayed in the Omission Browser to those from a specified list of thesauruses. The list of thesauruses is entered into the preferences field and thesaurus names must be separated by commas. The resulting SQL clause restricting the thesauruses appears in the Server Restriction field in the Thesaurus Browser.
- CTG_GENERAL_RESTRICT restricts the omissions displayed in the Omission Browser to those that are returned by a SQL restriction clause. The SQL restriction clause is entered into the preferences field and it appears in the Server Restriction field in the Omission Browser. Use of this preference requires knowledge of table and column names and SQL syntax, and should only be used when the CTG_PANEL-_RESTICT, CTG_PROT_RESTICT or CTG_THES-_RESTICT preferences are insufficient.
- CTG_QUICK_PROPOSE determines if the Proposed Solution dialog box is closed automatically after changes are saved. The default is Yes. If set to No, the dialog box remains displayed after performing a Save operation.
- CTG_REPORT_LIMIT restricts the number of results included in a report search. The default is 100. If the number of results exceeds the default value, the system displays a message that some results are not shown.
- CTG_SEARCH_LIMIT restricts the number of results returned in a thesaurus search. The default is 100. If the number of results exceeds the default value, the system displays a message that some results are not shown.
- CTG_SEARCH_WARNING determines if a dialog box is displayed before performing a text search with a wildcard as the leading character, warning that the search may tie up the computer for a significant amount of time. The default is Yes.

How the Manage parameters work

Two other parameters regulate the automatic coding process in Manage. The settings that you choose for these parameters affect Classify's omission management functionality, as follows:

- AUTOCODE_SET_FAIL is a system parameter. If No, automatic coding sets the workflow item value to AUTO for every record that is processed, regardless of the outcome of automatic coding. If Yes, the workflow item value is set to AUTO for records that code successfully and to FAIL for those that do not.
- AUTOCODE_RECODE_ALL is a protocol parameter. If No, automatic coding attempts to assign codes only to records that have never been processed (that is, with a workflow item value of null). If Yes, automatic coding is attempted on all records, including those that previously coded successfully or that failed to code (that is, the workflow item value is AUTO, INT, FAIL, or null), subject to the setting for that protocol's Override Coding attribute.

For more information on these parameters, see the *Admin* section of *Admin and Design*.

How the Override Coding attribute works

Your study designer sets the Override Coding attribute in Design for each clinical data protocol. For protocols with the AUTOCODE-_RECODE_ALL parameter set to Yes, this attribute controls whether records that have been interactively coded (workflow item value is INT) are included when automatic coding runs.

- When the Override Coding check box is checked, interactively coded records are included in automatic coding. This setting can help ensure standardized coding after you make changes to your coding thesaurus protocols and thesaurus algorithms.
- When the Override Coding check box is cleared, interactively coded records are not included in automatic coding. This setting prevents interactively assigned codes from being overridden automatically, and can improve system performance during automatic coding.

For more information on the Override Coding attribute, see the *Admin* section of *Admin and Design*.

Manage parameters and Classify

The settings that you select for the AUTOCODE_SET_FAIL and AUTOCODE_RECODE_ALL parameters affect both the omission records that are created, and the results of applying solutions to omission records in Classify.

When you install Classify, the following settings are recommended for these parameters:

Parameter:	**Recommended setting:**
AUTOCODE_SET_FAIL	Yes
AUTOCODE_RECODE_ALL	Yes

If the AUTOCODE_RECODE_ALL parameter is set to No, automatic coding cannot complete processing for omission records when you accept proposed solutions.

The recommended setting for AUTOCODE_RECODE_ALL is Yes; therefore, records that previously coded successfully are included when automatic coding runs. To eliminate processing redundancy and improve performance, you can include a SQL clause in the SQL Restriction field when you initiate automatic coding. This option is described in the following section.

How a SQL restriction works with Classify

In addition to setting the two Manage parameters as described in the previous section, you can include a SQL clause to select a subset of records when you initiate automatic coding in Manage.

When Classify is installed and the AUTOCODE_RECODE_ALL protocol parameter is set to Yes, a SQL clause that limits records processed by automatic coding to those that have not been processed before (workflow item value of null) and those that failed automatic coding (workflow item value of FAIL) is recommended. For example, include the following clause in the SQL Restriction field:

NVL(*workflow_item,* 'FAIL') = ‘FAIL’

While not required, you can improve the efficiency of automatic coding by including this or a similar SQL clause.

Note: To run automatic coding for all records in a protocol, check the Override Coding check box and do not include a SQL restriction clause. For example, you could process all records in this way after you add new terms or synonyms to a coding thesaurus protocol, or modify a coding thesaurus algorithm.

For more information on using a SQL restriction clause in automatic coding, see Chapter 13.

14 Classify and Omissions

Omissions and omission records

What is an omission?

When automatic coding runs in Manage, coding is attempted for every verbatim text item field in a coding target (subject to the parameter settings described in Chapter 13). An *omission* is a term or phrase that does not successfully match a single term in a coding thesaurus protocol during automatic coding.

What is an omission record?

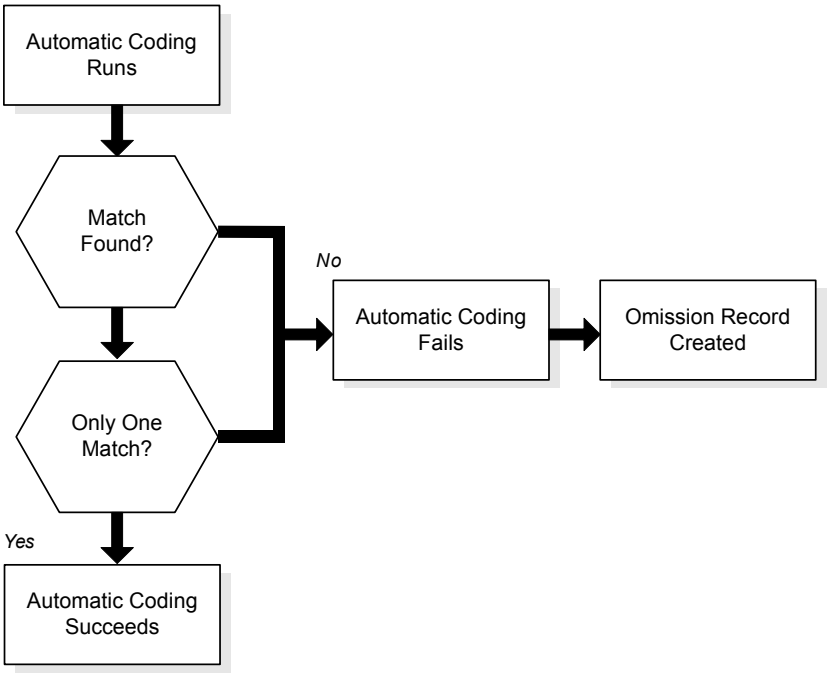
Each instance in which automatic coding fails results in a uniquely identified *omission record*. You use omission records to track, review, and find solutions for values that fail automatic coding.

How are omission records created?

Omission records are created when automatic coding runs in Manage and the following occurs:

- Text in the verbatim text item field of the coding target does not match any terms in the coding thesaurus protocol.
- There are multiple matches for the text in the verbatim text item field.

In either of these situations, Manage cannot assign a code automatically and an omission record is created:



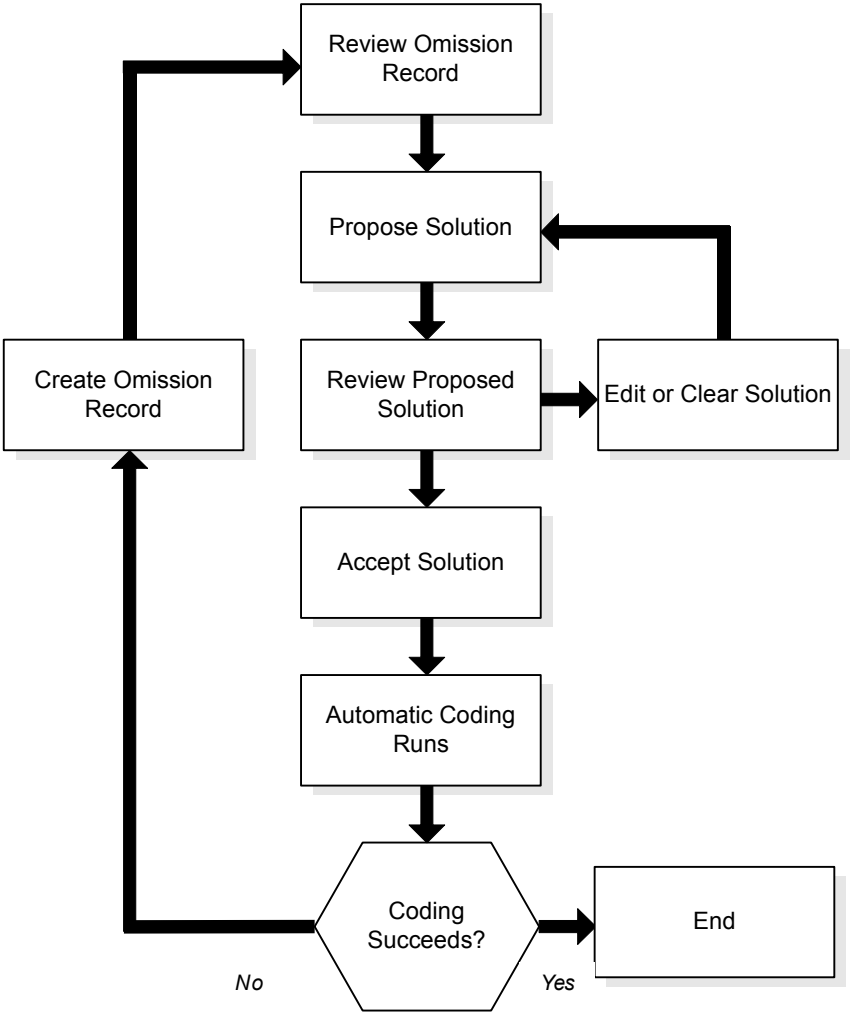
Note: Automatic coding does not create an omission record if the verbatim text item field has a null value. Automatic coding does create an omission record if the verbatim text does not have a null value, but the text normalizes to null.

Managing omission records

How managing omission records works

Once automatic coding creates omission records, you use Classify to track, review, and solve them.

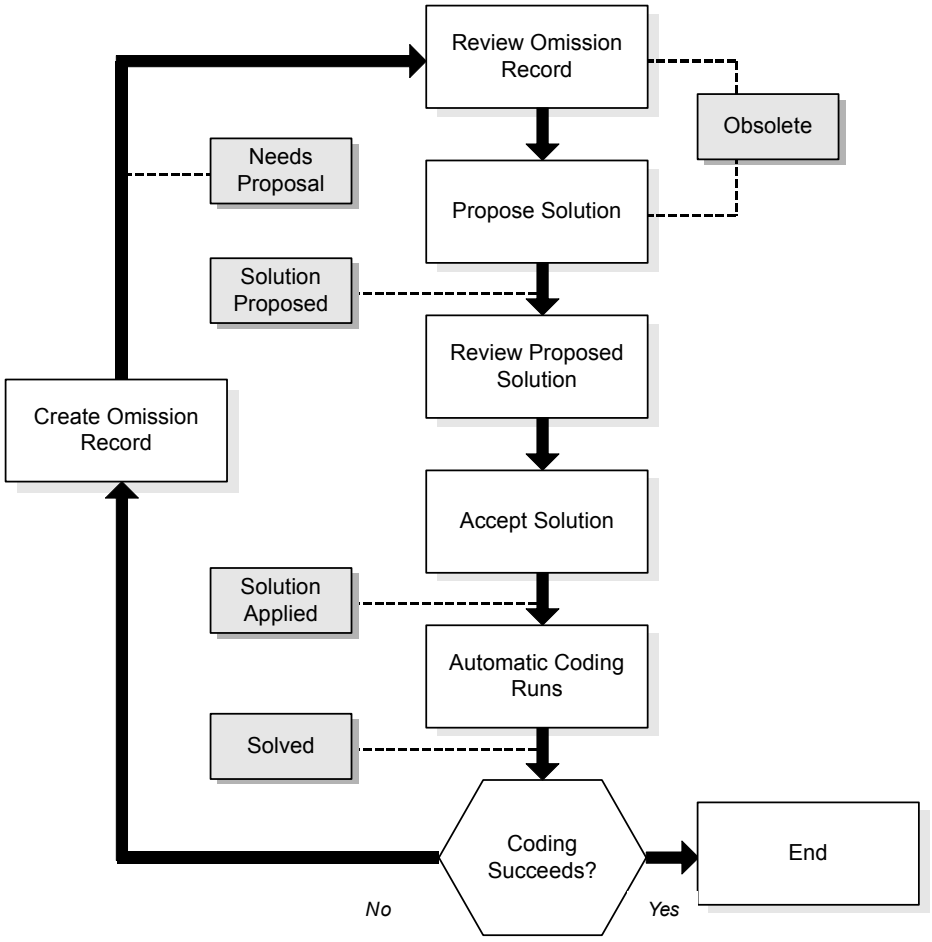
The following figure shows the Classify workflow for omission records:



What are omission statuses?

To help you track the progress of an omission record through this workflow and find a solution efficiently, Classify assigns a series of *omission statuses* to each omission record.

In the following figure, the shaded elements indicate the omission statuses that correspond to different points in your omission record management workflow:



Note: The Solution Pending omission status, which is not shown in this figure, can also be assigned in certain circumstances.

Omission statuses are assigned automatically based on your actions in Classify and the results of coding in Manage.

Classify's omission statuses

The following table describes Classify's omission statuses:

Status:	Description:
Needs Proposal	Indicates an omission record at the beginning of the Classify workflow. Automatic coding generally creates omission records with this status. Also assigned when you clear a proposed solution in Classify.
Solution Proposed	Indicates that your review of an omission record resulted in a possible solution. Assigned when you propose a solution in Classify. For more information on proposing solutions, see Chapter 15.
Solution Pending	Indicates that the proposed solution has been only partially implemented because this is a Multisite environment, and automatic coding has not yet been run at the autocoding site.
Solution Applied	Indicates that the proposed solution for an omission record is valid. Assigned when you accept a proposed solution in Classify. For more information on accepting proposed solutions, see Chapter 16.
Solved	Assigned by automatic coding to omission records with a Solution Applied status. Indicates that automatic coding now succeeds for a verbatim text item that previously resulted in an omission record, or that the omission record is no longer valid. For additional details on how this omission status closes omission records, see Chapter 16.
Obsolete	Assigned to Needs Proposal or Solution Proposed omission records that are no longer valid. For additional details on how this omission status closes omission records, see Chapter 16.
Error	Assigned if processing was interrupted by an unexpected event, such as a system failure, so the change to the verbatim text, creation of a discrepancy record, or application of a flag did not occur. This status is relevant only to Multisite users who are processing records at noncolocated sites. Otherwise, Classify simply displays an error message if an anticipated change cannot be implemented.

For more information

For more information on how to review omission records and their proposed solutions, see the following section.

For more information on proposing and changing solutions, see Chapter 15.

For more information on accepting proposed solutions, see Chapter 16.

For step-by-step instructions on any tasks described in this chapter, see the Help.

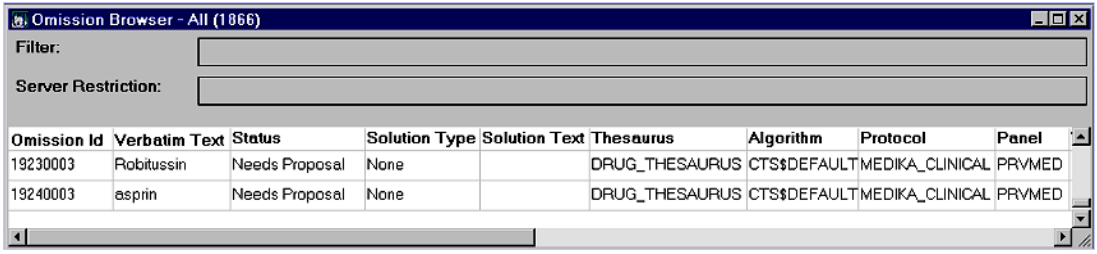
Reviewing omission records

In Classify, you can review omission records in two ways:

- The *Omission Browser* summarizes omission records as rows on a window display.
- The *Details for Omission window* shows data for a single omission record.

How to open the Omission Browser

To open the Omission Browser, from the **Objects** menu, select **Omission**, or click the Omission button on the toolbar. The Omission Browser opens, displaying omission records for the entire database instance:



The following table describes the information provided in the Omission Browser:

Column:	Description:
Omission Id	The unique identifying number for the omission record.

Column:	Description:
Verbatim Text	The literal value stored in the clinical data record's verbatim text item field.
Status	An omission status that helps you track your progress in finding a solution. Contains one of the following automatically assigned statuses: • Needs Proposal • Solution Proposed • Solution Pending • Solution Applied • Solved • Obsolete • Error For more information, see "Classify's omission statuses" on page 212.
Solution Type	For omission records with a Needs Proposal status, None displays. Otherwise, displays one of the following solution types: • Synonym • Verbatim • Request For information on proposing solutions, see Chapter 15.
Solution Text	Blank for omission records with a Needs Proposal status. Otherwise, displays information about the omission record's solution as follows: • If the Solution Type is Request, its Message value displays. • If the Solution Type is Synonym, its Synonym Text value displays. • If the Solution Type is Verbatim, its Verbatim Text value displays. For information on proposing solutions, see Chapter 15.
Thesaurus	The name of the coding thesaurus protocol used to code the verbatim item during automatic coding.
Algorithm	The name of the thesaurus algorithm used to normalize the verbatim item during automatic coding.
Protocol	The name of the clinical data record's protocol.

Column:	Description:
Panel	The name of the clinical data record's panel.
Verbatim Item	The name of the field in the clinical data record that contains the value that did not code automatically.
Creation Date	The date and time the omission record was created.
Modification Date	The date and time of the last change to the omission record; that is, when its solution was proposed, edited, cleared, or accepted.
Modified By	User name of the user who performed the last modification on this omission record.
Subject	The subject context item of the clinical data record whose verbatim text did not code automatically. For records on Type 0 panels, this item is null.
Block	The block context item of the clinical data record whose verbatim text did not code automatically. For records on Type 0 panels, this item is null. ***Note:*** This column displays the values stored in the Details for Omission window's Visit field.
Own	Whether the omission record is owned by the current site. Blank indicates no; the record is accessible only in Read mode.

Note: Omission records for the entire database instance display in the Omission Browser. Classify does not require you to select a specific protocol.

How to select an Omission Browser view

By default, only records that need a proposed solution (those with the Needs Proposal omission status) display when you open the Omission Browser. However, to review omission records more efficiently, you can limit the display to:

- Omission records with a particular status.
- Sets of omission records restricted by panel, protocol or thesaurus, or with a general SQL statement, by using one of the Classify user preferences.

Note: Restricting the number of displayed omission records is useful when the total number of records is so large that an inordinate amount of time is required to retrieve and display them all.

To review different subsets of omission records based on their corresponding omission statuses, you can select one of the following **View** menu commands:

- Needs Proposal
- Solution Proposed
- Solution Pending
- Solution Applied
- Solved
- Obsolete

You can also select the **View** menu's **All** command to display all omission records, regardless of their omission status.

Subsets of omission records can be created with the CTG_PANEL-_RESTICT, CTG_PROT_RESTICT and CTG_THES_RESTICT user preferences. These preferences restrict the source panels, source protocols, or source thesauruses from which the omission records are selected. A general SQL statement can also be supplied using the CTG_GENERAL_RESTRICT preference to limit the number of displayed records. The resulting SQL restriction clause generated by any or all of these preference values appears in the Server Restriction field of the Omission Browser. For more information on the Classify user preferences see Chapter 13.

Note: If a Filter restriction is also used, the intersection of the Filter and the Server Restriction clause applies.

Once you select the initial set of records for the Omission Browser, you can:

- Rearrange the records by modifying the sort specifications.
- Change the order and width of the Omission Browser's columns.

Your column layout, sort criteria, and filter string are automatically saved and reused the next time you open the Omission Browser.

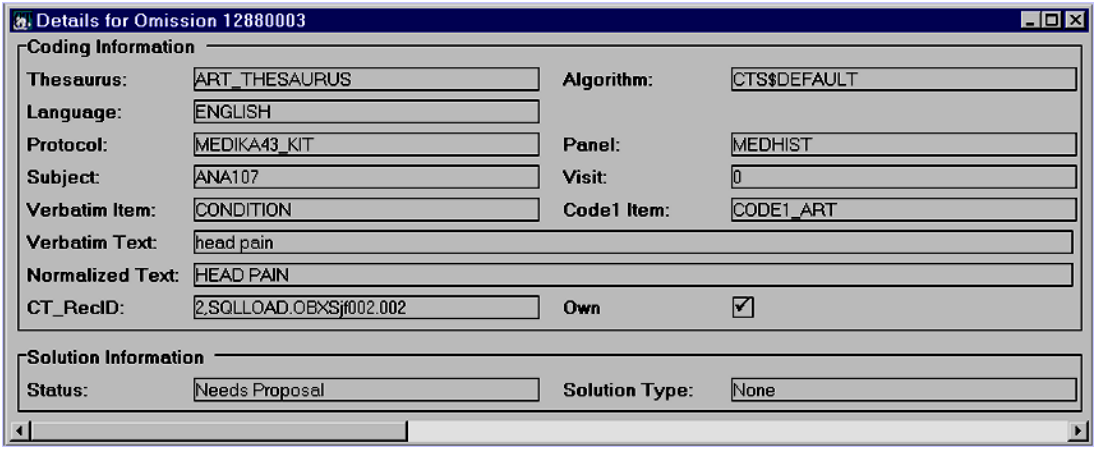
For information about views, filtering, sorting, and the layout revision options, see the Help.

How to open the Details for Omission window

The Details for Omission window provides additional information about one omission record. To open the Details for Omission window for a particular record, use one of these methods:

- In the Omission Browser, select a row. From the **Omission** menu, select **Show Details**.
- In the Omission Browser, select a row, then click the Shows Details icon on the Omission Browser toolbar.
- In the Omission Browser, double-click a row.

The following example shows the Details for Omission window:



This window consists of two sections. The top section displays the omission record's coding information, and the bottom section displays the omission record's solution information. The fields in the coding information section do not vary, however, the fields in the solution information section vary depending on the type and status of the omission.

List of coding information fields

The following table lists the fields in the Coding Information section of the Details for Omission window:

Field:	Description:
Thesaurus	The coding thesaurus protocol used to code the verbatim text.

Field:	Description:
Algorithm	The thesaurus algorithm used to normalize the verbatim text during automatic coding.
Language	The designated thesaurus language.
Protocol	The protocol of the clinical data record that has a verbatim text item value that did not code automatically.
Panel	The panel for the clinical data record that has a verbatim text item value that did not code automatically.
Subject	Subject context item of the clinical data record that has a verbatim text item value that did not code automatically. For records on Type 0 panels, this item is null.
Visit	Visit number of the clinical data record that has a verbatim text item value that did not code automatically. For records on Type 0 panels, this item is null.
Verbatim Item	The clinical data record field, identified as the verbatim text item of a coding target, that has a value that did not code automatically.
Code1 Item	The name of the coding target item that stores the code when assigned.
Verbatim Text	The literal phrase or term that did not match a single term or synonym in the coding thesaurus protocol, and therefore could not be coded during automatic coding.
Normalized Text	The phrase or term that resulted from applying the Code1 item's selected thesaurus algorithm to the verbatim text.
CT_RecID	The unique ID number of the clinical data record that has a verbatim text item value that did not code automatically.

List of solution information fields

The following table lists the fields in the Solution Information section of the Details for Omission window:

Field:	Description:
Status	The following omission statuses help you track your progress in finding a solution for an omission record: • Needs Proposal • Solution Proposed • Solution Applied • Solution Pending • Solved • Obsolete • Error For more information, see "Classify's omission statuses" on page 212.
Solution Type	The solution for an omission record can be: • Synonym • Verbatim • Request • None The solution type None displays when the omission record has a Needs Proposal status.

Depending on the solution type you select for an omission record, additional fields may display in the Solution Information section.

For more information on proposing solutions, see Chapter 15.

How to print omission record information

You can print the data that displays in the Omission Browser or Details for Omission window. To send information displayed in the active window to a printer, from the **File** menu, select **Print**.

- For the Omission Browser, selecting **Print** produces the list of omission records that display in the browser.
- For the Details for Omission window, selecting **Print** produces a detailed report of the information on file for that omission record.

15 Proposing Solutions

Proposing solutions for omission records

Types of solutions

After you review an omission record, you can propose one of the following types of solutions for it:

- Synonym — Create a new synonym
- Verbatim — Change the verbatim text
- Request — Request more information

The sections in this chapter describe the activities you perform in Classify to propose each of these types of solutions for your omission records. For step-by-step instructions on specific tasks, see the Help.

By default, when you propose a solution, only the omission record is updated. Changes to clinical data records (and thesaurus protocols, in the case of Synonym solutions) are delayed until after the proposal is accepted. For more information on accepting proposed solutions, see Chapter 16.

Note: You can use Classify's procedure for proposing and accepting solutions instead of, or in addition to, interactive coding in Manage.

Support for one-step processing

If you reset Classify's CTG_AUTOACCEPT parameter to Yes, then every solution you propose will be simultaneously accepted. This option is available only if you have the Full access level for the Propose access right, and either the Full or No Delete access level for the Accept access right (the same access rights and access levels are required to perform both tasks individually, as explained in Chapter 13).

Note: Because it is difficult to undo changes once they are propagated to the underlying data records, it is generally best to retain the default setting (No).

Creating synonyms

What is a synonym?

A *synonym* is a record in one of a coding thesaurus protocol's synonym views. In the Clintrial software, synonyms consist of a code and a description. In each coding thesaurus protocol, a terms view stores the standard, industry-accepted terms and their corresponding codes, while approved variations of the terms for each code are stored in one or more synonym views.

An entry in a synonym view consists of a code from a terms view and a synonym for that code's term. The following table lists the term and synonyms that correspond to a specific example code:

View:	Description:	Code:
Terms	ERYTHEMATOSQUAMOS DERMATOSIS	690
Synonym	SEBORRHEIC ECZEMA	690
Synonym	DANDRUFF	690
Synonym	SEBORRHEIC DERMATITIS	690

In this example, code 690 has a single official definition, the term ERYTHEMATOSQUAMOS DERMATOSIS. However, three additional, equivalent descriptions of this medical condition are on file as synonyms, corresponding to the same code.

Why create a synonym?

When automatic coding runs in Manage, the likelihood that a matching code will be found for the value in a verbatim text item field improves when synonyms are on file in the coding thesaurus protocol.

Using the previous example, if the coding target contains SEBORRHEIC ECZEMA, DANDRUFF, or one of the other descriptions, when automatic coding runs, it succeeds and code 690 is assigned. If no synonyms are on file for code 690, automatic coding fails for clinical data records with a value of

SEBORRHEIC ECZEMA, DANDRUFF, or SEBORRHEIC DERMATITIS, and succeeds only for records with a value of ERYTHEMATOSQUAMOS DERMATOSIS.

In Classify, an omission record may indicate that a valid variation of a synonymous term has not yet been identified as a synonym and filed in one of the coding thesaurus protocol's synonym views. If you create a new synonym, you solve:

- The current omission record
- All other omission records with the same verbatim text

This solution type also ensures that automatic coding will succeed whenever the same synonymous term is encountered in the future.

Note: When you accept a proposed new synonym in Classify, automated coding runs on affected clinical data records. However, if you add new synonyms in Enter, automatic coding does not run until you initiate it manually. For more information about accepting synonym solutions, see Chapter 16.

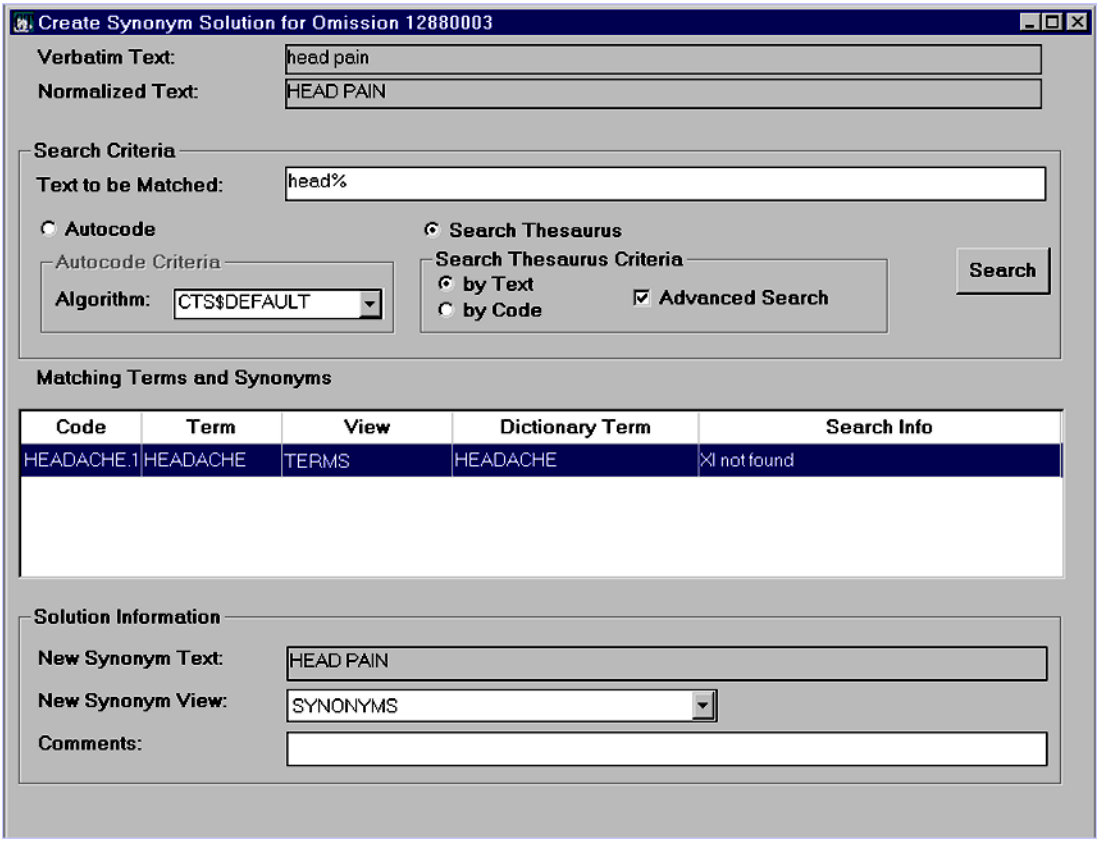
A synonym can also be added to an omission record that already has another solution type associated with it, or to a record that needs a solution proposal, without changing the record's solution status. For more information, see "Adding a synonym" on page 245.

How to create a synonym

To propose a solution with the Synonym solution type:

1. In the Omission Browser, select an omission record with a Needs Proposal status, or open the Details for Omission window for that particular omission record.
2. From the **Omission** menu, select **Propose Solution >> Create Synonym**, or click the corresponding toolbar icon.

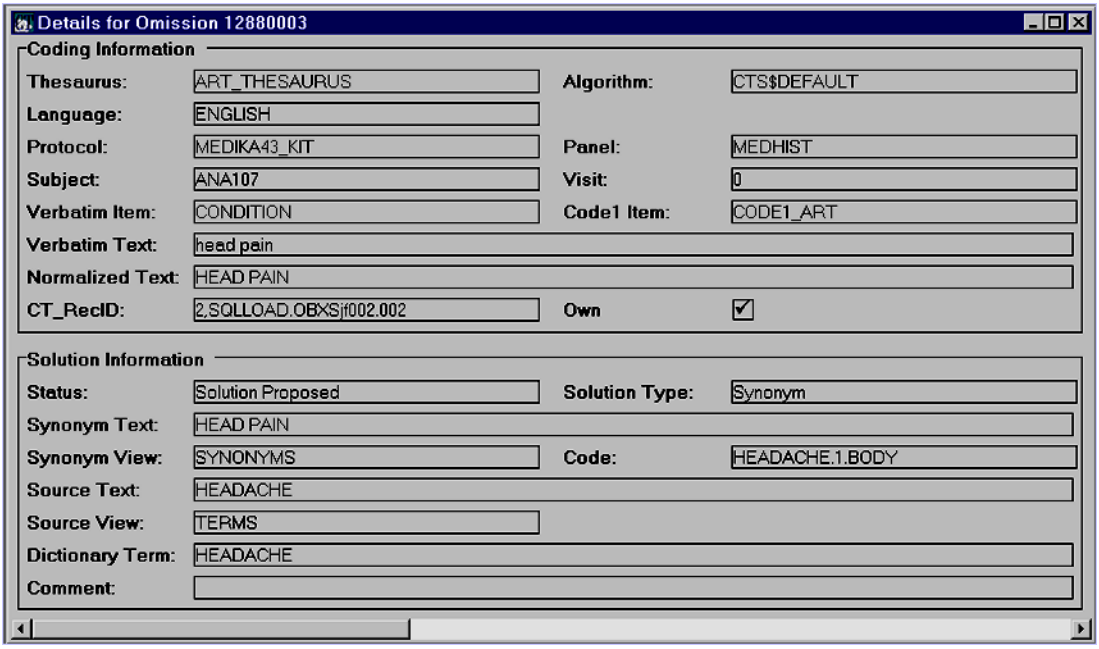
The Create Synonym Solution for Omission dialog box opens:



Note: Autocoding is attempted before this dialog box opens. If matches are found, they display in the Matching Terms and Synonyms list.

For step-by-step instructions on how to use this dialog box to propose a new synonym, see the Help.

After you select **Create Synonym** and propose a new synonym as the solution for an omission record, the Details for Omission window opens:



The following table describes the fields in the Details for Omission window's Solution Information section for omission records with a proposed Synonym solution type:

Field:	Description:
Status	Solution Proposed. For more information on omission statuses, see Chapter 14.
Solution Type	Synonym.
Synonym Text	The description that you propose for the new synonym.
Synonym View	The thesaurus view to which your new synonym will be added. Limited to synonym views.

Field:	Description:
Code	The code of an existing term that you want to associate with your proposed synonym text.
Source Text	The term that is currently on file for the selected code.
Source View	The thesaurus view in which the selected code was found; this view can be a terms or synonym view.
Dictionary Term	The description in the coding thesaurus protocol's terms view that corresponds to the selected code.
Comment	User-defined text describing your reason for creating this new synonym.

Synonym Details

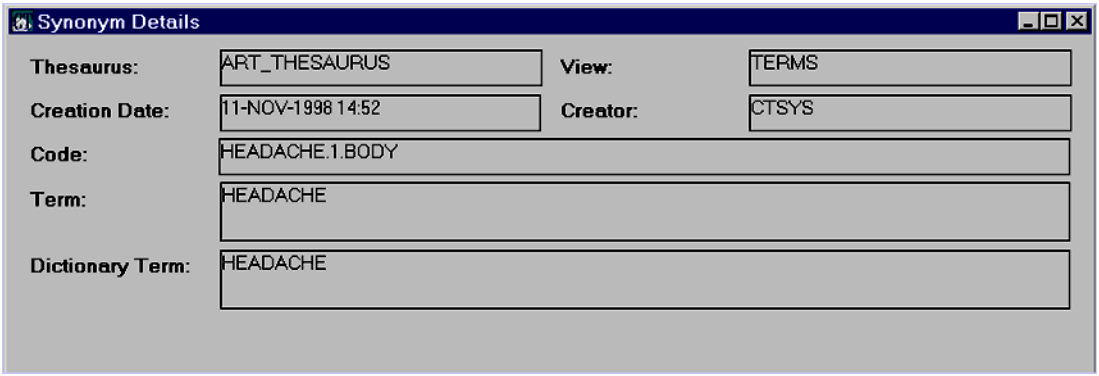
Viewing synonym details

Autocoding or performing a thesaurus search in the Create Synonym Solution for Omission dialog box often produces more than one result in the Matching Terms and Synonyms list. To assist in selecting which of the listed synonyms to propose as a solution, additional details about a highlighted result can be viewed by selecting **Details** from the **Synonym** menu before proposing the result as a synonym solution.

The Synonym Details window includes large fields capable of displaying the full text of the synonym's attributes, including the Synonym Code, Dictionary Term, and Synonym Text.

The content of the window will vary depending on whether the thesaurus is extended. For example, if the MedDRA extended thesaurus protocol is used, the window includes the Preferred Term (PT), High Level Term (HLT), High Level Group Term (HLGT), and System Organ Class (SOC) fields.

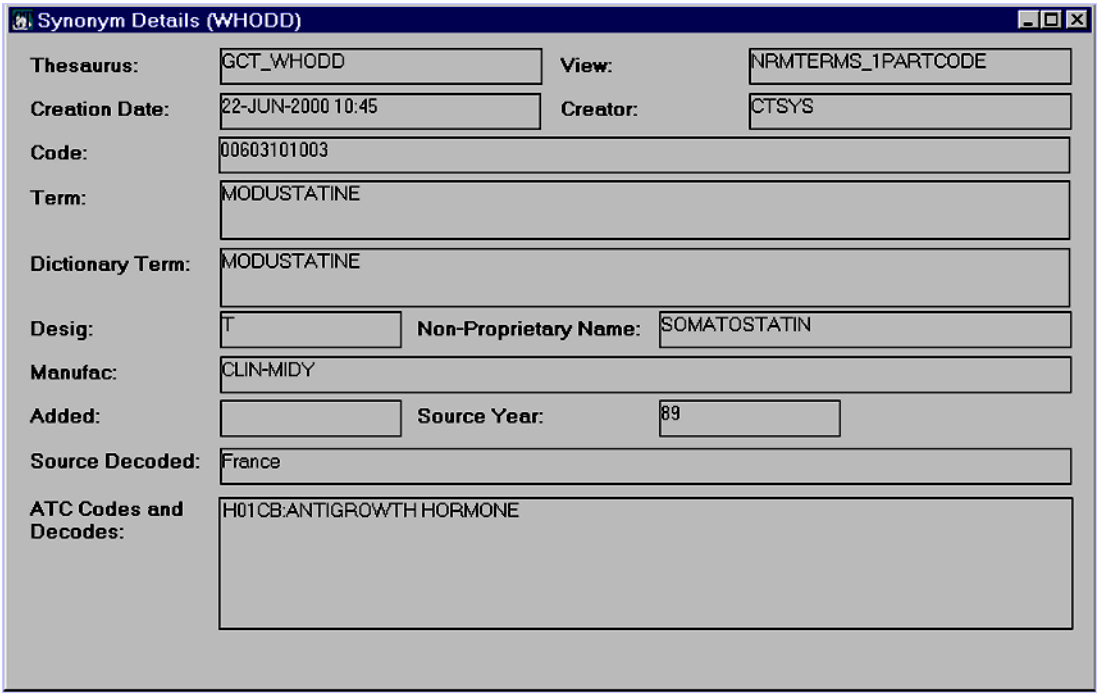
The following shows a Synonym Details window for a synonym from a nonextended thesaurus protocol:



The following table describes the fields in the Synonym Details window for a synonym from a nonextended thesaurus protocol:

Field:	Description:
Thesaurus	The thesaurus protocol containing the selected synonym.
View	The thesaurus view in which the selected synonym was found; this view can be a terms or synonym view.
Creation Date	The date when the creator entered the selected synonym into the coding thesaurus.
Creator	The user who created the selected synonym.
Code	The code of an existing term that is associated with the selected synonym text.
Term	The term that is currently on file for the selected code.
Dictionary Term	The description in the coding thesaurus protocol's terms view that corresponds to the selected code.

If the selected synonym is contained in the WHO drug dictionary extended thesaurus protocol (GCT_WHODD), a Synonym Details window displays the WHO drug dictionary information:



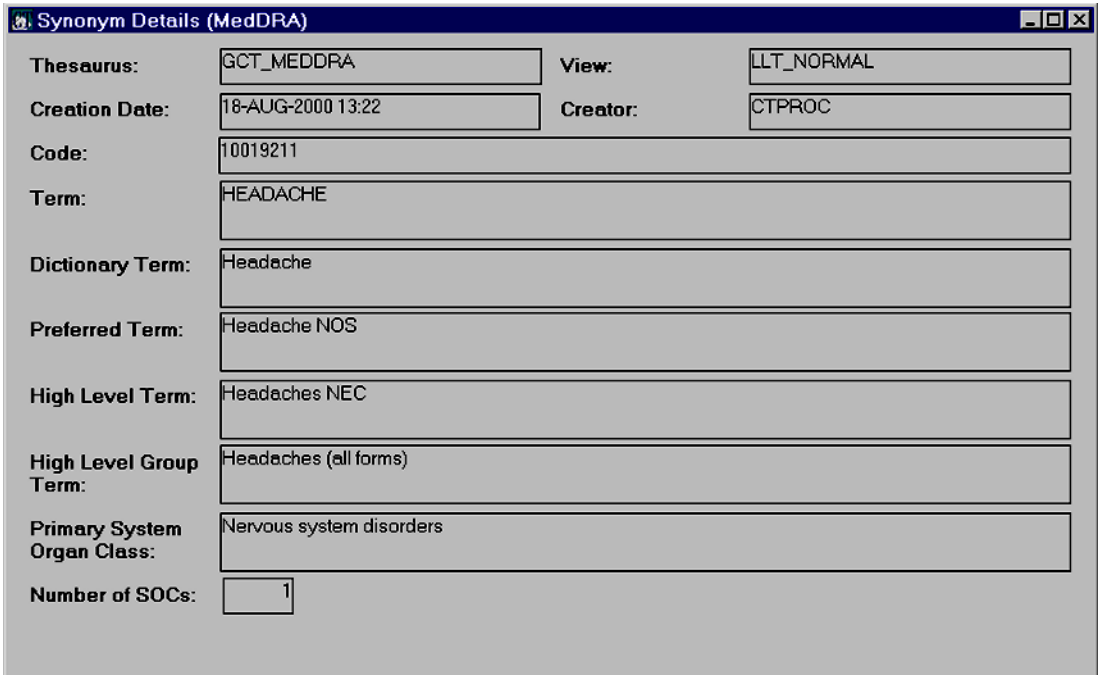
The following table describes the fields in the Synonym Details window for a synonym from the GTC_WHODD extended thesaurus protocol. The following fields are in addition to those fields displayed in the non-extended Synonym Details window:

Field:	Description:
Desig	A code indicating if the synonym is a trade name or a multiple-ingredient drug.
Non-Proprietary Name	The non-proprietary name of the drug.
Manufac	The manufacturer of the drug.

Field:	Description:
Added	The year and quarter that the drug was added to the dictionary.
Source Year	The source year of the drug.
Source Decoded	The decoded source text.
ATC Codes and Decodes	A list of ATC codes and the decoded source text.

MedDRA thesaurus synonym details

If the selected synonym is contained in the MedDRA extended thesaurus protocol (GCT_MEDDRA), a Synonym Details window displays the MedDRA-specific information:



The following table describes the fields in the Synonym Details window for a synonym from the GCT_MEDDRA extended thesaurus protocol. The following fields are in addition to those fields displayed in the non-extended Synonym Details window:

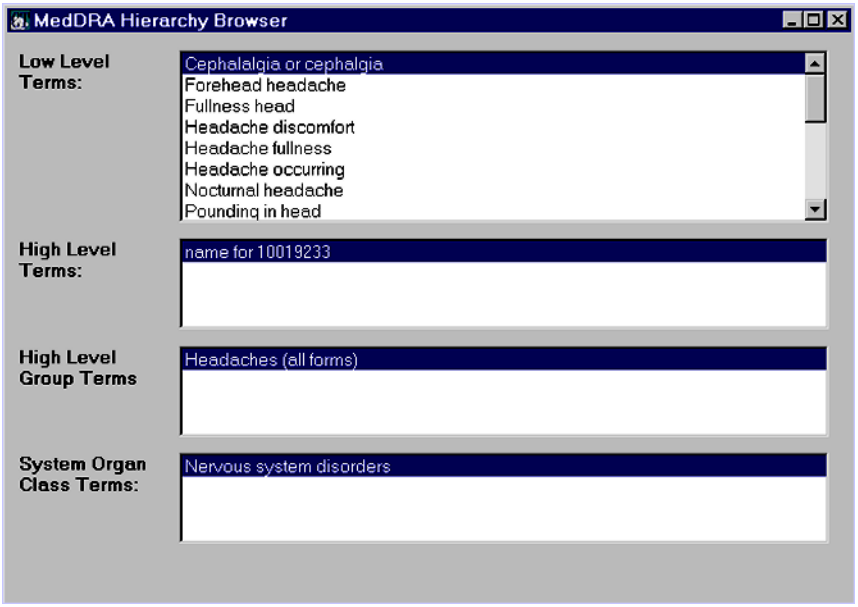
Field:	Description:
Preferred Term	The Preferred Term (PT) for the synonym.
High Level Term	The High Level Term (HLT) for the synonym.
High Level Group Term	The High Level Group Term (HLGT) for the synonym.
Primary System Organ Class	The Primary System Organ Class (SOC) for the synonym.
Number of SOCs	The number of potential SOCs for the PT.

For more information on extended thesaurus protocols, see "What is an extended thesaurus protocol?" on page 258.

MedDRA Hierarchy Browser

If a selected synonym in the Matching Terms and Synonyms box of the Create Synonym Solution for Omission dialog box is from the CTG_MEDDRA extended thesaurus protocol, the MedDRA Hierarchy Browser can be viewed. This browser is only available for synonyms in the CTG_MEDDRA extended thesaurus protocols, and it works only for algorithms based on GCT_MEDDRA views with CODE1 = LLT_CODE.

To open the MedDRA Hierarchy Browser, from the **Synonym** menu, select **MedDRA Browser**:



The following table describes the fields in the MedDRA Hierarchy Browser:

Field:	Description:
Low Level Terms	A list of Low Level Terms (LLT) for the Preferred Term (PT).
High Level Terms	A list of High Level Terms (HLT) related to the selected LLT. Selecting different LLTs produces different lists of associated HLTs.
High Level Group Terms	A list of High Level Group Terms (HLGT) related to the selected HLT. Selecting different HLTs produces different lists of associated HLGTs.
System Organ Class Terms	A list of System Organ Class (SOC) Terms related to the selected HLGT. This field usually contains only one SOC term.

For more information on extended thesaurus protocols and the GCT_MEDDRA and GCT_WHODD extended thesaurus protocols, see "What is an extended thesaurus protocol?" on page 258.

Changing verbatim text

What is verbatim text?

Verbatim text is the value entered by the user in a clinical data record's verbatim text item field. This value is recorded in every omission record.

Why change verbatim text?

When you review an omission record, you may find a straightforward explanation for why it did not code automatically: a misspelling, abbreviation, or typographical error may be evident when you examine the omission record. For example, if a record fails automatic coding and the resulting omission record has the verbatim text GLUACOMA, you may decide to change it to GLAUCOMA.

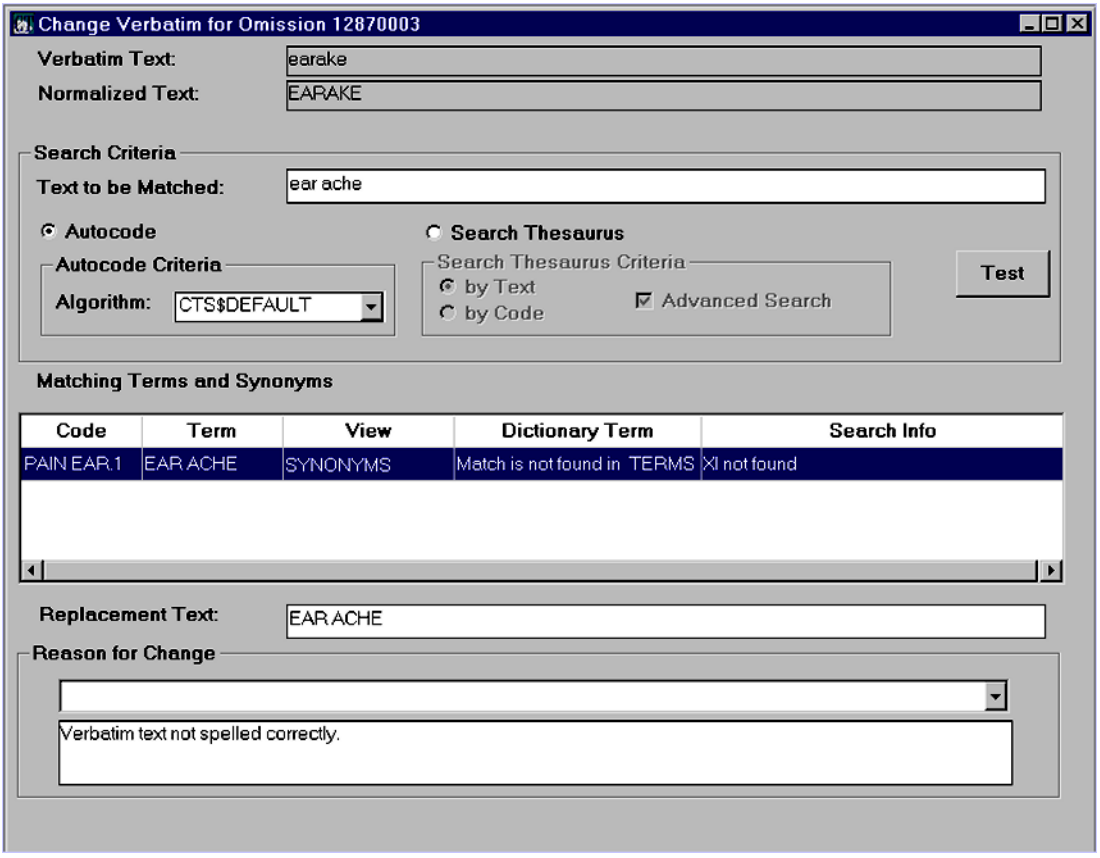
Note: When you propose a change to verbatim text in Classify, you can reuse the same solution for other omission records. However, if you edit the clinical data record in Enter, this feature is not available. For more information about reusing verbatim solutions, see "Reusing and propagating solutions" on page 239.

How to change verbatim text

To propose a solution with the Verbatim solution type:

1. In the Omission Browser, select an omission record with a Needs Proposal status, or open the Details for Omission window for that particular omission record.
2. From the **Omission** menu, select **Propose Solution >> Change Verbatim**, or click the corresponding toolbar icon.

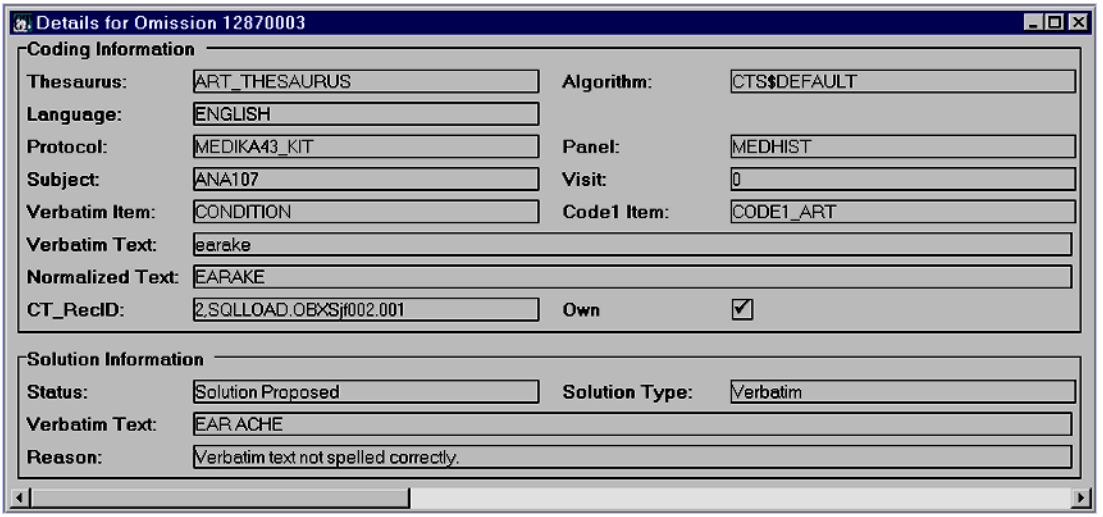
The Change Verbatim for Omission dialog box opens:



Note: Autocoding is attempted before this dialog box opens. If matches are found, they display in the Matching Terms and Synonyms box.

For step-by-step instructions on how to use this dialog box to propose a change to the verbatim text, see the Help.

After you select **Change Verbatim** and propose a different verbatim text value as the solution for an omission record, the Details for Omission window opens:



The following table describes the fields in the Details for Omission window's Solution Information section for omission records with a proposed Verbatim solution type:

Field:	Description:
Status	Solution Proposed. For more information on omission statuses, see Chapter 14.
Solution Type	Verbatim.
Verbatim Text	The new value that will replace the current verbatim text, as shown in the Coding Information section of this window, when this proposed solution is accepted. This value may or may not correspond to an existing term or synonym.
Reason	The reason for changing the verbatim text, such as a misspelling.

Requesting more information

What is a request?

A *request* is a method of seeking clarification or additional detail about verbatim text that cannot be coded automatically, and that results in an omission record.

Why request more information?

When you review an omission record in Classify, you may discover that its verbatim text is too vague or complex to be coded. To solve the coding omission, help is needed from an expert coder or from the investigative site that originated the data.

For example, if a record fails automatic coding and the resulting omission record has the verbatim text ULCER, you may decide that more information, such as a specific body site, is required.

In the Clintrial software, requests can be recorded by creating either:

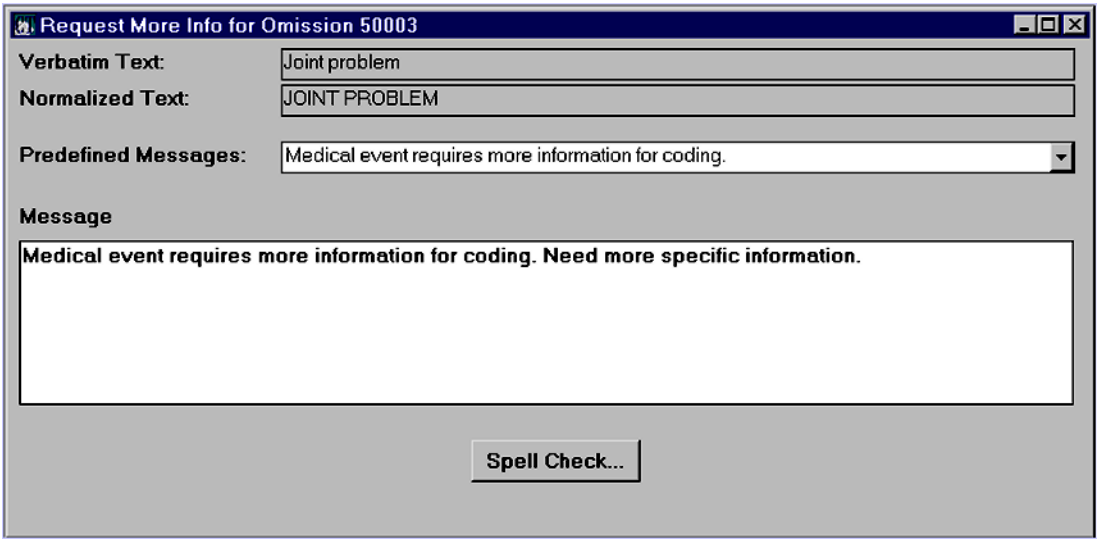
- A discrepancy record in Resolve (if that extended module is installed)
- An item flag on the verbatim text item in the clinical data record

How to request more information

To propose a solution with the Request solution type:

1. In the Omission Browser, select an omission record, or open the Details for Omission window for that particular omission record.
2. From the **Omission** menu, select **Propose Solution >> Request More Info**, or click the corresponding toolbar icon.

The Request More Info for Omission dialog box opens:

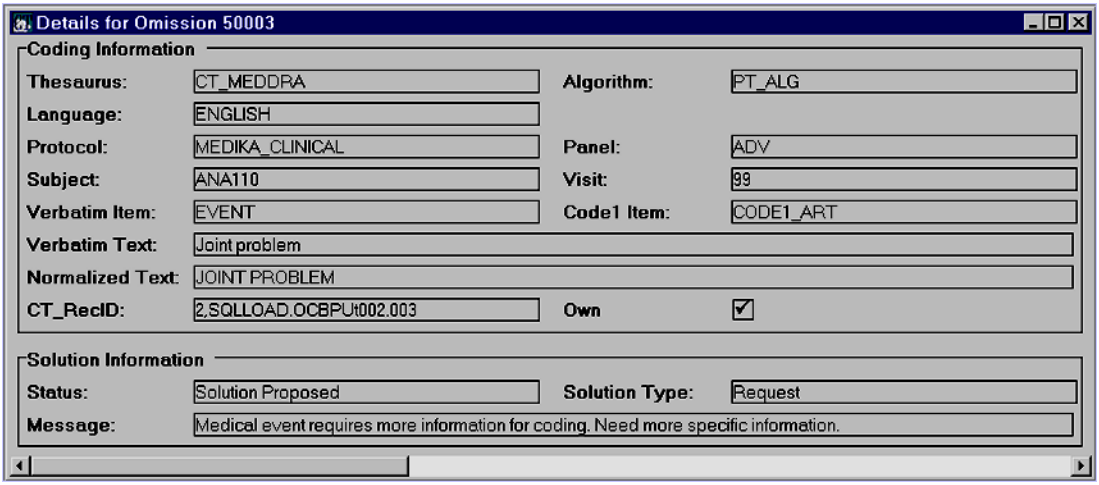


In this dialog box, you can enter your own message describing the problem and the clarification needed, or select a predefined message from the drop-down list, and add additional text if needed. The list messages are contained in the CTS_CTG_DSC_TXT codelist that is installed with Classify. The codelist contains three predefined messages. Your system administrator maintains this list, and can add additional messages in Design.

Note: Alternatively, you can use Enter to add a flag to the verbatim text item, or you can use Resolve to create a discrepancy record manually. In both cases, you will not be able to reuse this solution in Classify to solve other coding omissions.

For step-by-step instructions on how to use this dialog box to propose a request for more information, see the Help.

After you select **Request More Info** and propose a request for more information, the Details for Omission window opens:



The following table describes the fields in the Details for Omission window's Solution Information section for omission records with a proposed Request solution type:

Field:	Description:
Status	Solution Proposed. For more information on omission statuses, see Chapter 14.
Solution Type	Request.
Message	Comments on this omission record and its verbatim text.

Reusing and propagating solutions

Once you propose a solution for an omission record in Classify, you can use it for other omission records as needed.

If an omission record has a Synonym solution type, Classify identifies all other omission records with the same values in the Verbatim Text, Thesaurus, Algorithm, and Language fields and automatically proposes the same solution for those omission records.

If the proposed solution is a Verbatim or Request type, you can either reuse or propagate that solution, as follows:

- To reuse a solution, you select a single omission record with a Needs Proposal status, then specify the Verbatim or Request solution of any other omission record to propose for that record.
- To propagate a solution, you select an omission record that has a Verbatim or Request solution, and Classify proposes that solution for every other omission record that has the same values in the Verbatim Text, Thesaurus, Algorithm, and Language fields automatically.

How reusing Synonym solutions works

Whenever you propose a Synonym solution type for an omission record, Classify automatically searches for other omission records with a Needs Proposal status that have the same values in the Verbatim Text, Thesaurus, and Language fields. If matching records are found:

- The same solution is proposed for each of those omission records.
- The omission status is changed to Solution Proposed.
- The solution information is updated.

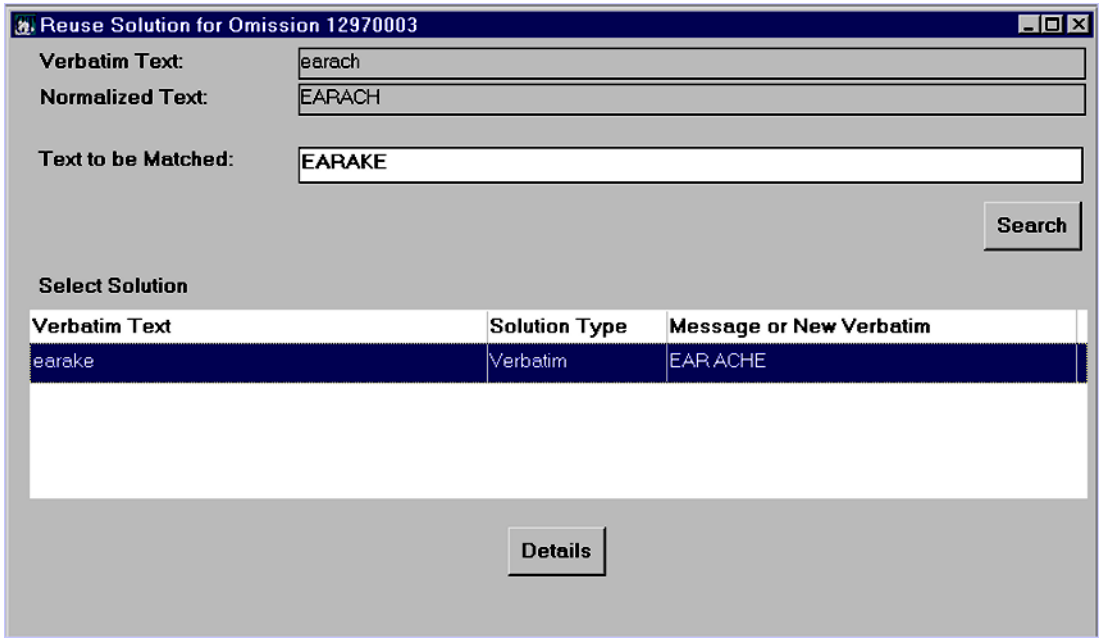
Until you accept the proposed synonym solution, any newly created omission records with the same verbatim text are created with a status of Solution Proposed (rather than Needs Proposal) and the same proposed solution.

How to reuse Verbatim or Request solutions

To reuse a Verbatim or Request solution type for another omission record:

1. In the Omission Browser, select an omission record with a Needs Proposal status, or open the Details for Omission window for that particular omission record.
2. From the **Omission** menu, select **Propose Solution >> Reuse Solution**.

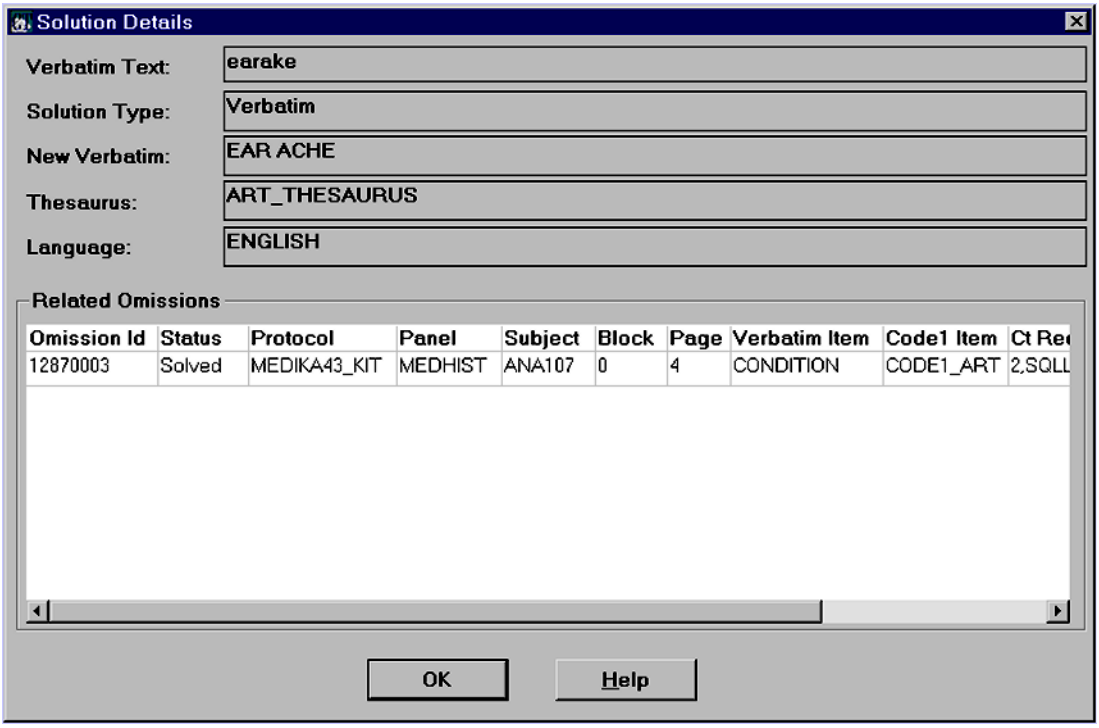
The Reuse Solution for Omission dialog box opens:



In this dialog box, you select the existing solution of another omission record to propose for your selected omission record. All Verbatim and Request solutions for omission records that have the same values in the Verbatim Text, Thesaurus, and Language fields as your selected omission record display in this dialog box automatically. To search for additional solutions, enter a term or phrase in the Text to be Matched field, then click **Search**.

Note: Classify does not use the value in the Algorithm field to determine potential matches for reusable solutions.

To review information about other omission records that were previously assigned a particular solution, in the Reuse Solution for Omission dialog box, select that solution, and then click **Details**. The Solution Details dialog box opens:



In this dialog box, you can review the other omission records that were assigned the same reusable solution. To return to the Reuse Solution for Omission dialog box, click **OK**. Then select a solution for your omission record. When you click **OK**:

- The solution is proposed for the omission record.
- The omission status of the omission record changes to Solution Proposed.
- The solution information for the omission record is updated.

For step-by-step instructions on using these dialog boxes, see the Help.

How to propagate Verbatim or Request solutions

To propagate a Verbatim or Request solution type to all other omission records that have the same values in the Verbatim Text, Algorithm, Thesaurus, and Language fields:

1. In the Omission Browser, select an omission record with a Verbatim or Request solution type, or open the Details for Omission window for that particular omission record.
2. From the **Omission** menu, select **Propagate Solution.** Classify searches for those omission records that have a Needs Proposal status and identical values for verbatim text, algorithm, thesaurus, and language. For each omission record found, Classify automatically:
   - Proposes the same solution
   - Changes the omission status to Solution Proposed
   - Updates the solution information
3. A confirmation message displays. This message includes the number of omission records that now have the same proposed solution as the omission record you selected in Step 1.

Changing proposed solutions

After you propose solutions for omission records, you can edit or clear the solution of any omission records that have a Solution Proposed omission status, as follows:

- Editing lets you alter the proposed solution.
- Clearing deletes the proposed solution from the omission record and its omission status reverts to Needs Proposal.

Note: If you propose a solution of one type, then determine that another solution type is more appropriate, you must clear the current solution before proposing the new one. For information on clearing solutions, see "How to clear a solution" on page 244.

How to edit a solution

To edit a proposed solution:

1. In the Omission Browser, select an omission record with the Solution Proposed omission status, or open the Details for Omission window for that omission record.
2. From the **Omission** menu, select **Edit Solution**.

A dialog box opens that is similar to the Propose Solution dialog box specific to the solution type for the omission record. In other words, if the selected record has a Request solution type proposed, editing this proposed solution will display a dialog box similar to the Request More Info for Omissions dialog box.

In the dialog box you can change the message for a Verbatim or Request solution, or change any of the attributes for a Synonym solution.

How to clear a solution

To clear, or delete, a proposed solution:

1. In the Omission Browser, select one or more omission records with the Solution Proposed omission status, or open the Details for Omission window for a single omission record.
2. From the **Omission** menu, select **Clear Solution**.

A confirmation message displays. To clear the proposed solution, click **OK.** To exit without clearing the proposed solution, click **Cancel**.

Note: The omission record must be reselected before a new solution can be proposed.

Results of changing a proposed solution

When you edit or clear a solution, keep in mind that:

- For Synonym solution types, the changes you make to a solution for one omission record affect every other omission record that uses it.
- For Verbatim or Request solution types, other omission records with the same solution are unaffected by the change. You must modify each omission record as needed.

Adding a synonym

What is adding a synonym?

You can add a synonym to an omission record with a Needs Proposal status, or to a record that already has a Verbatim or Request solution type. The new synonym is created in addition to any existing solution type the record may have. When you add a synonym, the omission
status of the record is not changed.

Note: A record that already has a Synonym solution type cannot have a synonym added.

Adding a synonym differs from a Create Synonym solution in that added synonyms are accepted immediately, without the need to Propose and Accept the synonym.

Why add a synonym?

Adding a synonym can be useful if:

- A change to the verbatim text is required, resulting in a Verbatim solution, but a synonym for the changed verbatim text is needed for successful coding.
- A Request solution type results in a response indicating that a new synonym is required.

How to add a synonym

To add a synonym:

1. In the Omission Browser, select an omission record, or open the Details for Omission window for that particular omission record.
2. From the **Omission** menu, select **Thesaurus Solution**.

The Thesaurus Solution for Omission dialog box opens. A synonym can be selected from the Matching Terms and Synonyms box. For information on creating a synonym, see "How to create a synonym" on page 225.

Note: Coding does not automatically follow the addition of a synonym, and the record's omission status is not changed.

16 Accepting Proposed Solutions

Proposed solution processing

How to accept a proposed solution

To accept a proposed solution:

1. In the Omission Browser, select one or more omission records with a status of Solution Proposed, or open the Details for Omission window for a particular omission record.
2. From the **Omission** menu, select **Accept Solution**.

Note: To accept proposed solutions, you must be assigned Classify's Accept access right. For more information, see "Accepting proposed solutions and access rights" on page 254.

This process changes the omission status of the selected omission record to Solution Applied or Solved. Additional processing, specific to each solution type, then occurs, as described in the following sections.

Note: If the status of your omission records is updated to Solution Pending, the AUTOCODE_RECODE_ALL parameter may be set to No for the protocol. For more information on setting this parameter, see Chapter 13.

For step-by-step instructions on tasks described in this chapter, see the Help.

Accepted solution processing

This section describes the processing that occurs when you accept a solution of one of the following solution types:

- Synonym — Assigned when you select the **Omission** menu's **Create Synonym** command.
- Verbatim — Assigned when you either select the **Omission** menu's **Change Verbatim** command, or reuse a Verbatim solution.
- Request — Assigned when you either select the **Omission** menu's **Request More Info** command, or reuse a Request solution.

How accepting a Synonym solution type works

When you accept a Synonym solution type, you specify the thesaurus view to which the new synonym will be added. Classify checks the coding thesaurus protocol to ensure that it is not locked. If it is locked, an error message displays and no processing occurs. If it is not locked, the following processing is initiated:

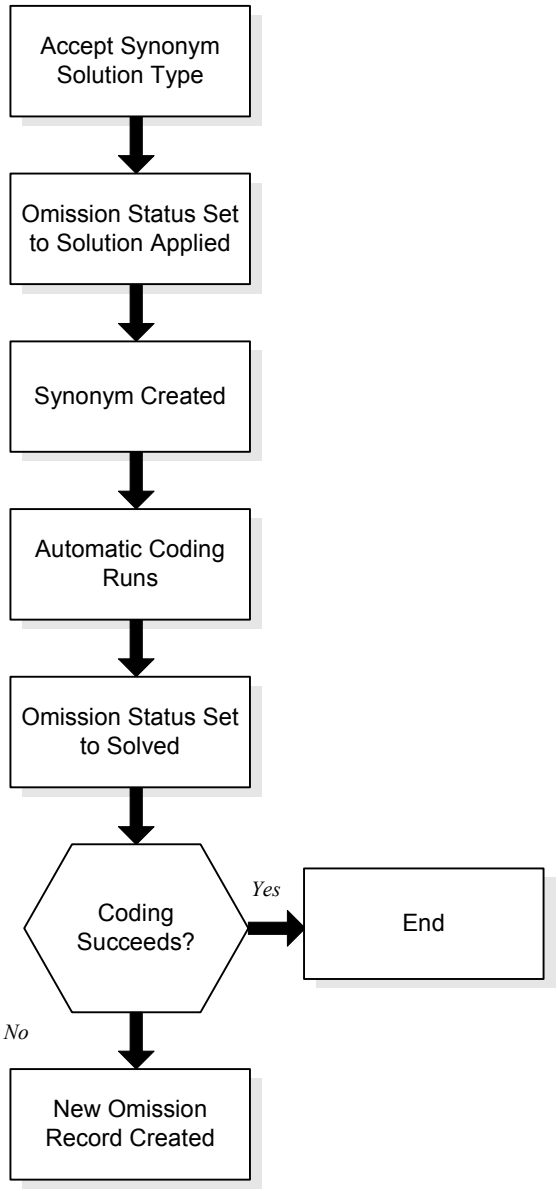
1. A new synonym is created and inserted into the specified thesaurus view.
2. Automatic coding executes on every clinical data record associated with the omission records that use this solution. This process runs automatically in Manage whenever you accept a Synonym solution type.
3. The omission status of each omission record is set to Solved, regardless of whether automatic coding completes successfully.

   If automatic coding fails, a new omission record is created to track the new coding problem. This may occur, for example, if the newly created synonym does not result in successful coding for that verbatim text.

Note: Classify does not prevent the creation of duplicate synonyms. You can review the contents of a coding thesaurus protocol for duplicates by using the Classify's Duplicates within Thesaurus report. For more information, see Chapter 18.

Note: In a Multisite installation, automatic coding at the omission processing site does not affect records at other sites.

The following figure illustrates the process that is initiated when you accept a Synonym solution type:



Note: Coding thesauruses can be implemented as external Oracle tables. If a table's columns do not match those of a thesaurus view, then values for Clintrial software system items (such as DB_ID and ENTRY_DATETIME) will be omitted when records representing newly created synonyms are created. To

populate the empty fields, your database administrator can specify DEFAULT values, or use an INSERT TRIGGER on the table when Classify inserts synonym records. If the columns have the NOT NULL attribute, they must be populated using one of these methods.

How accepting a Verbatim solution type works

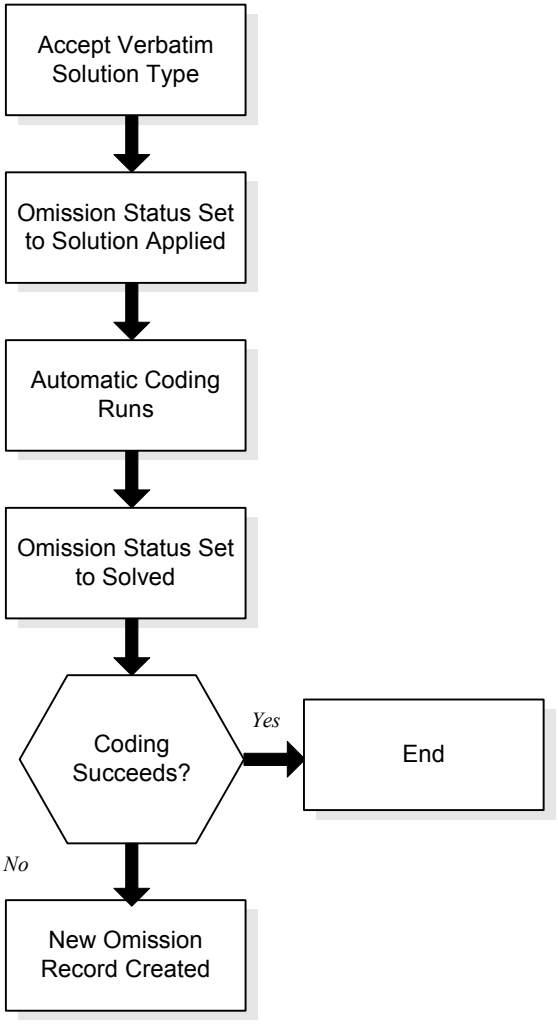
When you accept a Verbatim solution type, the following processing occurs:

1. The value in the Verbatim Text item is changed in the clinical data record.
2. Automatic coding executes on the omission record. This process runs automatically in Manage whenever you accept a Verbatim solution type.
3. The omission status of the omission record is set to Solved, regardless of whether automatic coding completes successfully.

   If automatic coding fails, a new omission record is created to track the new coding problem. This may occur, for example, if automatic coding does not find a single exact match for the new value in the verbatim text item field.

Note: In a Multisite installation, automatic coding at the omission processing site does not affect records at other sites.

The following figure illustrates the process that is initiated when you accept a Verbatim solution type:



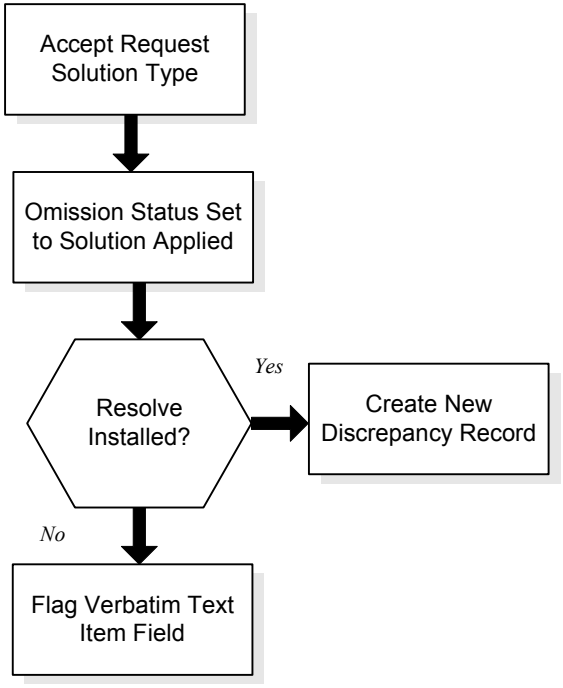
Note: In a Multisite installation, after the omission is replicated from the omission processing site to the automatic coding site, reselection of the record for automatic coding will apply the Change Verbatim solution.

How accepting a Request solution type works

When you accept a Request solution type, the processing that occurs depends on the Clintrial software modules installed at your site:

- If Resolve is installed and the clinical data protocol containing the verbatim text that failed to code has been set up for use with Resolve, a discrepancy record is created.
- If Resolve is not installed, or the protocol has not been set up for use with that module, an item flag is added to the Verbatim Text item of the clinical data record.

The following figure illustrates how the process that is initiated when you accept a Request solution type differs based on whether Resolve is installed:



Unlike the processing initiated for other Classify solution types, when you accept a Request solution type, coding does not run automatically. Instead, the omission record remains in Solution Applied status until the next time you initiate automatic coding in Manage. Even then, the omission status is not changed to Solved until automatic coding succeeds; that is, until after the verbatim text has been changed in response to your request for more information. No new omission record is created when automatic coding runs again.

If Resolve is installed and the protocol has been properly set up, a discrepancy record is created with the following characteristics:

- Discrepancy status is New.
- Error type is CLASSIFY.

- Discrepancy message is the text of your omission record's message.
- The Item Value in the Item Values for Discrepancy section of Resolve's Detailed window is the verbatim text.

Omission records and discrepancy records are managed separately, in Classify and Resolve respectively. Solving one does not necessarily solve the other.

If Resolve is not installed, or the protocol has not been set up for use with Resolve, an item flag is created with the following characteristics:

- Flag category is CLASSIFY.
- Flag name is REQUEST.
- Comment for the flag is your omission record's message.

The CLASSIFY flag category and REQUEST flag name are installed with Classify.

Note: In a Multisite installation, automatic coding at the omission processing site does not affect records at other sites. After the omission is replicated from the omission processing site to the automatic coding site, reselection of the record for automatic coding will apply the Request solution.

Accepting proposed solutions and access rights

To accept a proposed solution of any solution type, you must have an access level of either Full or No Delete for the Classify non-protocol access right Accept, and for the protocol access right Enter/Merged for the coding thesaurus protocol being used.

For more information about Classify's access rights and levels, see Chapter 13.

Closing omission records

Omission records with an omission status of Solved or Obsolete are considered closed. One of these omission statuses is assigned automatically in each of the following situations:

- The verbatim text item is interactively coded in Manage.
- The verbatim text item's record, panel, or protocol is deleted.
- The verbatim text item is changed.

- Automatic coding successfully codes a verbatim text item that previously failed automatic coding.
- Automatic coding detects a change in the thesaurus language for a clinical data record that was processed previously by automatic coding.

If one of these situations occurs, the current omission status of the corresponding omission record changes to either Obsolete or Solved, as follows:

Current omission status:	Automatic coding assigns:
Needs Proposal	Obsolete
Solution Proposed	Obsolete
Solution Applied	Solved

You can reuse or propagate the Verbatim or Request solution of a closed omission record until it is purged. For more information on purging omission records, see the following section.

Purging omission records

You can purge omission records that have one of the following omission statuses:

- Solved
- Obsolete

You may want to purge omission records to reclaim space on the server, or to prevent the outdated solution of an omission record from appearing as a valid, reusable solution for other omission records.

To purge an omission record:

1. In the Omission Browser, select one or more omission records with either the Solved or Obsolete omission status, or open the Details for Omission window for a single omission record.
2. From the **Omission** menu, select **Purge Solved** or **Purge Obsolete**.

A message displays to confirm this action before the omission record is purged.

Before you purge an omission record, keep in mind that:

- Verbatim and Request solutions for purged omission records are not available for use in solving other omission records.
- If the omission record's solution type is Verbatim or Request, only the selected omission record is purged.
- If the omission record's solution type is Synonym, all omission records sharing that solution are purged.

17 Classify and Coding Thesauruses

Using coding thesauruses in the Clintrial software

In the Clintrial software, you set up coding thesaurus protocols and coding targets so that clinical data can be grouped and standardized. This process, which is performed by automatic coding in Manage, allows clinical data to undergo statistical analysis and to be shared by a multilingual team.

This section includes a brief overview of the activities you perform in Design to prepare for automatic coding.

For more information on how you work with coding thesauruses in Classify, see "Using Classify to improve coding thesaurus protocols" on page 261.

What is a coding thesaurus?

A *coding thesaurus* is a dictionary that contains standard codes for a particular type of clinical data. There are two types of thesauruses: industry-standard and user-defined. For example, the industry-standard COSTART thesaurus contains the standard codes for clinical events such as HYPERACUSIS, which is the code that corresponds to the term PAINFUL SENSITIVENESS TO SOUND.

What is a coding thesaurus protocol?

In the Clintrial software, you use Design to set up coding thesaurus protocols. *Coding thesaurus protocols* contain the database tables, which store a coding thesaurus's terms and codes. After you create and install the required panels and items in the coding thesaurus protocol, you either batch load data into them using the batch-loading capability provided by Manage, or enter data in the panel's study book in Enter.

Note: To prevent the creation of duplicate synonyms, set up unique indexes on all thesaurus tables.

What is an extended thesaurus protocol?

A coding thesaurus protocol can be set up as an *extended thesaurus protocol*. If a thesaurus is set up as extended, Classify recognizes information specific to the type of extended thesaurus.

Currently, two types of extended thesaurus protocols are recognized by Classify, one for MedDRA data, and the other for WHO drug dictionary data. A thesaurus protocol is set to one of these two extended types with the protocol parameter CTG_THES_TYPE. There can be more than one of each extended thesaurus type in a database instance. For more information on setting up thesaurus protocols, see the *Design* section of *Admin and Design*.

When you view synonym details from an extended thesaurus, MedDRA-specific or WHO drug dictionary-specific information displays in the Synonym Details window, and you can use the MedDRA Hierarchy Browser to view MedDRA data. For more information, see "Synonym Details" on page 228.

Two extended thesaurus protocols are provided, one designed to hold MedDRA data (the GCT_MEDDRA protocol), and the other to hold WHO drug dictionary data (the GCT_WHODD protocol). Each protocol contains all of the panels, panel keys, views and sample algorithms necessary to perform coding. For more information on importing and setting up the GCT_MEDDRA and GCT_WHODD extended thesaurus protocols, see *Getting Started*.

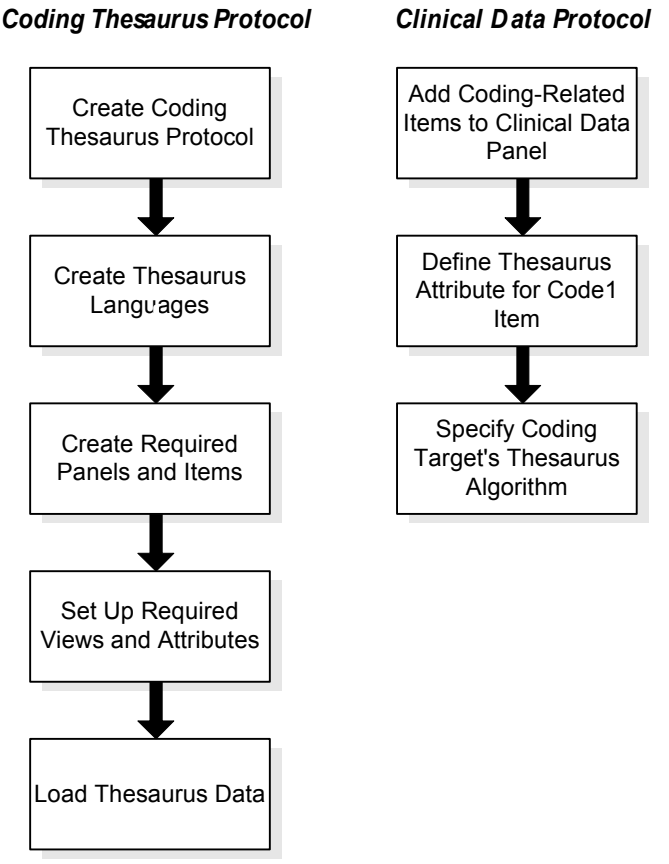
For more information about MedDRA and coding with MedDRA, see Chapter 17.

What is a coding target?

A *coding target* is a Clintrial software object that identifies a set of items in a panel of a clinical data protocol; these items are used with a coding thesaurus protocol during coding. Among these items are the verbatim text item whose text you want to code, the Code1 item with the code, and optionally one item containing each part of a multipart code.

How to prepare for automatic coding

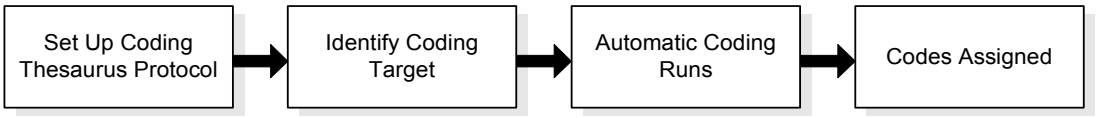
Before you run automatic coding, you must set up coding thesaurus protocols and coding targets in Design. The following figure summarizes these activities:



How automatic coding works

Once coding thesaurus protocol setup is complete and coding targets are identified, automatic coding can run. Automatic coding, which is initiated in Manage for a clinical data protocol, examines the value for each coding target's

verbatim text item, searches the views in the coding thesaurus protocol for a single term that matches it, and then assigns the code for that term to the coding target. The following figure describes this process:



For more information

For more information on setting up coding thesaurus protocols and coding targets, see the *Design* section of *Admin and Design*.

For more information on batch loading data and automatic coding, see Chapter 19.

For more information on thesaurus algorithms, see Chapter 19.

Using Classify to improve coding thesaurus protocols

Classify enhances automatic coding by allowing you to examine, evaluate, and compare the coding thesaurus protocols that you set up in Design. To help you improve coding thesaurus protocols, Classify provides:

- A Thesaurus Browser that allows you to review all coding thesaurus protocols in a database instance.
- Search capabilities that check for the presence of specified terms or codes in a coding thesaurus protocol.
- Reports that find duplicate codes in the views of a single coding thesaurus protocol, or that compare coding thesaurus protocols and views.

Once you evaluate the terms and codes in a coding thesaurus protocol, you can decide whether to modify its contents.

For more information

For more information on the Thesaurus Browser, see the following section, “Reviewing a coding thesaurus protocol.”

For more information on Classify's search capabilities, see "Searching a coding thesaurus protocol" on page 264.

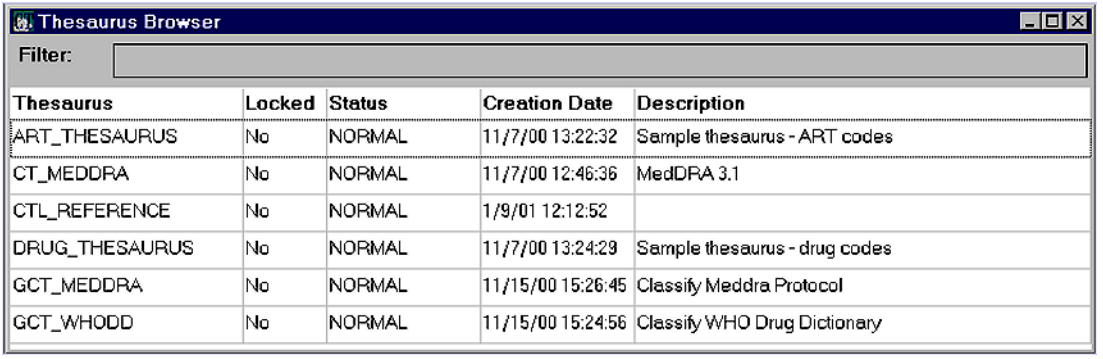
For more information on coding thesaurus protocol reports, see Chapter 18.

Reviewing a coding thesaurus protocol

In Classify, you use the *Thesaurus Browser* to review coding thesaurus protocols as rows on a window display.

How to open the Thesaurus Browser

To open the Thesaurus Browser, from the **Objects** menu select **Thesaurus**, or click the Thesaurus icon on the toolbar. The Thesaurus Browser opens, displaying coding thesaurus protocols for the current database instance:



The following table describes the information provided in the Thesaurus Browser:

Column:	Description:
Thesaurus	The name of a coding thesaurus protocol.
Locked	Indicates whether the coding thesaurus protocol is currently locked. Locked protocols must be unlocked before changes can be made in Enter or Design, and before Synonym solution types can be accepted for omission records.

Column:	Description:
Status	Indicates the current status of the coding thesaurus protocol.
Creation Date	The date and time that the coding thesaurus protocol was created.
Description	The description for the coding thesaurus protocol, if available.

Two commands in the **Synonym** menu are available when a record in the Thesaurus Browser is selected:

- **Delete** — Allows you to delete a synonym from a thesaurus view.
- **Modify** — Allows you to modify a synonym in a thesaurus view.

Note: To use these commands, you must have Full Thesaurus access rights and Full Enter/Merged protocol access rights for the selected thesaurus protocol.

If you select either of these commands, a dialog box opens that allows you to select the synonym to modify or delete.

Note: Classify does not automatically recode existing data that may reference the modified or deleted synonym.

Once you display the initial set of records in the Thesaurus Browser, you can select either of the following **View** menu commands:

- Filter
- Sort

You can also change the order and width of the Thesaurus Browser's columns.

For more information on filtering, sorting, and the layout revision options, see the Help.

How to print thesaurus information

You can print the data that displays in the Thesaurus Browser. To send information displayed in the active window to a printer, from the **File** menu, select **Print**. This produces a list of the coding thesaurus protocols currently listed in the Thesaurus Browser.

Searching a coding thesaurus protocol

For any coding thesaurus protocol in the Thesaurus Browser, you can search for:

- All code and term pairs that match a specified text string
- A particular code (or part of a code) within a coding thesaurus protocol

These search capabilities can help you to test a new coding thesaurus protocol before it is used, or to review an existing coding thesaurus protocol after new code and term pairs have been added.

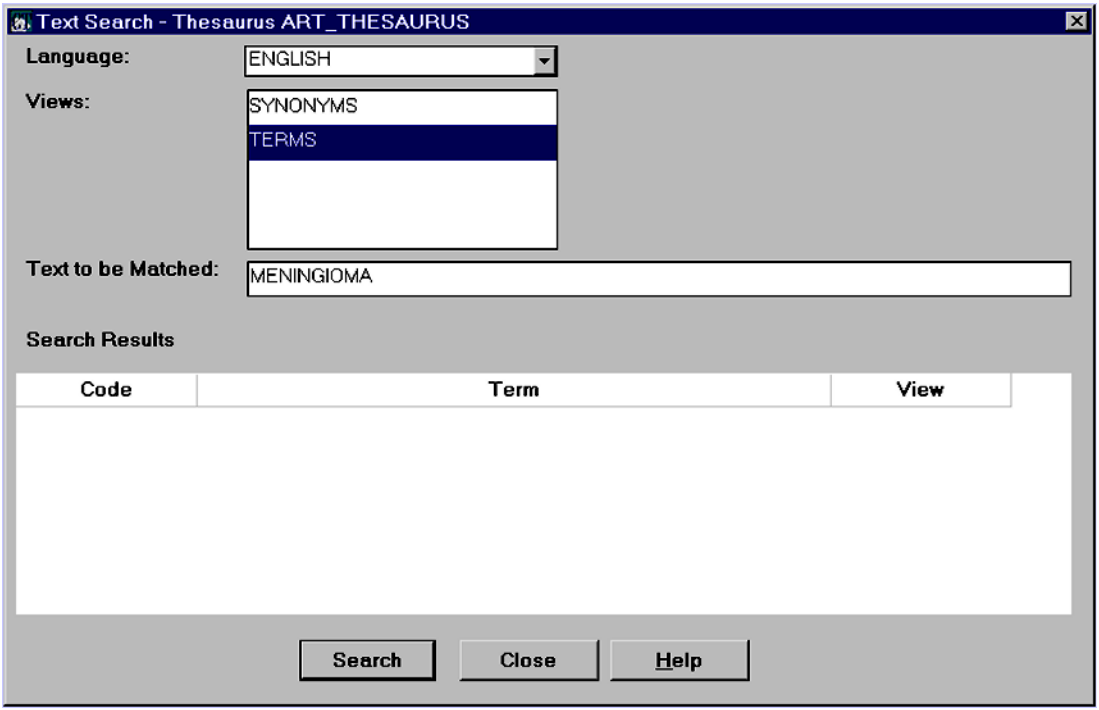
Note: To search for text or codes in a coding thesaurus protocol, you must have the Read or Full access level for Classify's Thesaurus access right for that protocol. In addition, you must have the Read or Full access level for Design's non-protocol System access right.

How to search for text

You search for text in a coding thesaurus protocol as follows:

1. Select a coding thesaurus protocol in the Thesaurus Browser.
2. From the **Thesaurus** menu, select **Text Search**, or double-click the row.

The Text Search Thesaurus dialog box opens:



In this dialog box, you enter a text value in the Text to be Matched field. Then, select a Language (ENGLISH is the default) and use **Ctrl+Click** or **Shift+Click** to select one or more thesaurus views. When you click **Search**, the selected thesaurus views are searched for all code and term pairs that match your text. Matches display in the Search Results section.

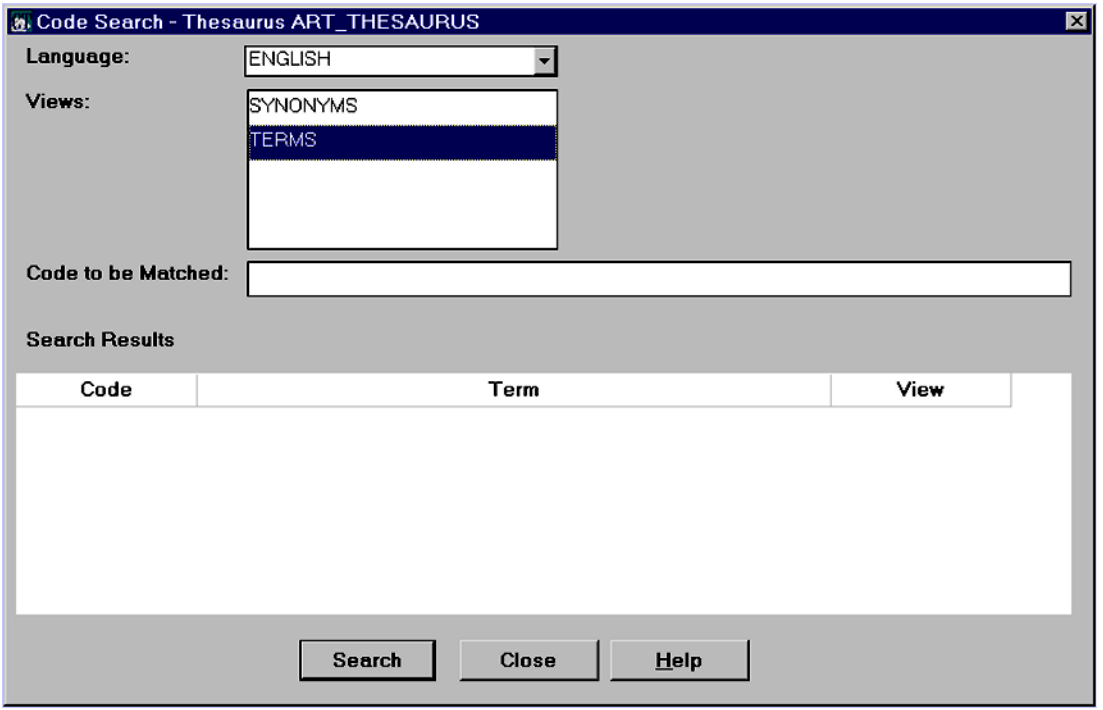
You can use the Oracle wildcard characters (% and _) to search for partial values. Use the percent sign (%) to replace any number of characters, or the underscore (_) to replace a single character. For example, if you search for MAN% in a coding thesaurus protocol that contains drug data, the resulting list may include the drug names MANDELAMINE, MANDOL, and MANNITOL. Alternatively, if you search for MAN_, the resulting list will be limited to drug names that begin with MAN and are precisely four characters long.

How to search for a code

You search for a code in a coding thesaurus protocol as follows:

1. Select a row in the Thesaurus Browser.
2. From the **Thesaurus** menu, select **Code Search**.

The Code Search Thesaurus dialog box opens:



You use this dialog box to determine whether a specified code exists in a coding thesaurus protocol. You enter a code in the Code to be Matched field, select one or more views in the Views to Search list, and click **Search**. The resulting match(es) displays in the Search Results section.

If the coding thesaurus protocol contains multipart codes, you can use a wildcard character to search for a subset of a code. For example, if you search for 472._, the resulting list may include all of the following codes: 472.0, 472.1, and 472.2.

For more information

For step-by-step instructions on searching coding thesaurus protocols, see the Help.

18 Reporting Thesaurus Data

Overview

In Classify, you can produce reports that find:

- Terms that are duplicated within a single coding thesaurus protocol
- Code and term pairs that are different in two different coding thesaurus protocols
- Code and term pairs that are identical in two different coding thesaurus protocols

You can use Classify's thesaurus reports when you prepare for or implement changes to your organization's coding thesaurus protocols, such as upgrading to a new version of an industry-standard coding thesaurus, or developing a new project-specific coding thesaurus.

Types of reports

You can produce these reports in Classify:

- Duplicates within Thesaurus
- Thesaurus Comparisons
- Thesaurus View Comparisons

The following sections describe these reports in more detail.

For step-by-step instructions on printing reports, see the Help.

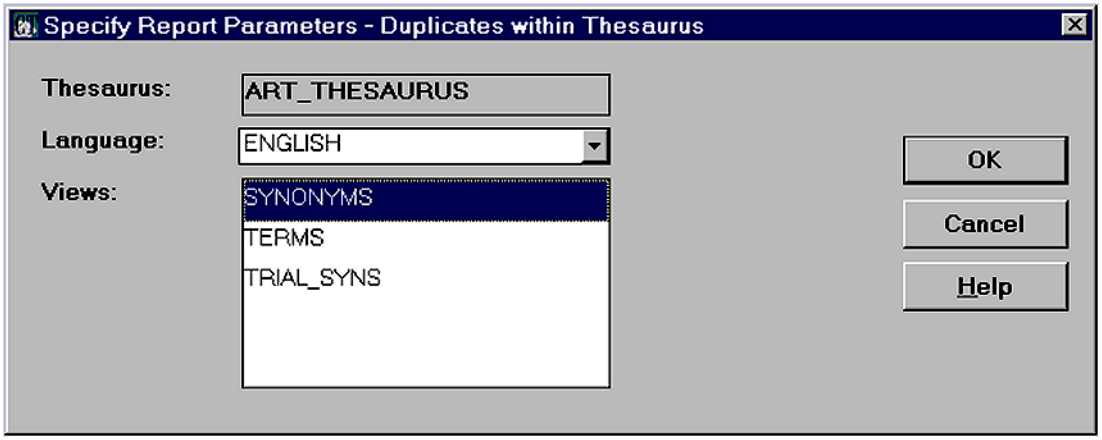
Duplicates within Thesaurus report

The Duplicates within Thesaurus report finds terms that are on file more than once in the same coding thesaurus protocol. This can occur if the same term is:

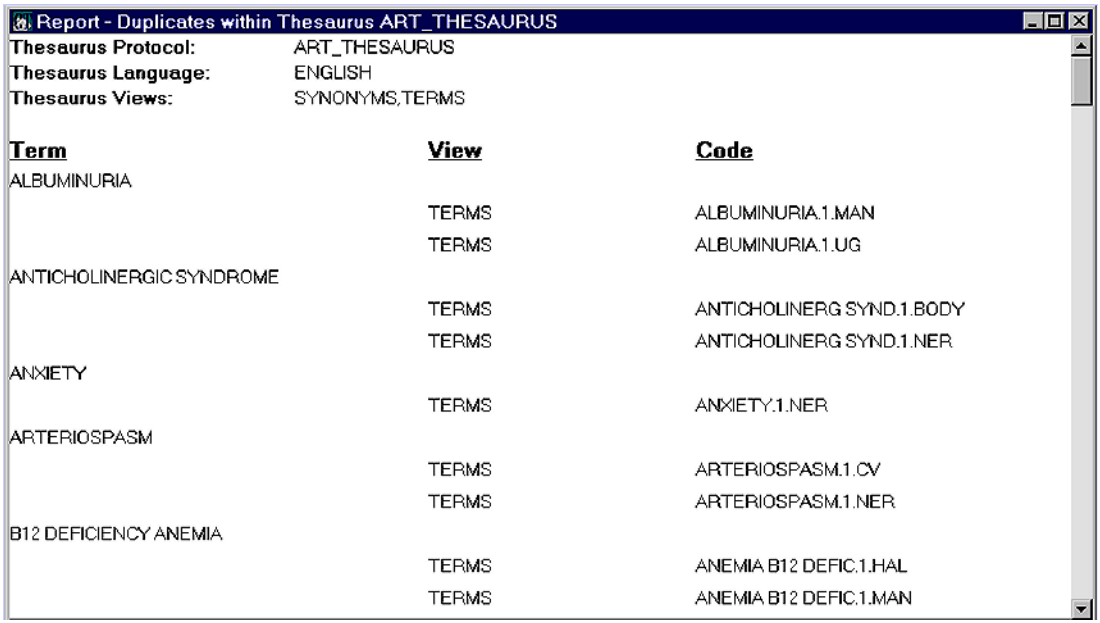
- Assigned two different codes
- Included in two different thesaurus views

This report lists the duplicated terms, their corresponding codes, and the thesaurus view in which they occur.

To display the Duplicates within Thesaurus report, in the Thesaurus Browser, select a single coding thesaurus protocol. Then, from the **Reports** menu, select **Duplicates within Thesaurus**. The following dialog box opens:



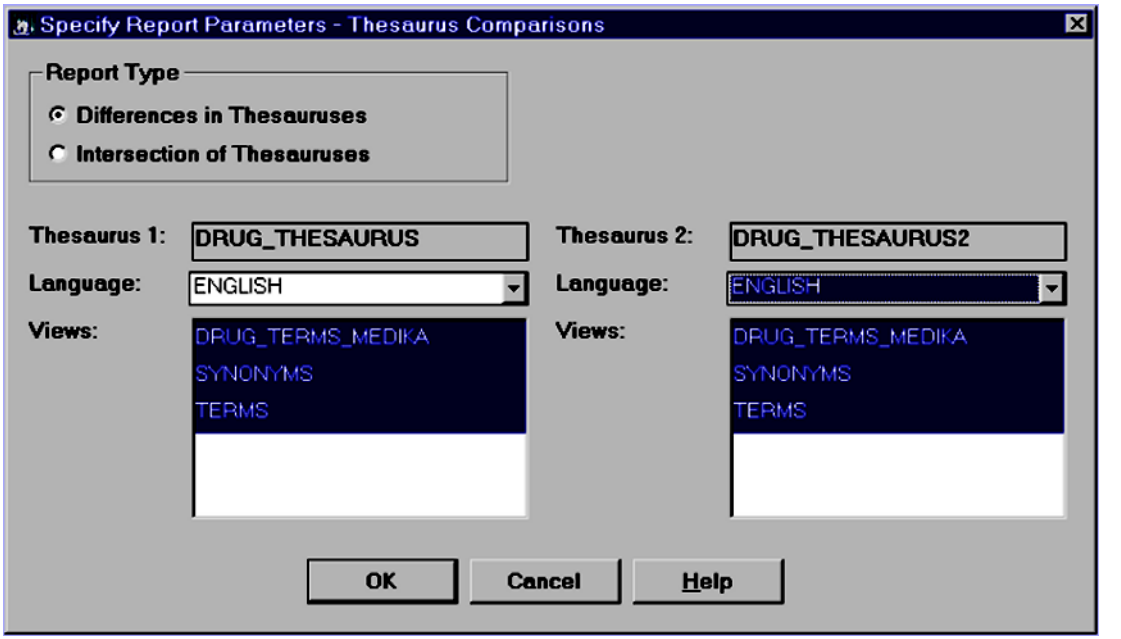
After you select the language to report on and the thesaurus views to include, click **OK**. The following example shows a sample of this report:



Thesaurus Comparisons reports

A Thesaurus Comparisons report compares data in two different coding thesaurus protocols and reports on either the differences between them or their similarities.

To produce these reports, in the Thesaurus Browser you must select two coding thesaurus protocols. Then, from the **Reports** menu, select **Thesaurus Comparisons**. The following dialog box opens:



In this dialog box, you select the Report Type:

- Differences in Thesauruses
- Intersection of Thesauruses

You also select the specific language and thesaurus view(s) that you want to compare.

Differences in Thesauruses

If you select **Differences in Thesauruses**, the resulting report lists each code and term pair that is present in only one of the two coding thesaurus protocols. Code and term pairs that are present in both coding thesaurus protocols but in

differently named views (for example, in the terms view of one coding thesaurus protocol and a synonyms view of the other) are considered the same, and therefore are not included on this report.

The following example shows a sample of this report:

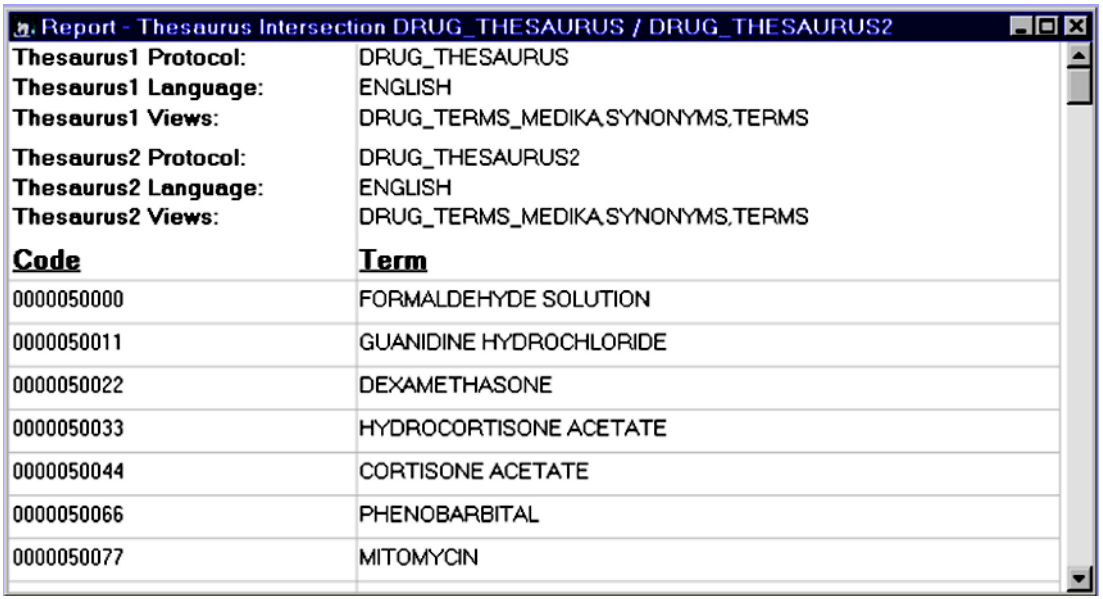
Report - Thesaurus Differences DRUG_THESAURUS / DRUG_THESAURUS2

Thesaurus1 Protocol:	DRUG_THESAURUS	
Thesaurus1 Language:	ENGLISH	
Thesaurus1 Views:	DRUG_TERMS_MEDIKA,SYNONYMS,TERMS	
Thesaurus2 Protocol:	DRUG_THESAURUS2	
Thesaurus2 Language:	ENGLISH	
Thesaurus2 Views:	DRUG_TERMS_MEDIKA,SYNONYMS,TERMS	
Code	**Term**	**Thesaurus**
8001126534	BIGZIMAX	DRUG_THESAURUS2
8001328454	BITTYMIN	DRUG_THESAURUS2
8001343345	MIDINAC	DRUG_THESAURUS2

Intersection of Thesauruses

If you select **Intersection of Thesauruses**, the resulting report lists the code and term pairs that are present in both of the selected coding thesaurus protocols, regardless of the view in which they occur.

The following example shows a sample of this report:



Report - Thesaurus Intersection DRUG_THESAURUS / DRUG_THESAURUS2

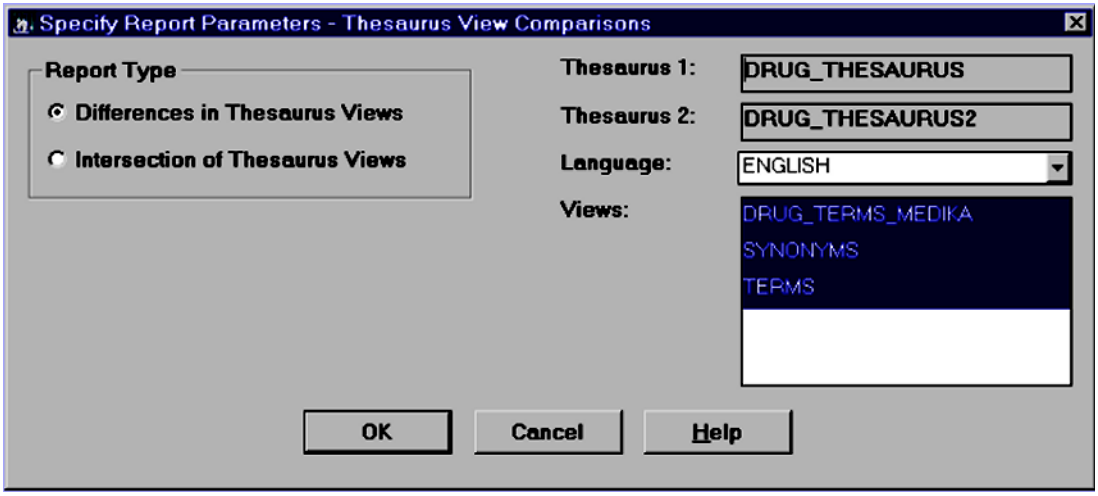
Thesaurus1 Protocol:	DRUG_THESAURUS
Thesaurus1 Language:	ENGLISH
Thesaurus1 Views:	DRUG_TERMS_MEDIKA,SYNONYMS,TERMS
Thesaurus2 Protocol:	DRUG_THESAURUS2
Thesaurus2 Language:	ENGLISH
Thesaurus2 Views:	DRUG_TERMS_MEDIKA,SYNONYMS,TERMS

Code	**Term**
0000050000	FORMALDEHYDE SOLUTION
0000050011	GUANIDINE HYDROCHLORIDE
0000050022	DEXAMETHASONE
0000050033	HYDROCORTISONE ACETATE
0000050044	CORTISONE ACETATE
0000050066	PHENOBARBITAL
0000050077	MITOMYCIN

Thesaurus View Comparisons reports

Thesaurus View Comparisons reports are similar to the Thesaurus Comparisons reports; however, the thesaurus view in which each code and term pair is found is considered as well.

For these reports, in the Thesaurus Browser you must select two coding thesaurus protocols. Then, from the **Reports** menu, select **Thesaurus View Comparisons**. The following dialog box opens:



In this dialog box, you select the Report Type:

- Differences in Thesaurus Views
- Intersection of Thesaurus Views

You also select the language and the view(s) to include for each coding thesaurus protocol. Only languages and views that have the same name in both coding thesaurus protocols appear.

Differences in Thesaurus Views

If you select **Differences in Thesaurus Views**, the report lists each code and term pair that is present in only one of the selected coding thesaurus protocols, and code and term pairs that exist in both coding thesaurus protocols, but in differently named views.

The following example shows a sample of this report:

Report - Thesaurus View Differences DRUG_THESAURUS / DRUG_THESAURUS2

Thesaurus1 Protocol:	DRUG_THESAURUS
Thesaurus2 Protocol:	DRUG_THESAURUS2
Thesaurus Language:	ENGLISH
Thesaurus Views:	DRUG_TERMS_MEDIKA,SYNONYMS,TERMS

Code	Term	Thesaurus	View
8001126534	BIGZIMAX	DRUG_THESAURUS2	TERMS
8001328454	BITTYMIN	DRUG_THESAURUS2	TERMS
8001343345	MIDINAC	DRUG_THESAURUS2	TERMS

Note: By default, this report is not formatted for printing on 8 1/2 x 11 (portrait mode) paper. Like the previous example, you can adjust the column widths of this report so it prints in portrait mode. To do so, from the **File** menu, select **Print Preview**, then click the column dividers and drag to resize the report's columns.

Intersection of Thesaurus Views

If you select **Intersection of Thesaurus Views**, the report lists the code and term pairs that are present in both of the selected coding thesaurus protocols in views that have the same name, such as TERMS.

The following example shows a sample of this report:

Report - Thesaurus View Intersection DRUG_THESAURUS / DRUG_THESAURUS2

Thesaurus1 Protocol:	DRUG_THESAURUS
Thesaurus2 Protocol:	DRUG_THESAURUS2
Thesaurus Language:	ENGLISH
Thesaurus Views:	DRUG_TERMS_MEDIKA,SYNONYMS,TERMS

Code	Term	View
0000050000	FORMALDEHYDE SOLUTION	TERMS
0000050011	GUANIDINE HYDROCHLORIDE	TERMS
0000050022	DEXAMETHASONE	TERMS
0000050033	HYDROCORTISONE ACETATE	TERMS
0000050044	CORTISONE ACETATE	TERMS
0000050066	PHENOBARBITAL	TERMS
0000050077	MITOMYCIN	TERMS
0000050099	HEXOBARBITAL SODIUM	TERMS

19 Classify and Thesaurus Algorithms

Thesaurus algorithms

What is a thesaurus algorithm?

Automatic coding matches to the standardized terms in a coding thesaurus protocol the verbatim text (that is, text entered by the user) such as the names of diseases or drugs. A *thesaurus algorithm* is a sequence of steps that determines the most appropriate code match for the verbatim text. The Clintrial software supplies a default thesaurus algorithm, and you can create customized thesaurus algorithms. When automatic coding runs in Manage, thesaurus algorithms are applied to increase the likelihood of finding a matching term in a coding thesaurus protocol.

Example: thesaurus algorithm

For example, suppose that a record contains the following verbatim text for a medical history event:

History of bleeding small intestinal ulcers

When automatic coding runs, a thesaurus algorithm might automatically transform it as follows:

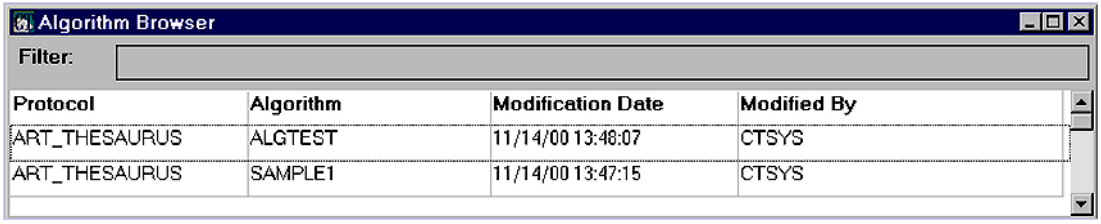
Thesaurus algorithm step:	**Resulting text:**
Step 1. Change text to uppercase.	HISTORY OF BLEEDING SMALL INTESTINAL ULCERS
Step 2. Remove words: HISTORY OF	BLEEDING SMALL INTESTINAL ULCERS
Step 3. Change plural words to singular.	BLEEDING SMALL INTESTINAL ULCER
Step 4. Replace words: BLEEDING with HEMMORRHAGE, and SMALL INTESTINAL with DUODENAL	HEMORRHAGE DUODENAL ULCER

Thesaurus algorithm step:	Resulting text:
Step 5. Alphabetize words.	DUODENAL HEMORRHAGE ULCER
Step 6. Attempt an exact match in the terms view.	Exact match found, code ULCER DUODEN HEM assigned.

A thesaurus algorithm's steps either transform the verbatim text in some manner, or attempt to find a matching code by looking up a term in a thesaurus view. You use Design to create thesaurus algorithms and associate them with your coding targets. You use Manage to initiate automatic coding.

What is the Algorithm Browser?

The *Algorithm Browser* summarizes all of the thesaurus algorithms in a single window display. To open the Algorithm Browser, from the **Objects** menu select **Algorithm**, or click the Algorithm icon on the toolbar. The Algorithm Browser opens:



The following table describes the information provided in the Algorithm Browser:

Column:	Description:
Protocol	The name of a coding thesaurus protocol.
Algorithm	The name of a thesaurus algorithm.
Modification Date	The date and time when this thesaurus algorithm was last modified.
Modified By	The name of the user who last modified this thesaurus algorithm.

Once you display the initial set of algorithms in the Algorithm Browser, you can select either of these **View** menu commands:

- Filter
- Sort

You can also change the order and width of the Algorithm Browser's columns.

For more information on filtering, sorting, and the layout revision options, see the Help.

How to print algorithm information

You can print the data that displays in the Algorithm Browser. To send information displayed in the active window to a printer, from the **File** menu, select **Print**. This produces a list of the thesaurus algorithms currently listed in the Algorithm Browser.

For more information

For more information on thesaurus algorithms, see the *Design* section of *Admin and Design*.

For more information on automatic coding, see Chapter 19.

Thesaurus algorithm step types

What are step types?

Step types are the different transformations and lookup steps that you can combine to create a thesaurus algorithm.

What is a transformation?

A *transformation* is a change made to verbatim text that converts it into a semantically equivalent construction. Examples of different types of transformations include changing all letters to uppercase, or making all plural words singular. In the example starting on page 278, Steps 1 through 5 are all transformations.

You can include as few or as many transformations in a thesaurus algorithm as you need for effective coding.

What is a lookup step?

A *lookup step* is a thesaurus algorithm step that attempts to match a text string to an official term in a thesaurus. You can add a lookup step as one of the first steps in a thesaurus algorithm. After you apply one or more transformations to the verbatim text, you can add another lookup step. In the example starting on page 278, Step 6 is a lookup step.

Design's step types

You use Design to create and modify thesaurus algorithms, which usually consist of a combination of both transformations and lookup steps. If Classify is not installed, you can include only the following step types in a thesaurus algorithm:

- *Filter* is a transformation that removes words previously filed in a stopwords view of a coding thesaurus protocol.
- *Contains* is a lookup step that attempts to match the verbatim text to a thesaurus term. The words in the verbatim text can be in any order.
- *Exact* is a lookup step that attempts to match the exact verbatim text to a thesaurus term.

Another way to include transformations in a thesaurus algorithm is by checking the Comprehensive Normalization check box in the Create or Modify Algorithm window. When this check box is checked, the thesaurus algorithm performs a series of transformations on the text before applying the other steps.

After you install Classify, additional transformations are available for use in your thesaurus algorithms. When you create or modify a thesaurus algorithm, you can include any of Classify's transformations in addition to the step types supplied in Design. The transformations supplied with Classify are described in the following section.

For more information

For more information on using Design step types and the Comprehensive Normalization check box in thesaurus algorithms,
see the *Design* section of *Admin and Design*.

Transformations added by Classify

What do Classify transformations do?

Each Classify transformation makes a specific change to the verbatim text, such as changing all characters to uppercase or making all plural words singular. Then, each transformation also makes the following changes:

- Removes nonprinting control characters, including line feed indicators (carriage returns).
- Replaces multiple spaces with a single space.
- Removes extra spaces before and after the verbatim text.

List of Classify transformations

Classify's transformations are described in the following table. For examples of each transformation and tips on usage, see Chapter 20.

Transformation:	Description:
Alphabetize	Alphabetizes words to remove dependence on word order.
Iterative Replace Words	Replaces previously defined words or phrases with previously defined replacements; then, after all replacements are made to the original text, reruns the process to replace any newly created phrases as needed. ***Note*:** For information on replacing words, see "Support elements for transformations" on page 284.
Lower Case	Converts all uppercase letters to lowercase. Non-alphabetic characters are not transformed.

Transformation:	Description:
Plural to Singular	Converts all lowercase letters to uppercase, then removes the final character(s) S, IES, or ES from words.
Protected Stemming	Converts all lowercase letters to uppercase, then: 1. Replaces previously defined words or phrases with previously defined replacements. 2. Removes suffixes from words that were not replaced, leaving the word root followed by *.
Remove Bracketed Text	Removes all text found within a pair of brackets [ ] or parentheses ( ), including the brackets or parentheses themselves.
Remove Chars	Replaces specific, previously defined characters, such as punctuation marks, with a space.
Remove Dates	Removes any string of numbers that includes periods (.), hyphens (-), or slashes (/).
Remove Dups	Removes the second (and all subsequent) occurrence of a word. The first occurrence is preserved.
Remove Numbers	Removes strings composed of numbers. Also removes plus signs (+), minus signs (-), asterisks (*), slashes (/), periods (.), and commas (,) when these symbols are found in the string of numbers.
Remove Quotes	Removes all apostrophes (') and single (‘) and double (“) quotation marks.
Remove Words	Removes previously defined words and phrases.
Replace Words	Replaces previously defined words or phrases with previously defined replacements. Removes words or phrases if the defined replacements are null. ***Note*:** For information on replacing words, see "Support elements for transformations" on page 284.
Reset	Resets the verbatim text back to its original form, that is, back to the value entered in the Verbatim Text field, before any transformations were performed.

Transformation:	Description:
Stemming	Converts all lowercase letters to uppercase, then removes suffixes from words, leaving the word root followed by *. (Prefixes are not removed.)
Upper Case	Converts all lowercase letters to uppercase. Non-alphabetic characters are not transformed.

Support elements for transformations

What are support elements?

Support elements are the characters, words, and phrases that you define in advance so that Classify transformations can operate correctly. For example, when you include Remove Words as a step in a thesaurus algorithm, you must separately define the words (and phrases) that the transformation should remove, such as AND, THE, and A.

Not all Classify transformations require support elements. For example, Remove Dups removes words that are repeated within a text string without requiring any specific definition to be made as a support element.

Which transformations require support elements?

The following Classify transformations require user-defined support elements:

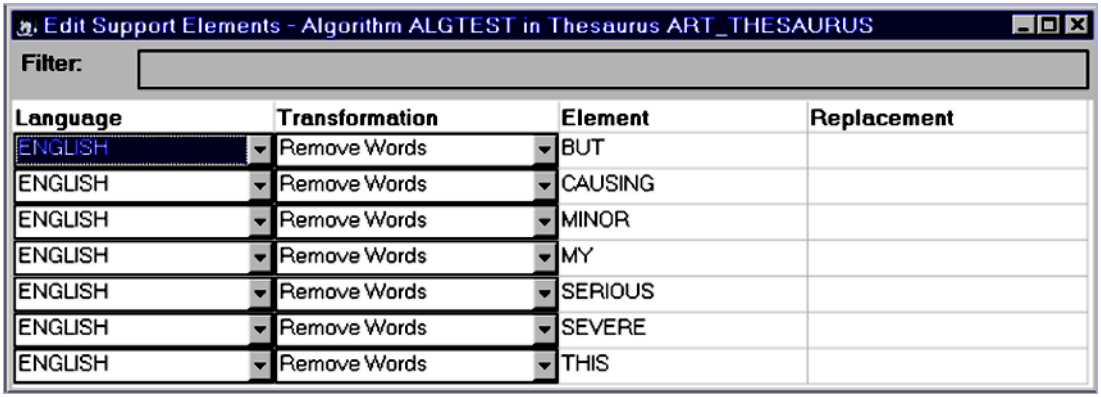
Transformation:	You define:
Iterative Replace Words	Each word or phrase to replace and its corresponding replacement. ***Note:*** The same support elements are used for both this transformation and the Replace Words transformation.
Protected Stemming	Each word or phrase to replace and its corresponding replacement.

Transformation:	You define:
Remove Chars	The characters to remove. ***Note:*** If you do not define support elements for this transformation, the characters (if any) listed in the Punctuation item of the Thesaurus Language are removed instead.
Remove Words	Each word or phrase to remove.
Replace Words	Each word or phrase to replace and its corresponding replacement. ***Note:*** The same support elements are used for both this transformation and the Iterative Replace Words transformation.

How to edit support elements

You use Classify to add, change, and delete support elements for the transformations that require them.

After you select a thesaurus algorithm in the Algorithm Browser, from the **Algorithm** menu, select **Edit Support Elements**. The Edit Support Elements window opens:



Note: To edit support elements for a thesaurus algorithm, you must be assigned the following access rights and access levels:

- The Full access level for Classify's Thesaurus access right for that algorithm's coding thesaurus protocol.

- The Read or Full access level for Design's non-protocol System access right.

When the Edit Support Elements window is active, you use the **Edit** menu's commands to insert new rows or to delete existing rows. In each row, you specify:

- Language — The specific language view to which the entered element applies. You can establish different support elements for each language view.
- Transformation — Select Protected Stemming, Remove Chars, Remove Words, or Replace Words.
- Element — A single word or phrase to remove or replace. For Remove Chars, you can specify multiple characters in a single row; you do not need to add a separate row for each one.
- Replacement — For Replace Words and Protected Stemming, you can specify a replacement word or phrase for each element. If blank, the element will be replaced by null.

Once you enter the necessary support elements in Classify, you can use all of the Classify transformations in the thesaurus algorithms you create and maintain in Design.

For more information

For more information on maintaining transformation support elements, see the Help.

Comparing Design's transformation and algorithm attribute to Classify's transformations

When you use Design to create thesaurus algorithms, you can use a transformation and an algorithm attribute to transform verbatim text in ways that are also performed by Classify transformations, as follows:

- The Filter transformation, which removes words from the verbatim text.
- The Comprehensive Normalization check box, an algorithm attribute that, if checked, removes extra spaces and changes text to uppercase, as well as making other changes.

For more information on this transformation and attribute, see the *Design* section of *Admin and Design*.

When Classify is installed, if you want your thesaurus algorithm to remove words, you can include either Design's Filter transformation or Classify's Remove Words transformation, or both. If you want your thesaurus algorithm to change letters to uppercase and remove extra spaces, you can check Design's Comprehensive Normalization check box or include specific Classify transformations. These options are compared in the following sections.

How to remove words

In Design, a stopwords panel is a required component of each coding thesaurus protocol. This panel (and its corresponding view) stores the words that are extracted from verbatim text when Filter is one of the steps in a thesaurus algorithm.

Because Filter is included in the default algorithm supplied with the Clintrial software, you should continue to maintain the stopwords panel if any of your coding targets use the default algorithm during automatic coding.

Note: The Clintrial software uses the default algorithm for any coding targets that have an undefined Algorithm attribute.

When Classify is installed, you can use a Remove Words step in your thesaurus algorithms instead of, or in addition to, a Filter step. If you include the Remove Words transformation in a thesaurus algorithm, you must also maintain a list of support elements, consisting of a list of words to be extracted. You must maintain this list of support elements in Classify instead of, or in addition to, maintaining the stopwords panel in Design.

How to normalize verbatim text

In Design, the Create and Modify Algorithm windows include the Comprehensive Normalization checkbox. If you check this check box, the verbatim text is transformed in all of the following ways:

- Removes characters defined in the Punctuation item of the Thesaurus Language.
- Changes text to uppercase.
- Replaces end-of-line sequences (carriage returns) with a space.
- Replaces multiple spaces with a single space.
- Removes spaces before and after the text.

Automatic coding makes all of these preliminary changes to the verbatim text before performing the other steps in the thesaurus algorithm.

When Classify is installed, you can use the Remove Chars and Upper Case transformations to perform the first two of these changes; in addition, the Plural to Singular, Stemming, and Protected Stemming transformations all convert text to uppercase. Every Classify transformation performs all of the remaining three normalization activities listed above.

As a result, if you clear the Comprehensive Normalization check box, you should consider including Remove Chars, Upper Case, or other Classify transformations in your thesaurus algorithm.

Note: To determine the characters to remove, the Remove Chars transformation first references a list of support elements in Classify. Only if this list is empty does it refer to the Punctuation item of the Thesaurus Language.

20 Designing and Testing Thesaurus Algorithms

Designing thesaurus algorithms

The Clintrial software supplies a thesaurus algorithm which every coding target uses by default. To create and modify your own customized thesaurus algorithms, you use Design. By designing your own thesaurus algorithms, you can:

- Increase the number of values that code successfully during automatic coding
- Adapt thesaurus algorithms to specific coding thesaurus protocols
- Make project-specific thesaurus algorithms

When Classify is installed, you can include any of Classify's transformations, as well as Design's Filter transformation and Contains and Exact lookup steps, in your thesaurus algorithms.

After you create a thesaurus algorithm, you can assign it to any coding target to use during coding. You do this in the coding target's Algorithm attribute.

For more information on creating and modifying thesaurus algorithms and coding targets, see the *Design* section of *Admin and Design*.

How to use transformations

When you design a thesaurus algorithm, you choose the different types of transformations to include as its steps, and decide on their order, including when to attempt matches with the Contains and Exact lookup steps.

The following table provides usage notes for each of the Classify transformations to assist you in your thesaurus algorithm design. For a description of each transformation, see Chapter 19.

Transformation:	**Usage:**
Alphabetize	Sorts words using ASCII sort order: words beginning with special characters are placed first, followed by those beginning with numbers, uppercase letters, and lowercase letters. For example, changes SEVERE HEAD ACHE to ACHE HEAD SEVERE. Normally used after either Replace Words or Iterative Replace Words. ***Note:*** This transformation is suited for use only with coding thesaurus protocols that store terms in alphabetized form.

Transformation:	Usage:
Iterative Replace Words	Case sensitive. Rather than using both Remove Words and Replace Words transformations, you can use Iterative Replace Words for cases in which changing or removing a word in the middle of a phrase will allow the phrase to be matched. For example, if the word BELLY is to be replaced by STOMACH, and STOMACH PAIN is to be replaced by STOMACH ACHE, then this transformation will change BELLY PAIN to STOMACH PAIN first, then change that to STOMACH ACHE. (The Replace Words transformation would transform this text to STOMACH PAIN only.) This transformation removes a word or phrase if the defined replacement is left null.
Lower Case	Used if other transformations rely on lowercase entries. For example, if all of your support elements for Replace Words are lowercase, this transformation is needed first. Also used if the terms in your coding thesaurus protocols are lowercase.
Plural to Singular	This transformation changes Pains to PAIN and ABSCESSES to ABSCESS. Special consideration is made for words that end in SS or in an S preceded by a vowel other than E; as a result, PUS, ABSCESS, and PERTUSSIS are not changed to singular form. ***Note:*** The words HURTS and SORES are not changed by this transformation. The location of this transformation in relation to other transformations in a thesaurus algorithm is critical. If this transformation precedes Replace Words or Remove Words in the algorithm, all corresponding support elements must be singular. ***Note:*** Because this transformation results in words in singular form only, it is suited for use only with coding thesaurus protocols that use the same convention for its terms.

Transformation:	Usage:
Protected Stemming	Suited for use with English words only. Use instead of Stemming, so that you can define exceptions to words that are transformed to their root form. For example, the Stemming transformation would transform both PATIENT SUICIDAL and PATIENT SUICIDE to PATIENT SUICID*. To prevent SUICIDAL and SUICIDE from being stemmed, use Protected Stemming instead, and define each word as its own replacement: replace SUICIDAL with SUICIDAL and SUICIDE with SUICIDE. Protected Stemming would then transform PATIENT SUICIDAL to PATIENT SUICIDAL, and PATIENT SUICIDE to PATIENT SUICIDE. Normally used after Replace Words or Iterative Replace Words. ***Note:*** Because this transformation results in word roots that end in an asterisk (*), it is suited for use only with coding thesaurus protocols that use the same convention for its terms. As a result, it should come after Remove Chars if asterisks are removed.
Remove Bracketed Text	Text is removed only if enclosed within one pair of brackets or parentheses; a series of nested parenthetical statements is not removed. For example, transforms HYOSCINE [SCOPOLAMINE] to HYOSCINE. Remove Bracketed Text requires that all brackets within a given string be of the same type. For example, this transformation would remove the bracketed text from (HAS) HEADACHE (FREQUENT), but not from (HAS) HEADACHE [FREQUENT]. Include before a Remove Chars transformation if either brackets [ ] or parentheses ( ) are defined as characters to remove.
Remove Chars	You define characters for this transformation to remove in Classify. Characters defined in the Punctuation item of the Thesaurus Language are removed only if you do not define any characters in Classify. This step replaces each removed character with a space (extra spaces are then eliminated). For example, transforms KAPOSI'S SARCOMA to KAPOSI S SARCOMA (including the extra space). To prevent these results, use a Remove Quotes step before this transformation.
Remove Dates	Removes 10/10/87 and 123-45-6789; however, does not remove 04-MAY-1995. Normally used before Remove Numbers.

Transformation:	Usage:
Remove Dups	Normally used after Replace Words or Iterative Replace Words. You do not need an Alphabetize step before this step. For example, transforms ULCER: STOMACH ULCER to ULCER: STOMACH.
Remove Numbers	Removes any strings that are made up of numbers. Also removes the following symbols if they are part of a numeric string: + - * / . , If the string contains one or more letters, it is not removed. As a result, TEMPERATURE OF 99. DEGREES is transformed to TEMPERATURE OF DEGREES, but PATIENT201 is not changed.
Remove Quotes	For example, transforms STEIN'S SYNDROME to STEINS SYNDROME. Generally used instead of or before Remove Chars.
Remove Words	Usually, only words that do not add meaning to the verbatim text, and that also do not change the meaning when they are removed, should be defined as support elements. Removes the longest defined phrase first. For example, if you specify both the word COMPLAINED and the phrase PATIENT COMPLAINED OF for removal, changes PATIENT COMPLAINED OF BAD DREAMS to BAD DREAMS (not PATIENT OF BAD DREAMS). Case sensitive. Use either before or after Replace Words, based on the support elements defined for each transformation. If your sequence uses Remove Words first, followed by Replace Words, your replacement phrases should not contain words that would otherwise be removed. If both processes are needed, consider using Iterative Replace Words, which may be more efficient and produce better results. ***Note:*** You define words and phrases for this transformation to remove as support elements in Classify. Words defined in a stopwords view are not removed by this transformation; use the Filter transformation to remove stopwords.

Transformation:	Usage:
Replace Words	Replaces the longest defined phrase first. For example, if you specify that BELLY is to be replaced by STOMACH, and BELLY PAIN is to be replaced by STOMACH ACHE, changes MILD BELLY PAIN to MILD STOMACH ACHE (not MILD STOMACH PAIN). Case sensitive. If Remove Words is also used, you should consider the support elements defined for each transformation. Typically, Remove Words will be used first, followed by Replace Words, which therefore should not contain words that are defined to be removed.
Reset	Can be included in a thesaurus algorithm after other transformations and lookup steps, so that a different set of transformations and lookup steps can be performed to find a unique match. ***Note:*** If you check the Comprehensive Normalization check box for the thesaurus algorithm, its effects are not reset by this transformation.
Stemming	Suited for use with English words only. For example, transforms INCREASE, INCREASED, and INCREASING to INCREAS*. Because this transformation results in word roots that end in an asterisk (*), it is suited for use only with coding thesaurus protocols that use the same convention for its terms. Also, it should come after Remove Chars if asterisks are removed. Generally used after Replace Words or Iterative Replace Words.
Upper Case	Used if other transformations rely on uppercase entries. For example, if all of your support elements for Remove Words are in uppercase, this transformation is needed before Remove Words. Also used if the terms in your coding thesaurus protocols are uppercase. ***Note:*** Other transformations, including Plural to Singular and Protected Stemming, also convert characters to uppercase.

Example thesaurus algorithms

This section contains example thesaurus algorithms that consist of Classify and Design step types.

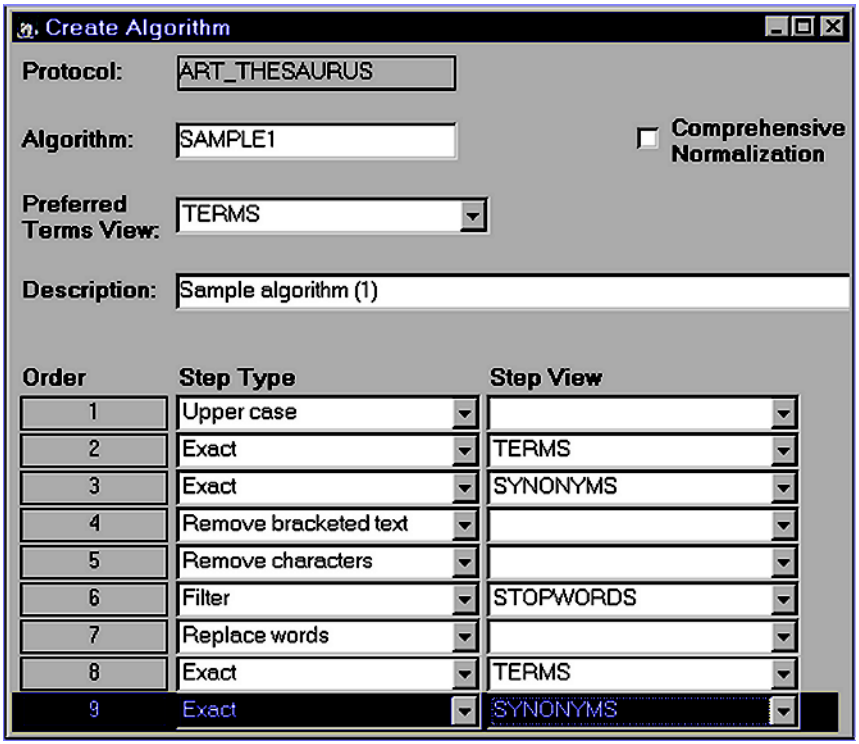
Thesaurus algorithm: first example

The following table shows the thesaurus algorithm design created by a coding group to improve the success rate of automatic coding. The approved changes to the verbatim text, and the points at which a match should be attempted, are listed, along with the step types that perform these functions.

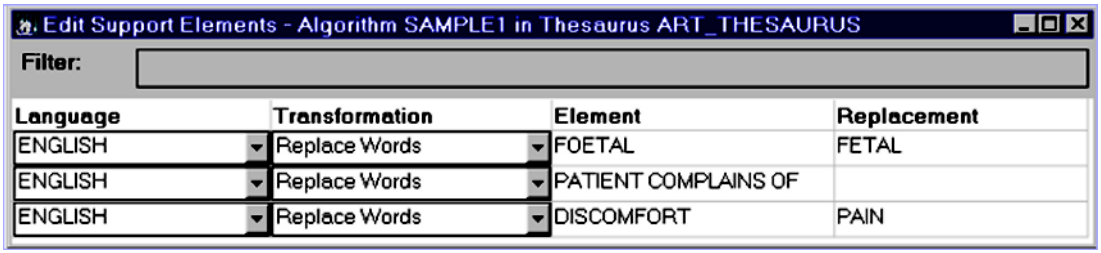
Change needed:	**Step type:**
1. Capitalize verbatim text.	Upper Case
2. Attempt a direct match of the transformed text to the terms view.	Exact, step view is the terms view
3. Attempt a direct match of the transformed text with a synonym view.	Exact, step view is a synonym view
4. Remove items in parentheses, including the parentheses ( ).	Remove Bracketed Text
5. Remove characters in the Punctuation item for the Thesaurus Language.	Remove Chars (which, in this case, has no support elements, as explained in the ***Note*** below)
6. Remove words in the stopwords view.	Filter
7. Perform word substitutions contained in the replace word table.	Replace Words
8. Remove more than one space between the words and any spaces at the beginning of the text.	(Done by Steps 1, 4, 5, and 7)
9. Attempt a direct match of the transformed text with the terms view.	Exact, step view is the terms view
10. Attempt a direct match of the transformed text with a synonym view.	Exact, step view is a synonym view

Note: By default, Remove Chars removes the characters defined as its support elements. It removes the characters defined in the Punctuation item of the Thesaurus Language only if its support elements are null. You can achieve the same effect by checking the Comprehensive Normalization check box and omitting this step from the thesaurus algorithm.

The following example shows how this sample thesaurus algorithm appears in Design:



After you save this thesaurus algorithm in Design, you edit the support elements for its Replace Words transformation in Classify:



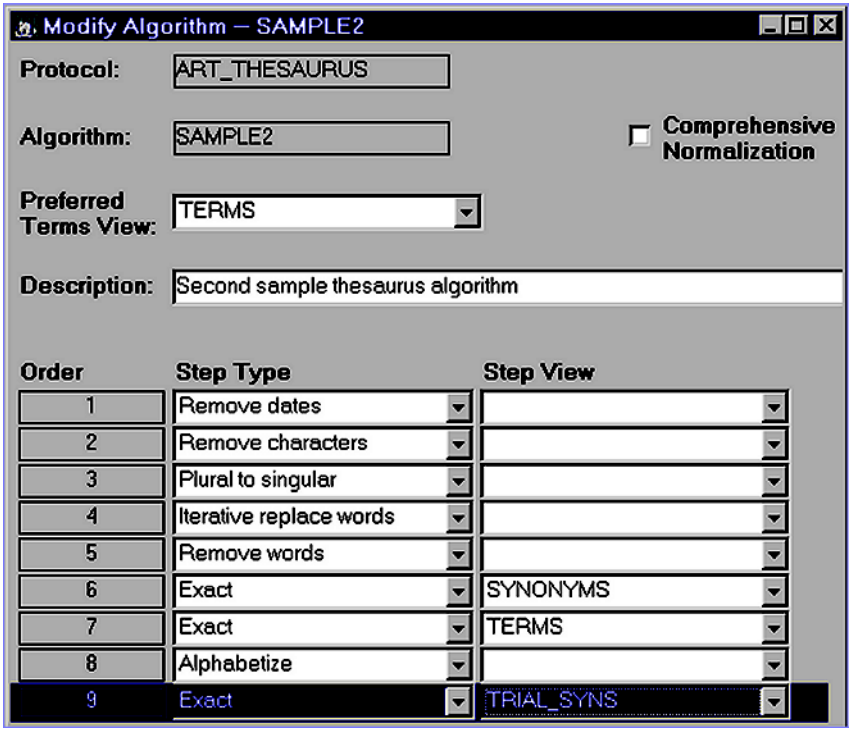
You can test this thesaurus algorithm before you begin using it for automatic coding. For more information, see "How to test a thesaurus algorithm" on page 299.

Thesaurus algorithm: second example

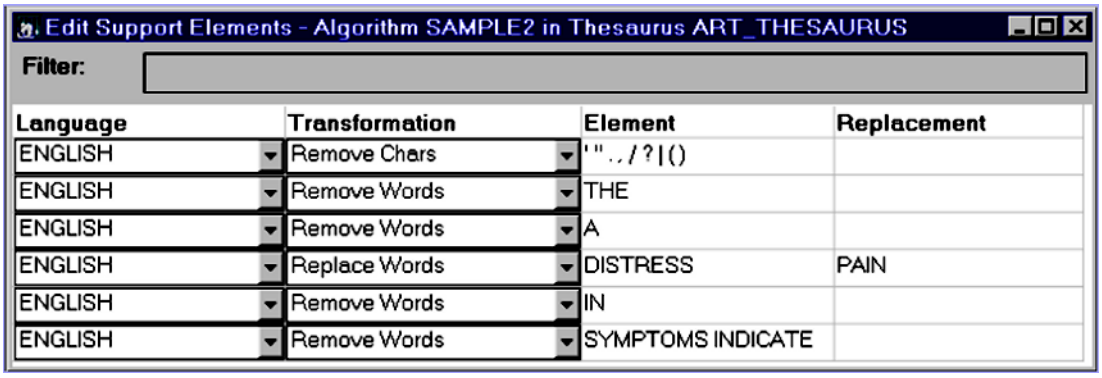
The following table shows another example of a thesaurus algorithm design and its corresponding step types:

Change needed:	Step type:
1. Remove any date-formatted numbers.	Remove Dates
2. Remove characters defined as support elements.	Remove Chars
3. Make all plural words singular.	Plural to Singular
4. Perform word substitutions iteratively, as defined in this transformation's support elements.	Iterative Replace Words
5. Remove all words defined as support elements.	Remove Words
6. Attempt a direct match of the transformed text with a synonym view.	Exact, step view is a synonym view
7. Attempt a direct match of the transformed text with the terms view.	Exact, step view is the terms view
8. Reorder words in alphabetical order.	Alphabetize Words
9. Attempt a direct match of the transformed text with a different synonym view.	Exact, step view is a different synonym view

The following example shows how this sample thesaurus algorithm appears when you create it in Design:



In Classify, you define the support elements for this thesaurus algorithm's Remove Chars, Iterative Replace Words, and Remove Words transformations. The following example shows the Edit Support Elements window for this thesaurus algorithm:



When support elements are entered for this thesaurus algorithm, all words and phrases entered are uppercase and singular. Because the third step in the thesaurus algorithm, Plural to Singular, makes all characters uppercase and changes all words to the singular form, this convention reflects the format that words and phrases will have when the thesaurus algorithm performs the Iterative Replace Words and Remove Words transformations, which are its fourth and fifth steps.

Testing a thesaurus algorithm in Classify

After you complete your design for a thesaurus algorithm and then create it in Design, you can use Classify to test its performance before it is used during automatic coding.

How to test a thesaurus algorithm

You test a thesaurus algorithm as follows:

1. In Classify's Algorithm Browser, select a thesaurus algorithm.
2. From the **Algorithm** menu, select **Test**, or double-click the row. The Test Algorithm dialog box opens.
3. Select a language view. The default is ENGLISH.
4. Enter a word or phrase in the Text to be Matched field.
5. Click **Test** or press **Enter**.

The thesaurus algorithm's transformations and lookup steps are applied to your entered text value to simulate automatic coding. All of the terms in the coding thesaurus protocol that match the transformed text display.

Note: To test a thesaurus algorithm, you must be assigned the following access rights and access levels:

- The Read or Full access level for Classify's Thesaurus access right for that algorithm's coding thesaurus protocol.
- The Read or Full access level for Design's non-protocol System access right.

How to test the first example

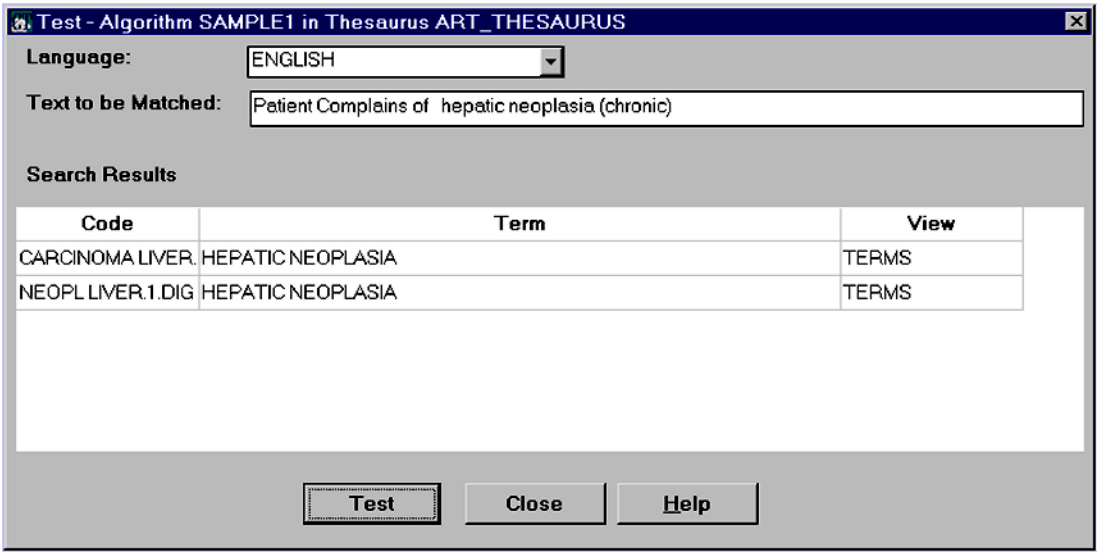
The verbatim text

Patient complains of hepatic neoplasia (chronic)

is transformed by the thesaurus algorithm created for the first example on page 295 by the following steps:

- The transformations in this thesaurus algorithm will capitalize all characters, and remove extra spaces and bracketed text.
- Support elements must be defined for the transformations that require them. When you test a thesaurus algorithm, you also test its support elements.
- The lookup steps attempt matches against the terms and synonyms views of the ART_THESAURUS coding thesaurus protocol, which is a version of the COSTART coding thesaurus.

The following example shows the results of this test in Classify:



By testing this thesaurus algorithm before you assign it to a coding target, you can determine if automatic coding will succeed or fail for any given text string. In this example, when the value

Patient complains of hepatic neoplasia (chronic)

is encountered during automatic coding, it will fail, because there are two different potential matches after the algorithm is applied. As a result, you may want to modify your thesaurus algorithm's step types or edit their defined support elements, or review the contents of the coding thesaurus protocol by using one of Classify's thesaurus reports.

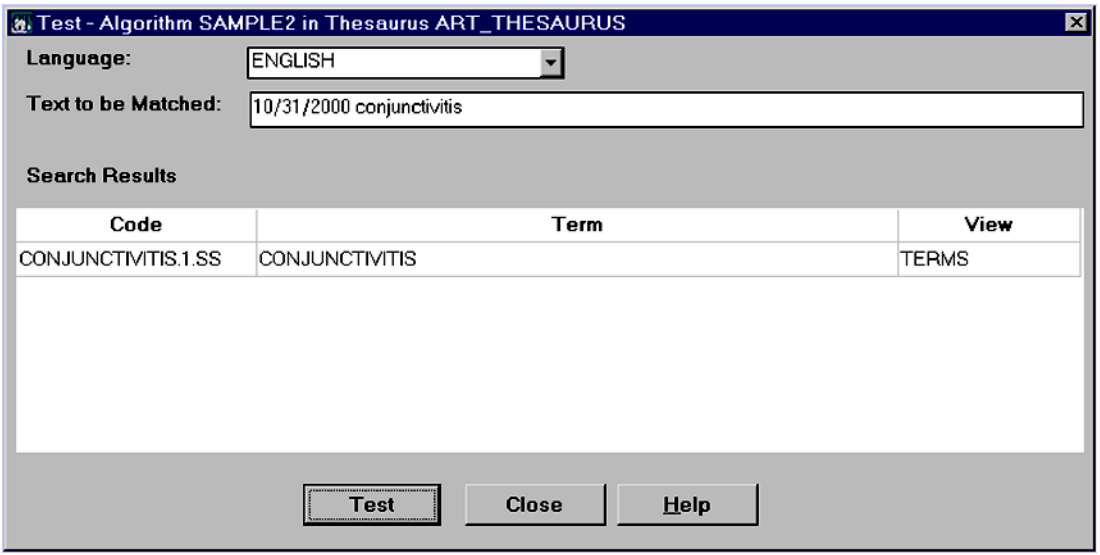
For more information on Classify's thesaurus reports, see Chapter 18.

How to test the second example

The following example displays the results of testing the verbatim text:

10/31/2000 conjunctivitis

against the thesaurus algorithm created for the second example, on page 297. Like the first example, the lookup steps in this thesaurus algorithm attempt matches to terms and synonyms views in a COSTART coding thesaurus protocol.



When automatic coding encounters the value

10/31/2000 conjunctivitis

and this thesaurus algorithm is used, coding succeeds at Step 7.

21 Classify and Multisite

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

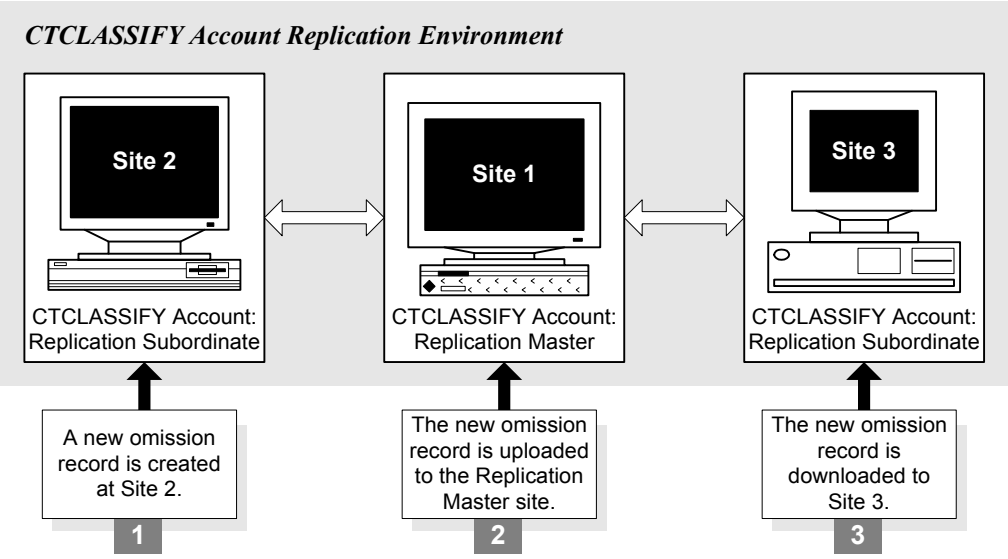
Creating Classify objects

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 *Multisite*.

What is an omission handling site?

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

The omission 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 which omissions, 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 in *Multisite*, 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, then 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 *Multisite*.

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. ***Note*:** Synonym solutions are *autoproposed* if the verbatim, thesaurus, algorithm, and omission handling sites are identical.	Status changes to *Solution Applied* once a flag is added to the source record or a discrepancy record is created.
Non-colocated Sites	Status changes to *Solved* if the verbatim change was autocoded. 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*. ***Note:*** This solution type requires two invocations of the autocoder.	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 *Solved*. See the previous Note in this table for information about autoproposed solutions.	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*.

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.

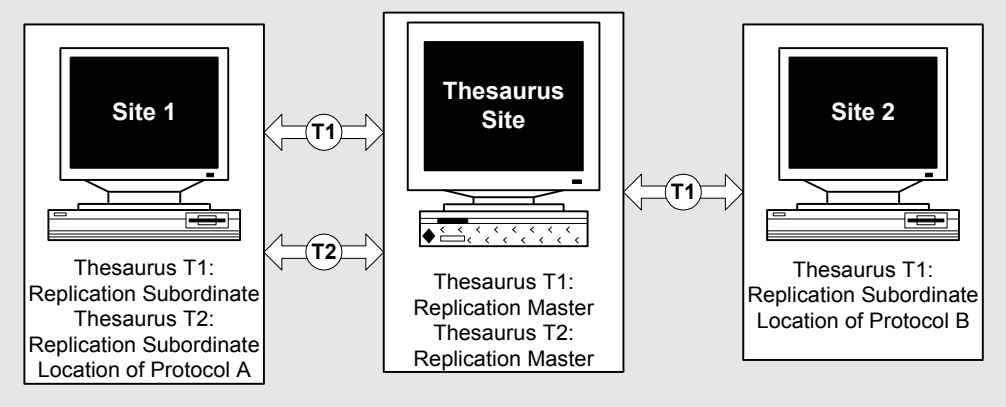
   Note: Do not use an asterisk (*) as a wildcard character in the Omission Handling Site field.

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

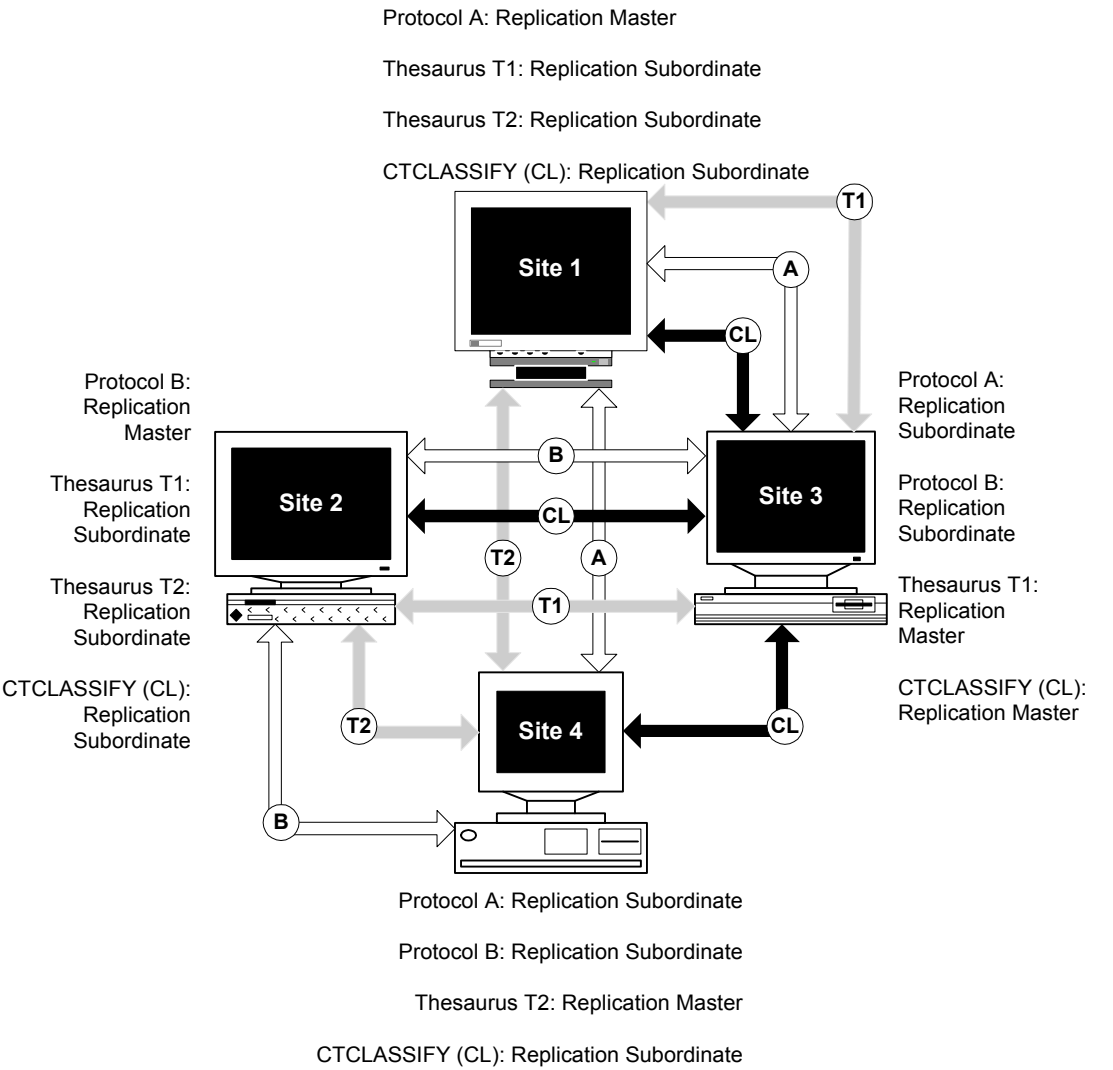
The following figure shows a Classify replication environment with two levels:

- 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 tables lists and describes the objects in this figure:

Object:	Description:
Thesaurus T1	Replicates between Site 3 and Site 1, and between Site 3 and Site 2. Synonyms added at Site 1, Site 2, or Site 3 replicate to the other two sites.

Object:	Description:
Thesaurus T2	Replicates between Site 4 and Site 1, and between Site 4 and Site 2. Synonyms added at Site 1, Site 2, or Site 4 replicate to the other two sites.
Protocol A	Replicates between Site 1 and Site 3, and between Site 1 and Site 4. Uses both Thesaurus T1 and Thesaurus T2. Coding in Manage is done at the site where clinical data was entered. Omission records are generated at Site 1. For coding targets that use Thesaurus T1, omission records are handled at Site 3. For coding targets that use Thesaurus T2, omission records are handled at Site 4.
Protocol B	Replicates between Site 2 and Site 3, and between Site 2 and Site 4. Uses both Thesaurus T1 and Thesaurus T2. Coding in Manage is done at the site where clinical data was entered. Omission records are generated at Site 2. For coding targets that use Thesaurus T1, omission records are handled at Site 3. For coding targets that use Thesaurus T2, omission records are handled at Site 4.
CTCLASSIFY account	Solutions generated at Site 3 or Site 4 are replicated as part of the CTCLASSIFY account to all other sites.

Example C

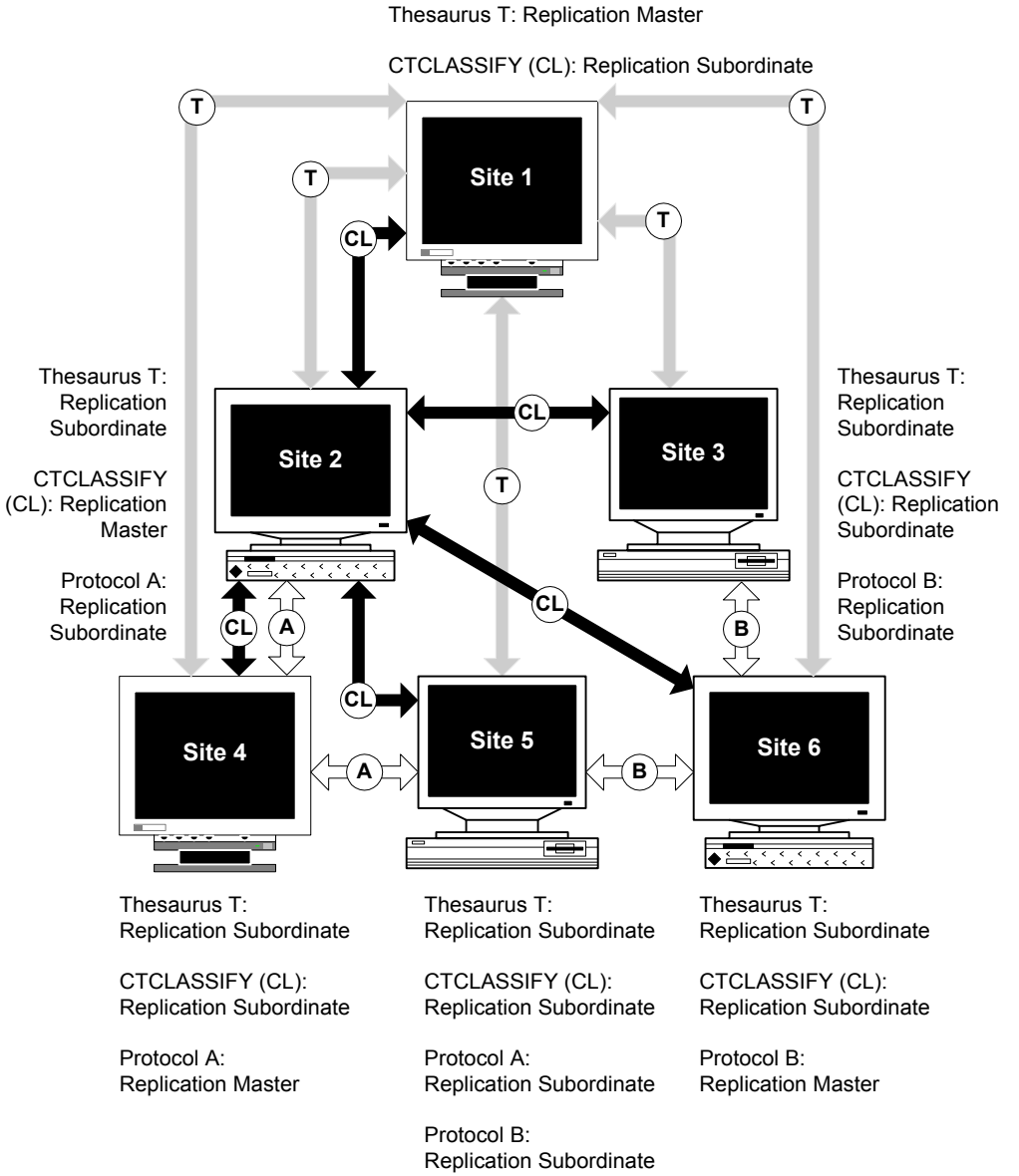
The following figure shows a Classify replication environment with three levels :

- 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 tables lists and describes the objects in this figure:

Object:	Description:
Thesaurus T	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. If Site 1, Site 2, or Site 3 adds synonyms, these synonyms are replicated to each site in the Multisite environment.
Protocol A	Replicates between Site 4 and Site 2, and between Site 4 and Site 5. Coding in Manage is done at the site where clinical data was entered. Omission records are generated at Site 4 and Site 5. Omission records are handled at Site 2.
Protocol B	Replicates between Site 6 and Site 3, and between Site 6 and Site 5. Coding in Manage is done at the site where clinical data was entered. Omission records are generated at Site 5 and Site 6. Omission records are handled at Site 3.
CTCLASSIFY account	Solutions generated at Site 2 or Site 3 are replicated as part of the CTCLASSIFY account to all other sites.

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.

Lab Loader

Chapter 31: Lab Loader and Multisite

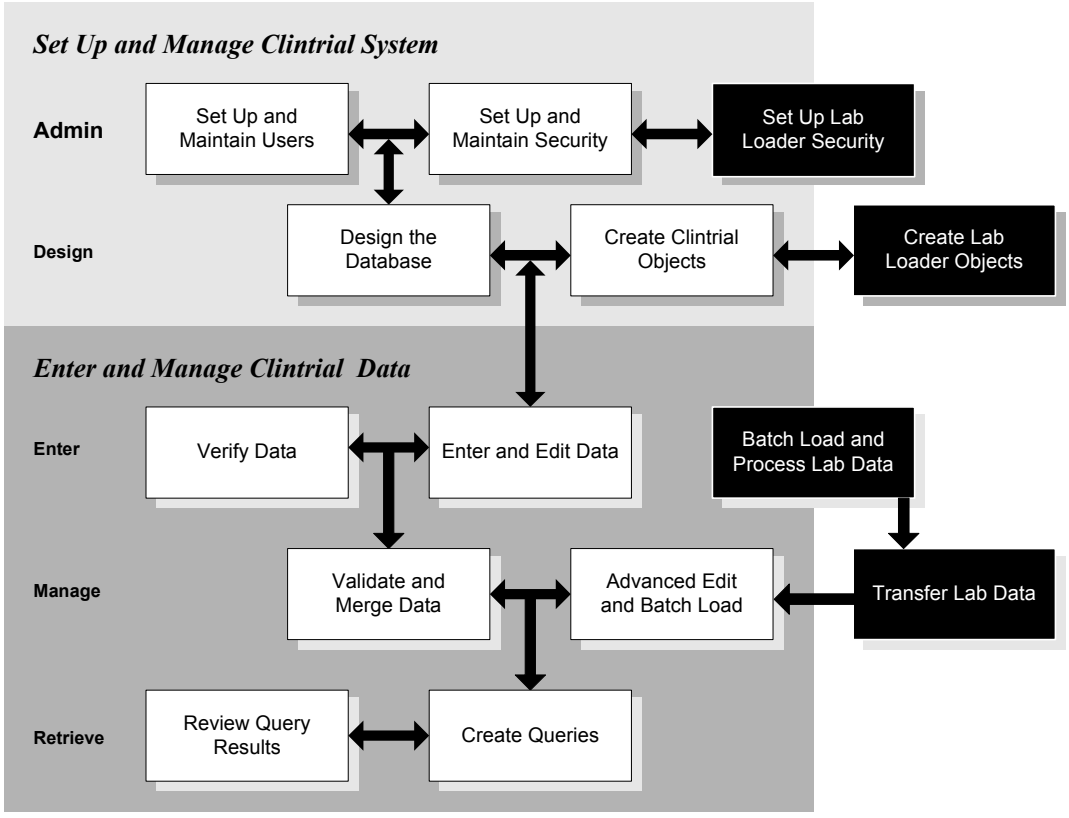
22 Introduction to Lab Loader

Overview

The Clintrial software Lab Loader module is a Clintrial software extended module that you use to:

- Batch load lab data into a source protocol
- Process the data
- Transfer the data into a clinical data destination protocol

The following figure shows how to set up the Clintrial software system and manage Clintrial software data. The figure indicates where Lab Loader fits in this system:



Why use Lab Loader?

Lab Loader extends the batch-loading capabilities that are provided in Manage.

Using Lab Loader, you first batch load data into a source protocol. You can then prepare the data through editing, screening, and validation to ensure that it is in the form that you want before transferring the data into the destination protocol.

What are source and destination protocols?

When you use Lab Loader to batch load laboratory data, you use two different types of protocols:

- A *source protocol* is a Lab Loader protocol (Type 4) into which you batch load lab data. You work with the lab data in this protocol to prepare it for transfer to the destination protocol.
- A *destination protocol* is a clinical data protocol (Type 1) that contains the clinical data for a study. You transfer the lab data into this protocol after preparing it in the source protocol.

Who uses Lab Loader?

Lab Loader users are generally data managers who are responsible for receiving lab data from central laboratories, and then preparing the lab data to be placed in the destination protocol for a study.

This module is also used by designers, who may be responsible for creating control files and transfer maps.

Batch loading data

Using Lab Loader, you can place lab data into the update tables of a source protocol. *Batch loading* is the process of taking data that is stored in an ASCII file and placing that data directly into a Clintrial software database table.

Lab Loader uses Oracle SQL*Loader to perform the initial step in the batch-loading process.

What is an input file?

An *input file* is an ASCII file that contains lab data to be batch loaded into the Clintrial software. Each line in the input file is a record composed of delimited fields. Each field in a record contains data that will be batch loaded into an item in the source protocol.

For each input file, you create a control file to describe how data from the input file will be batch loaded into the source protocol.

What is a control file?

A *control file* is a file that describes how data from an input file will be batch loaded into the source protocol. The control file:

- Interprets the organization and format of data in the input file for SQL*Loader.
- Provides instructions on how SQL*Loader loads data from the input file into the database table.

Preparing data for transfer

The structure of the data in the input file may differ from the structure of the data in the destination protocol. For example, one item in the destination protocol may be the result of a calculation between two different items in the input file. Or, the data type of an item in the input file may be different from the data type of the same item in the destination protocol.

You can manipulate the data in the source protocol using editing, screening, and validation procedures to prepare the data for transfer. You must prepare the data to ensure that it corresponds to the structure of the data in the destination protocol.

After you batch load data, you must perform the following tasks to prepare the data for transfer:

- Screen the data.
- Validate the records.

Optionally, you can perform the following additional tasks:

- Edit the records.
- Delete unscreened records.

About screening records

Screening is a combination of several processes performed from one menu command. You screen records after data is batch loaded into the source protocol. When you screen records, Lab Loader performs the following:

- **Updates the system items.** The system items in records that were successfully batch loaded into the database table are given values. The values assigned are equivalent to those assigned when you interactively enter records through Enter. A *system item* is an internal item used by the Clintrial software to uniquely identify records. System items are automatically attached to each record.
- **Groups the records into observations**, if grouping items are indicated in Design. Grouping the records organizes batch-loaded records into observations. An *observation* is a group of records in a page section that contains repeating items, or a group of records in a non-subject study book that has been configured for grouping. For example, you might group multiple blood tests that were taken on one sample into a single observation.
- **Applies data checks to batch-loaded data.** When data checks are applied to batch-loaded data, the same checks that are applied to interactively entered data are applied.

About validating records

Validation is the process of running a validation procedure on clinical data to ensure that the data meets the requirements of the clinical trial for logical and consistent data. Validation also applies any derivations that are defined. Data can either pass or fail validation.

Each panel has one validation procedure. A *validation procedure* is a PL/SQL procedure that is built automatically from the derivations and rules associated with the panel:

- *Derivations* calculate values of items or temporary variables that the designer has set up as Derived based on constants or on the values of other items.
- *Rules* are PL/SQL statements that evaluate to either true or false.

Because the panels in the source protocol can differ from the panels in the destination protocol, you may need to use the validation procedure to help prepare the data for transfer.

Transferring data

Data transfer is the process of moving data from a source protocol to a destination protocol. The transfer is directed by criteria specified in a transfer map.

You can only transfer data from a Type 4 - Lab Loader protocol into a Type 1 - Clinical Data protocol. That is, the source protocol must be a Lab Loader type protocol, and the destination protocol must be a Clinical Data type protocol.

What is a transfer map?

A *transfer map* indicates the data to be transferred from a source protocol to a destination protocol by establishing a direct connection from the source items to the destination items. The transfer map indicates which data will be transferred, and indicates the location for the transferred data to be stored.

How data is transferred

When you transfer data, you set the current protocol to the destination protocol into which you want to transfer data. You then select the transfer map that you want to use to transfer data, and then start the transfer.

After transferring data

After you transfer the data into the destination protocol, you can use the following reports to check the status of the data transfer and the records:

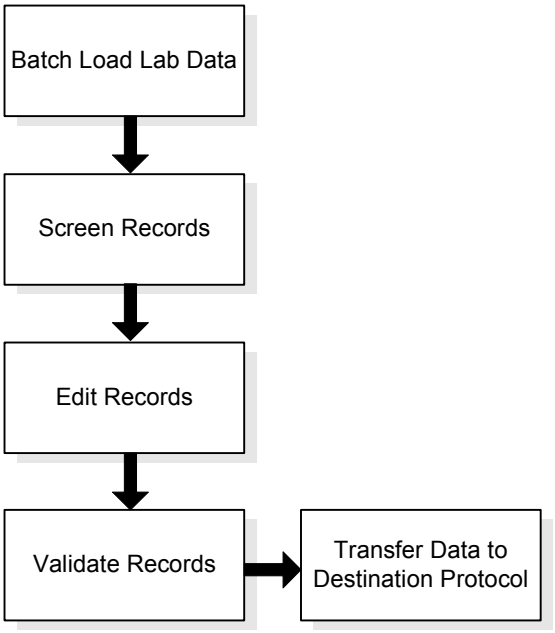
- Duplicates Report
- Error Log
- Transfer Log

If errors occur during the transfer, entries appear in the source protocol's Error Log for records that did not transfer. Entries appear in the destination protocol's Error Log for records that transferred, but that encountered an error, such as a screening error, during the transfer process.

If the data transferred successfully, you can work with the data in the destination protocol as you would with any interactively entered data, or with data that was batch loaded through Manage.

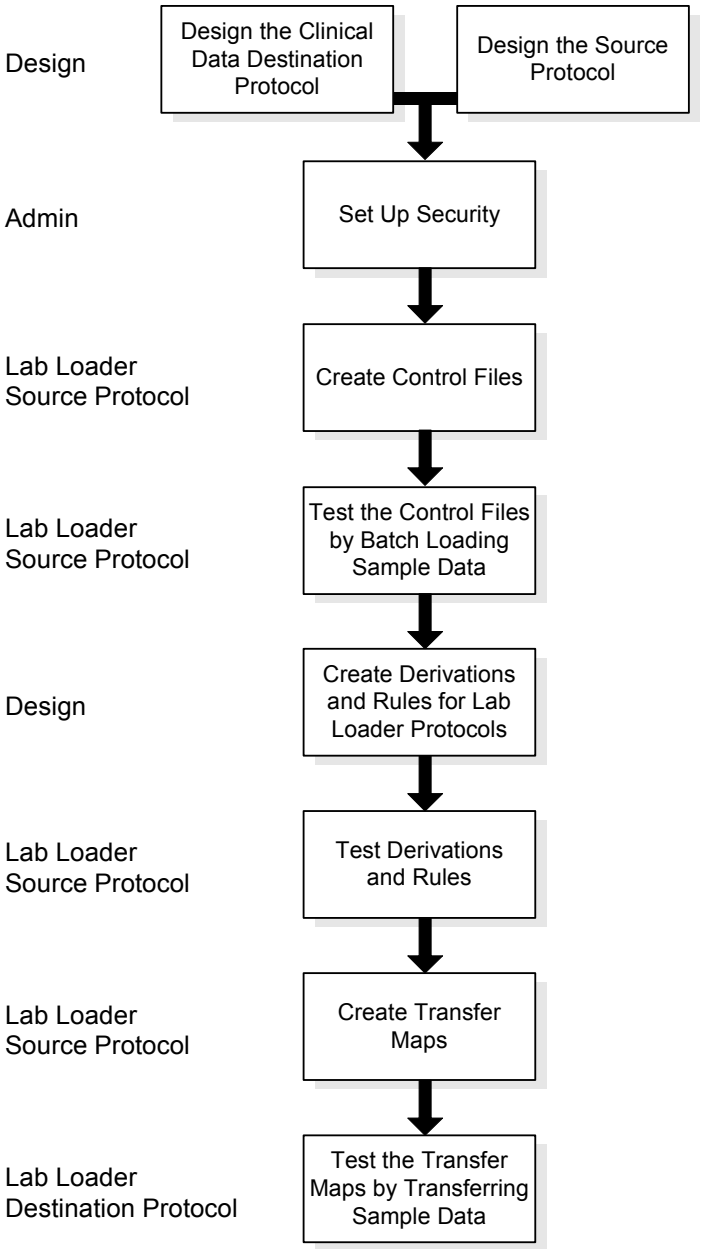
Lab Loader workflow

The following figure shows the workflow that you should follow to batch load and transfer lab data using Lab Loader. These tasks are described in Part I:



Lab Loader setup workflow

The following figure shows the workflow you should use to set up Lab Loader. These tasks are described in Part II:

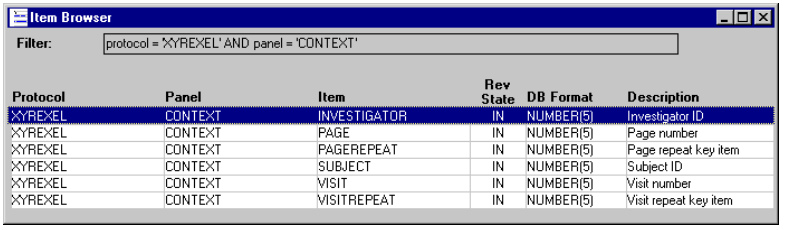


Example

The following example demonstrates the batch loading, screening, validation, and transferring processes.

Destination panel structure

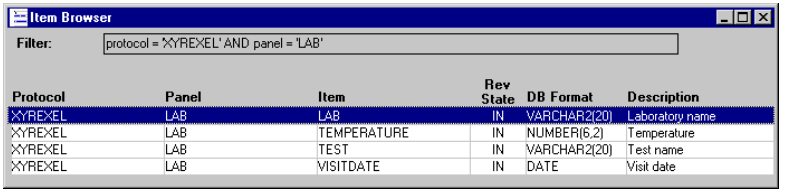
The following CONTEXT panel and LAB panel were set up for the XYREXEL protocol to be used as the destination panels:



Item Browser

Filter: protocol = 'XYREXEL' AND panel = 'CONTEXT'

Protocol	Panel	Item	Rev State	DB Format	Description
XYREXEL	CONTEXT	INVESTIGATOR	IN	NUMBER(5)	Investigator ID
XYREXEL	CONTEXT	PAGE	IN	NUMBER(5)	Page number
XYREXEL	CONTEXT	PAGEREPEAT	IN	NUMBER(5)	Page repeat key item
XYREXEL	CONTEXT	SUBJECT	IN	NUMBER(5)	Subject ID
XYREXEL	CONTEXT	VISIT	IN	NUMBER(5)	Visit number
XYREXEL	CONTEXT	VISITREPEAT	IN	NUMBER(5)	Visit repeat key item



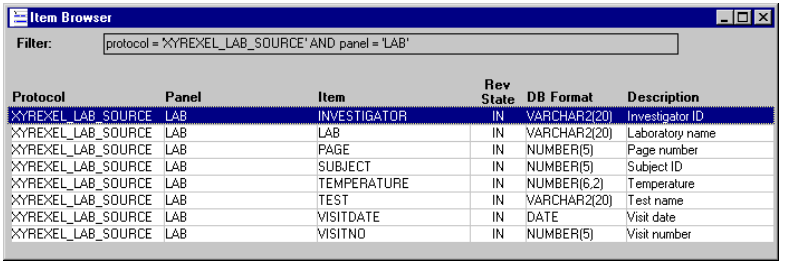
Item Browser

Filter: protocol = 'XYREXEL' AND panel = 'LAB'

Protocol	Panel	Item	Rev State	DB Format	Description
XYREXEL	LAB	LAB	IN	VARCHAR2(20)	Laboratory name
XYREXEL	LAB	TEMPERATURE	IN	NUMBER(6,2)	Temperature
XYREXEL	LAB	TEST	IN	VARCHAR2(20)	Test name
XYREXEL	LAB	VISITDATE	IN	DATE	Visit date

Source panel structure

The following LAB panel was set up for the XYREXEL_LAB_SRC protocol to be used as the source panel:



Item Browser

Filter: protocol = 'XYREXEL_LAB_SOURCE' AND panel = 'LAB'

Protocol	Panel	Item	Rev State	DB Format	Description
XYREXEL_LAB_SOURCE	LAB	INVESTIGATOR	IN	VARCHAR2(20)	Investigator ID
XYREXEL_LAB_SOURCE	LAB	LAB	IN	VARCHAR2(20)	Laboratory name
XYREXEL_LAB_SOURCE	LAB	PAGE	IN	NUMBER(5)	Page number
XYREXEL_LAB_SOURCE	LAB	SUBJECT	IN	NUMBER(5)	Subject ID
XYREXEL_LAB_SOURCE	LAB	TEMPERATURE	IN	NUMBER(6,2)	Temperature
XYREXEL_LAB_SOURCE	LAB	TEST	IN	VARCHAR2(20)	Test name
XYREXEL_LAB_SOURCE	LAB	VISITDATE	IN	DATE	Visit date
XYREXEL_LAB_SOURCE	LAB	VISITNO	IN	NUMBER(5)	Visit number

Input file

The following input file, named SOURCE.TXT, contains six records that provide results of two specific lab tests (XGT and XGX) for six patients:

```
001,NATIONAL LABS,XGT,012,1,1,12/11/1998,98.1
002,NATIONAL LABS,XGX,013,1,1,12/11/1998,98.5
003,NATIONAL LABS,XGX,012,1,1,12/11/1998,98.5
004,NATIONAL LABS,XGX,012,1,1,12/11/1998,99.6
005,NATIONAL LABS,XGT,013,1,1,12/11/1998,100.0
006,NATIONAL LABS,XGT,013,1,1,12/11/1998,100.2
```

Control file

The lab data from the SOURCE.TXT input file was loaded into the LAB panel of the XYREXEL_LAB_SRC protocol using the following control file named LAB.CTL:

```
----------Control file for loading data into:
XYREXEL_LAB_SRC.LAB_UPDATE
----------LOAD DATA
REPLACE
INTO TABLE XYREXEL_LAB_SRC.LAB_UPDATE
-- Note: Change @ to your file's separator character and adjust the 'ENCLOSED BY' clause
FIELDS TERMINATED BY ',' OPTIONALLY ENCLOSED BY ""
TRAILING NULLCOLS
(STATUS              constant    3,
CT_RECID             sequence    (count),
SUBJECT_ID           constant    0,
SUBJECT              "RTRIM(LTRIM(:SUBJECT))",
LAB                  "RTRIM(LTRIM(:LAB))",
TEST                 "RTRIM(LTRIM(:TEST))",
INVESTIGATOR         NULLIF INVESTIGATOR=BLANKS,
PAGE                 NULLIF PAGE=BLANKS,
VISITNO              NULLIF VISITNO=BLANKS,
VISITDATE            DATE "MM/DD/YYYY" ,
TEMPERATURE          NULLIF TEMPERATURE=BLANKS)
```

Batch Load Log

The batch load completed successfully, as indicated in the following Batch Load Log:

```
SQL*Loader: Release 11.2.0.1.0 - Production on Mon Mar 19 14:45:02 2012

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 (Allow all discards)

Number to load: ALL
Number to skip: 0
Errors allowed: 50
Bind array:     64 rows, maximum of 256000 bytes
Continuation:    none specified
Path used:      Conventional

Table XYREXEL_LAB_SRC.LAB_UPDATE, loaded from every logical record.
Insert option in effect for this table: APPEND
TRAILING NULLCOLS option in effect

  Column Name                  Position   Len  Term Encl Datatype
------------------------------ ---------- ----- ---- ---- ---------------------
STATUS                         CONSTANT       Value is '3'
CT_RECID                       SEQUENCE       (COUNT, 1)
SUBJECT_ID                     CONSTANT       Value is '0'
SUBJECT                        FIRST     *   , O(") CHARACTER
SQL string for column : "RTRIM(LTRIM(:SUBJECT))"
LAB                            NEXT      *   , O(") CHARACTER
   SQL string for column : "RTRIM(LTRIM(:LAB))"
TEST                           NEXT      *   , O(") CHARACTER
   SQL string for column : "RTRIM(LTRIM(:TEST))"
INVESTIGATOR                   NEXT      *   , O(") CHARACTER
   NULL if INVESTIGATOR = BLANKS
PAGE                           NEXT      *   , O(") CHARACTER
   NULL if PAGE = BLANKS
VISITNO                        NEXT      *   , O(") CHARACTER
   NULL if VISITNO = BLANKS
VISITDATE                      NEXT      *   , O(") DATE MM/DD/YYYY
TEMPERATURE                    NEXT      *   , O(") CHARACTER
```

```
    NULL if TEMPERATURE = BLANKS

Table XYREXEL_LAB_SRC.LAB_UPDATE:
  6 Rows successfully loaded.
  0 Rows not loaded due to data errors.
  0 Rows not loaded because all WHEN clauses were failed.
  0 Rows not loaded because all fields were null.

Space allocated for bind array:                133824 bytes(64 rows)
Read   buffer bytes: 1048576

Total logical records skipped:          0
Total logical records read:             6
Total logical records rejected:         0
Total logical records discarded:        0

Run began on Mon Mar 19 14:45:02 2012
Run ended on Mon Mar 19 14:45:04 2012

Elapsed time was:     00:00:01.31
CPU time was:         00:00:00.07
```

Records after batch loading

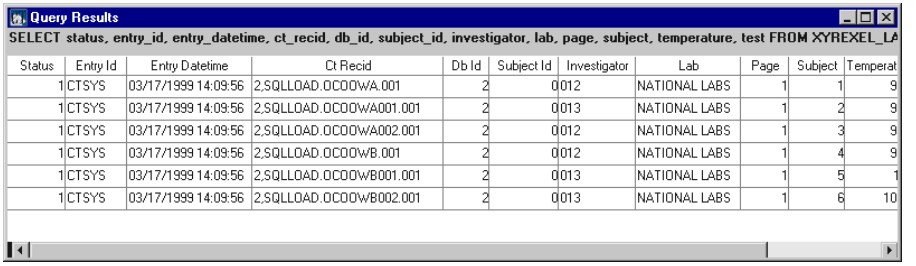
The following example shows the records as they initially appear in the LAB_UPDATE table after batch loading, but before any of the data preparation tasks have occurred. Note the values for the system items ENTRY_ID and CT_RECID:

Loaded Records

Status	Entry Id	Entry Datetime	Ct Recid	Db Id	Subject Id	Investigator	Lab	Page	Subject	Temperature	
3	CTS$LOAD_XYREXEL_LAB	03/17/1999 14:09:56	1	2	0	012	NATIONAL LABS	1	1	98.1	XGT
3	CTS$LOAD_XYREXEL_LAB	03/17/1999 14:09:56	2	2	0	013	NATIONAL LABS	1	2	98.5	XGX
3	CTS$LOAD_XYREXEL_LAB	03/17/1999 14:09:56	3	2	0	012	NATIONAL LABS	1	3	98.5	XGX
3	CTS$LOAD_XYREXEL_LAB	03/17/1999 14:09:56	4	2	0	012	NATIONAL LABS	1	4	99.6	XGX
3	CTS$LOAD_XYREXEL_LAB	03/17/1999 14:09:56	5	2	0	013	NATIONAL LABS	1	5	100	XGT
3	CTS$LOAD_XYREXEL_LAB	03/17/1999 14:09:56	6	2	0	013	NATIONAL LABS	1	6	100.2	XGT

Records after screening

The following example shows the records as they appear in the LAB_UPDATE table after screening. Note the new value for the system item STATUS:



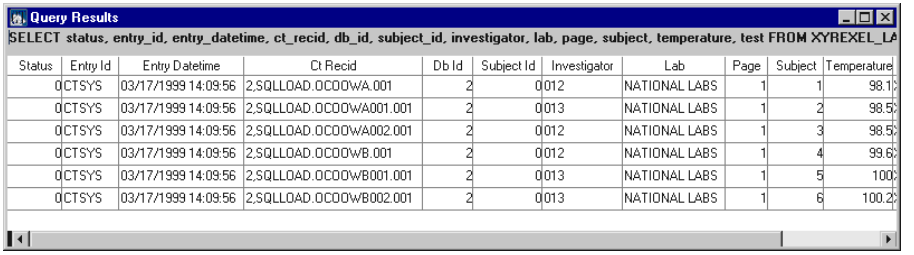
Query Results

SELECT status, entry_id, entry_datetime, ct_recid, db_id, subject_id, investigator, lab, page, subject, temperature, test FROM XYREXEL_LA

Status	Entry Id	Entry Datetime	Ct Recid	Db Id	Subject Id	Investigator	Lab	Page	Subject	Temperat
1	CTSYS	03/17/1999 14:09:56	2,SQLLOAD.OCOOWA.001	2	0	012	NATIONAL LABS	1	1	9
1	CTSYS	03/17/1999 14:09:56	2,SQLLOAD.OCOOWA001.001	2	0	013	NATIONAL LABS	1	2	9
1	CTSYS	03/17/1999 14:09:56	2,SQLLOAD.OCOOWA002.001	2	0	012	NATIONAL LABS	1	3	9
1	CTSYS	03/17/1999 14:09:56	2,SQLLOAD.OCOOWB.001	2	0	012	NATIONAL LABS	1	4	9
1	CTSYS	03/17/1999 14:09:56	2,SQLLOAD.OCOOWB001.001	2	0	013	NATIONAL LABS	1	5	1
1	CTSYS	03/17/1999 14:09:56	2,SQLLOAD.OCOOWB002.001	2	0	013	NATIONAL LABS	1	6	10

Records after validation

The following example shows the records as they appear in the LAB_UPDATE table after successful validation. Note the new value for the system item STATUS:



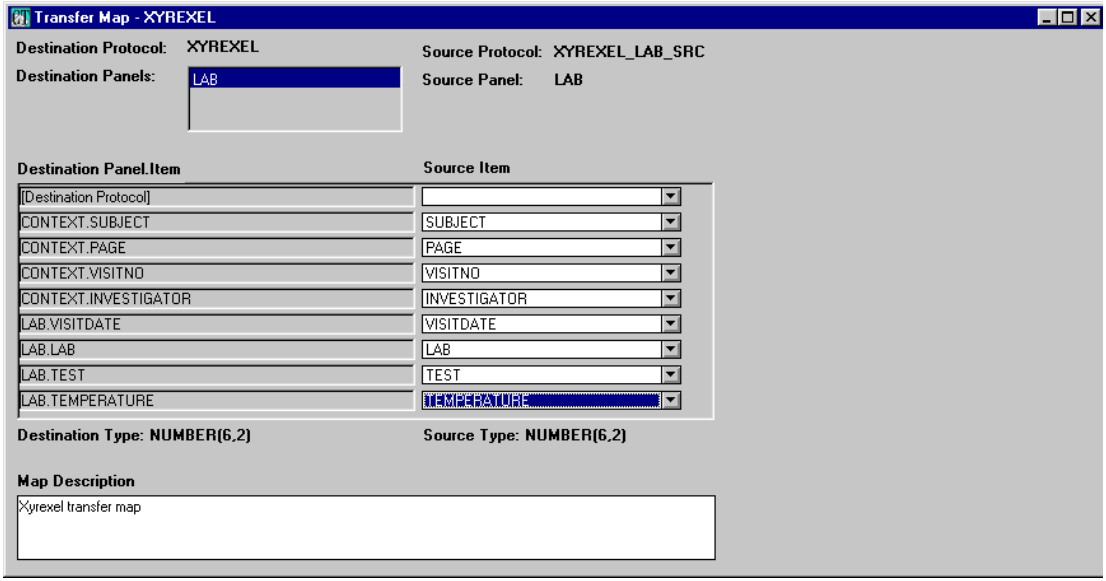
Query Results

SELECT status, entry_id, entry_datetime, ct_recid, db_id, subject_id, investigator, lab, page, subject, temperature, test FROM XYREXEL_LA

Status	Entry Id	Entry Datetime	Ct Recid	Db Id	Subject Id	Investigator	Lab	Page	Subject	Temperature
0	CTSYS	03/17/1999 14:09:56	2,SQLLOAD.OCOOWA.001	2	0	012	NATIONAL LABS	1	1	98.1
0	CTSYS	03/17/1999 14:09:56	2,SQLLOAD.OCOOWA001.001	2	0	013	NATIONAL LABS	1	2	98.5
0	CTSYS	03/17/1999 14:09:56	2,SQLLOAD.OCOOWA002.001	2	0	012	NATIONAL LABS	1	3	98.5
0	CTSYS	03/17/1999 14:09:56	2,SQLLOAD.OCOOWB.001	2	0	012	NATIONAL LABS	1	4	99.6
0	CTSYS	03/17/1999 14:09:56	2,SQLLOAD.OCOOWB001.001	2	0	013	NATIONAL LABS	1	5	100
0	CTSYS	03/17/1999 14:09:56	2,SQLLOAD.OCOOWB002.001	2	0	013	NATIONAL LABS	1	6	100.2

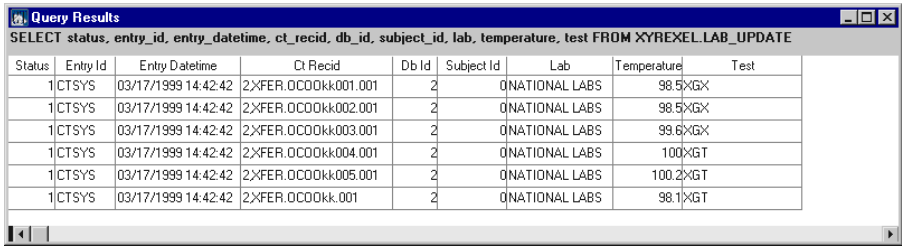
Transfer map

The following transfer map transfers the records from the LAB panel of the XYREXEL_LAB_SRC source protocol to the CONTEXT and LAB panels of the XYREXEL destination protocol:



Records after transfer

The following example shows the records as they appear in the LAB_UPDATE table in the XYREXEL protocol after they have been transferred. Note the new values for the system items CT_RECID and SUBJECT_ID:



Status	Entry Id	Entry Datetime	Ct Recid	Db Id	Subject Id	Lab	Temperature	Test
1	CTSYS	03/17/1999 14:42:42	2:XFER.OCOOkk001.001	2	0	NATIONAL LABS	98.5	XGX
1	CTSYS	03/17/1999 14:42:42	2:XFER.OCOOkk002.001	2	0	NATIONAL LABS	98.5	XGX
1	CTSYS	03/17/1999 14:42:42	2:XFER.OCOOkk003.001	2	0	NATIONAL LABS	99.6	XGX
1	CTSYS	03/17/1999 14:42:42	2:XFER.OCOOkk004.001	2	0	NATIONAL LABS	100	XGT
1	CTSYS	03/17/1999 14:42:42	2:XFER.OCOOkk005.001	2	0	NATIONAL LABS	100.2	XGT
1	CTSYS	03/17/1999 14:42:42	2:XFER.OCOOkk.001	2	0	NATIONAL LABS	98.1	XGT

23 Batch Loading Lab Data

Overview

Lab data for a clinical study typically comes from a central laboratory as raw data in an ASCII file. Using Lab Loader, you batch load this data into a source protocol, and then perform the following tasks:

- Edit the raw data.
- Validate the data.
- Transfer the prepared data into a destination protocol.

You cannot batch load data directly into a clinical data protocol. You perform batch loading in the source protocol. You must first set the current protocol to the source protocol to batch load data.

If you are using master-detail panels, you must batch load the master panel data before you batch load the detail panel data.

What is batch loading?

Batch loading is the process of taking data that is stored in an ASCII file and placing the data directly into a Clintrial software database table.

When you batch load data, you need two files:

- An input file. An *input file* is an ASCII file that contains lab data.
- A control file. A *control file* is a file that describes how data from an input file will be batch loaded into the source protocol

What is an input file?

An *input file* is an ASCII file that contains lab data. Each line in the file is a record composed of fields. Each field contains data that will be batch loaded into a Clintrial software item.

There can be data for one specific protocol or for multiple protocols in the same input file. The input file can be in either fixed format or variable format.

The following example shows records in a variable format input file. Each line corresponds to a single record, with fields separated by commas:

```
325,M89,0,022,3/9,5/15/1995 00:00:00,0,ASH,,4/13/1994 00:00:00,5/15/1995 00:00:00,1
325,M89,0,023,3/9,4/5/1995 00:00:00,1,L-W,,6/7/1980 00:00:00,4/5/1995 00:00:00,14,1
325,M42,0,007,3/9,7/9/1976 00:00:00,1,MDS,,1/1/1961 00:00:00,1/1/1976 00:00:00,,1,2
325,99,0,998,3/9,1/1/1911 00:00:00,1,MEH,,2/2/1922 00:00:00,1/1/1911 00:00:00,,1,1,
```

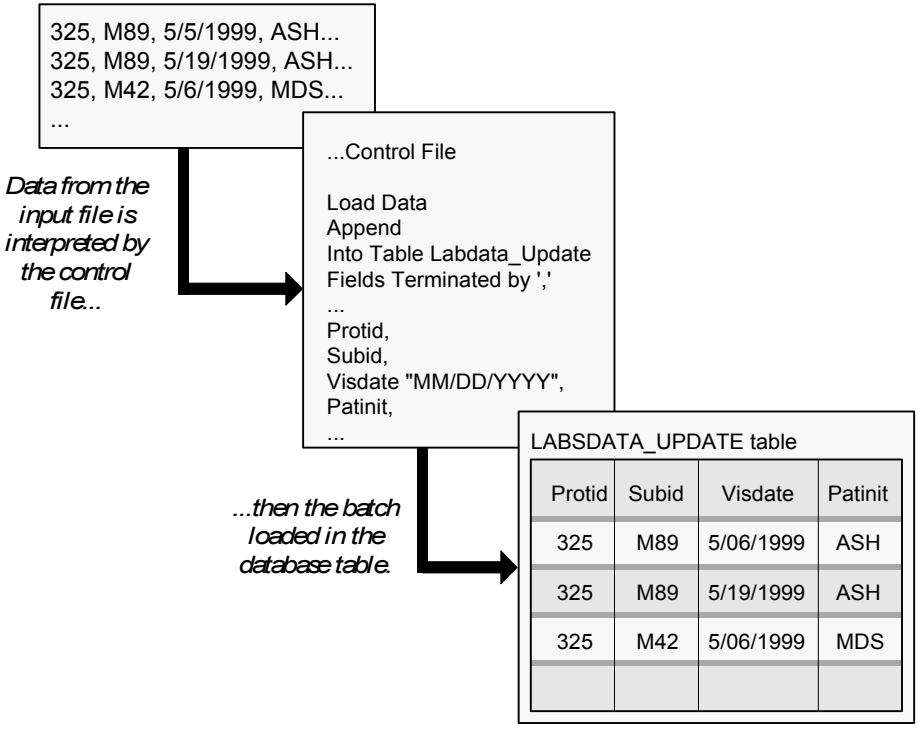
Note: You must edit the control file to match the structure and order of the data you will be batch loading.

What is a control file?

A *control file* is a file that describes how data from an input file will be batch loaded into the source protocol. It functions as the interface between the input file and the Clintrial software database tables, and specifies the location where the Clintrial software should store the data. In Lab Loader, this initial storage location is a panel in a source protocol.

You do not need to batch load all of the information in the input file to the source protocol. You can selectively eliminate information that should not be batch loaded by removing the associated item from the control file.

The following figure shows the interaction between the input file, the control file, and the Clintrial software database:



Using Lab Loader, you can create new control files or edit existing control files. These control files can be stored in the database control file library, and are then available to any user with the correct privileges. You can also save control files to a file on your client.

Note: You must save the control file to a file on your client before you can use it to batch load data.

The following example shows a sample control file for batch loading data into the LAB panel of the XYREXEL_LAB_SRC protocol:

```
---------- Control file for loading data into:
    XYREXEL_LAB_SRC.LAB_UPDATE
----------LOAD DATA
REPLACE
INTO TABLE XYREXEL_LAB_SRC.LAB_UPDATE

-- Note: Change @ to your file's separator character and adjust the 'ENCLOSED BY' clause
FIELDS TERMINATED BY ',' OPTIONALLY ENCLOSED BY ""
TRAILING NULLCOLS
(STATUS              constant    3,
CT_RECID             sequence    (count),
SUBJECT_ID           constant    0,
SUBJECT              "RTRIM(LTRIM(:SUBJECT))",
LAB                  "RTRIM(LTRIM(:LAB))",
TEST                 "RTRIM(LTRIM(:TEST))",
INVESTIGATOR         NULLIF INVESTIGATOR=BLANKS,
PAGE                 NULLIF PAGE=BLANKS,
VISITNO              NULLIF VISITNO=BLANKS,
VISITDATE            DATE "MM/DD/YYYY" ,
TEMPERATURE          NULLIF TEMPERATURE=BLANKS)
```

Additional information

For more information on creating, editing, and saving control files, see Chapter 30.

Using the control file library

During the course of a clinical study, you may receive multiple input files from different labs. You can create standard control files to batch load the data, and then store the control files in the database control file library.

After the control files are saved to the library, they can be accessed by any user who has the correct privileges, and can then be used multiple times. You and other users do not have to recreate the control files each time you receive data from the labs.

Batch loading data

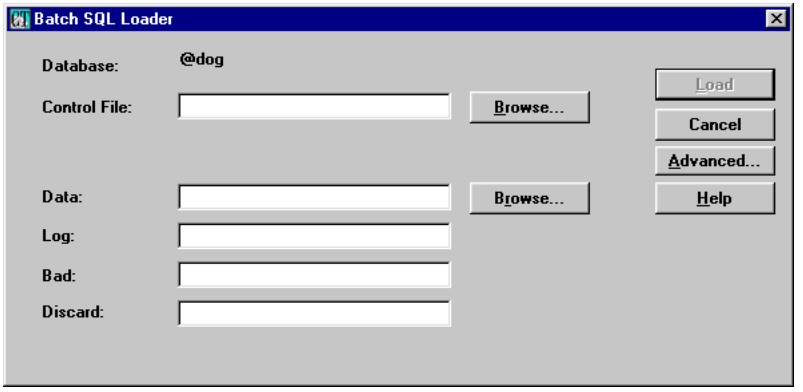
When you batch load data, the input file and the control file that you want to use must be saved as files on your client or on a network in an accessible location. You cannot use a control file for batch loading data while it is stored in the control file library. If either the input file or the control file is missing, the Clintrial software cannot batch load the data.

The Clintrial software uses Oracle SQL Loader to batch load data. For more information on batch loading, see your Oracle SQL Loader documentation.

Note: To batch load data, you must have the Oracle SQL Loader Utilities included with Oracle8 installed on your client, and you must connect to the Clintrial software using an Oracle Net8 alias.

How to batch load data

To batch load data, from the **Load** menu, select **Load Data**. The Batch SQL Loader dialog box opens:



In this dialog box, you specify the control file and the input file that you want to use for the batch load. The Clintrial software saves the files in this dialog box as default values for the next session. You can change these default values.

The Clintrial software also creates default names for three additional files. You can change the default names of the files. The following table describes the files:

File:	Description:
Log	The Log file is a SQL Loader file that records information about the batch load. For example, the Log file specifies any errors that occur with a record during the batch load. You can use this file to determine if the batch load was successful. The default name for the Log file is the name of the control file with the three-character extension .LOG. For example, if the control file name is **loaddata.ctl**, then the default Log file name is **loaddata.LOG**. This file is stored by default in the same directory as the control file. You can change this default. For information on viewing this file, see page 343.
Bad	The Bad file contains records that could not be successfully batch loaded. For example, if a value exceeds its maximum length, then the record is copied into this file. After the batch load completes, you can edit the records in the Bad file, and then use the Bad file as the new input file. The default name for the Bad file is the name of the input file with the three-character extension .BAD. For example, if the name of the input file is **labdata.dat**, then the default Bad file name is **labdata.BAD**. This file is stored by default in the same directory as the input file. You can change this default.
Discard	The Discard file contains records that do not meet the batch load criteria. You can edit the records in this Discard file, and then use this file as the new input file. The default name for the Discard file is the name of the input file with the three-character extension .DIS. For example, if the name if the input file is **labdata.dat**, then the default Discard file name is **labdata.DIS**. This file is stored by default in the same directory as the input file.You can change this default. For information on specifying batch load criteria, see your Oracle SQL Loader documentation.

Note: Although the Clintrial software creates default names for the Bad file and the Discard file, these files are optional. The files will not be generated if you delete the default names from the dialog box.

About advanced Batch Loader options

You can set advanced SQL Loader options by clicking **Advanced** to open the Advanced Batch Loader dialog box.

The following table describes the options you can set in the Advanced Batch Loader dialog box:

Option:	Description:	SQL Loader parameter:
Records to Skip	The number of logical records from the beginning of the file that should not be loaded. Use this option to continue batch loads that have been interrupted.	SKIP
Records to Load	The number of logical records to load after skipping the number of records specified in Records to Skip.	LOAD
Rows per Commit	The number of rows in the bind array.	ROWS
Maximum Errors	The number of insert errors allowed before SQL Loader terminates with an error.	ERRORS
Maximum Discards	The number of discards allowed before SQL Loader terminates with an error.	DISCARDMAX
Maximum Bind Array	The maximum size in bytes of the bind array.	BINDSIZE

How to begin batch loading

Once you have indicated the control file and the input file to use and have optionally set advanced SQL Loader options, you can begin the batch load.

To begin the batch load in the Batch SQL Loader dialog box, click **Load**. The batch load begins.

About the record status and system items

The system items STATUS, CT_RECID, and SUBJECT_ID are included in the default control file. When you batch load records into Lab Loader, values for the system items are defined automatically. The following table lists the system items and the values to which they are set:

System item:	Default value:
STATUS	Unscreened (3)
CT_RECID	An increasing integer that is one number higher than the largest current value
SUBJECT_ID	0

Note: New values for these system items are created when you screen the items.

For more information on screening items, see page 347.

About the Batch Load Log

The *Batch Load Log* (also called the Log file) is a SQL Loader file that records information about the batch load as it occurs. You can use this report to help determine if the batch load completed successfully.

To display the Batch Load Log from within the Clintrial software, from the **Reports** menu, select **Batch Load Log**. The Open dialog box displays.

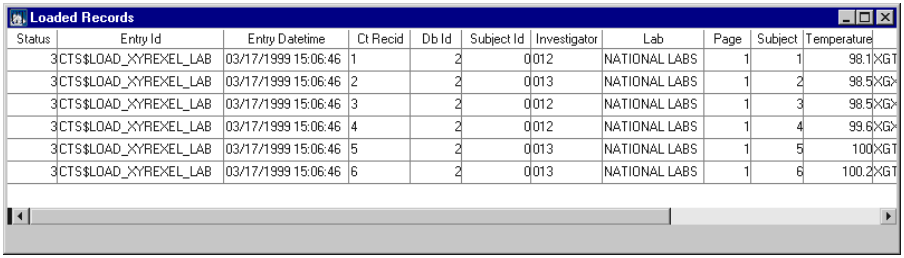
Select the Batch Load Log that you want to view. The file is stored in the same directory as the control file that you used to load the data. The Batch Load Log displays.

You can also view this file using any text editor.

Note: The name for the Batch Load Log file is the name that you specified for the Log file in the Batch SQL Loader dialog box.

It is recommended that you verify that the records that you batch loaded were loaded correctly. To view the records, from the **Load** menu, select **Show Raw Loaded Records**.

After you select a panel and table for which you want to edit unscreened records, the Loaded Records window opens:



Status	Entry Id	Entry Datetime	Ct Recid	Db Id	Subject Id	Investigator	Lab	Page	Subject	Temperature	
3	CTS$LOAD_XYREXEL_LAB	03/17/1999 15:06:46	1	2	0	012	NATIONAL LABS	1	1	98.1	XGT
3	CTS$LOAD_XYREXEL_LAB	03/17/1999 15:06:46	2	2	0	013	NATIONAL LABS	1	2	98.5	XGT
3	CTS$LOAD_XYREXEL_LAB	03/17/1999 15:06:46	3	2	0	012	NATIONAL LABS	1	3	98.5	XGT
3	CTS$LOAD_XYREXEL_LAB	03/17/1999 15:06:46	4	2	0	012	NATIONAL LABS	1	4	99.6	XGT
3	CTS$LOAD_XYREXEL_LAB	03/17/1999 15:06:46	5	2	0	013	NATIONAL LABS	1	5	100	XGT
3	CTS$LOAD_XYREXEL_LAB	03/17/1999 15:06:46	6	2	0	013	NATIONAL LABS	1	6	100.2	XGT

Note: The Loaded Records window displays only those records that have not yet been screened. When you have successfully screened the items, the items no longer display in the window, and you must use interactive SQL to view the records.

If there is more than one page of records, then you can use the **View** menu commands to navigate through the records. From the **View** menu, select:

- **First Page** to display the first page of records
- **Prior Page** to display the previous page of records
- **Next Page** to display the subsequent page of records
- **Last Page** to display the last page of records

You can also use the arrow buttons on the Task toolbar to navigate the pages of records.

24 Preparing Data for Transfer

Overview

After you have batch loaded the lab data into the source protocol, you can prepare the data for transfer into the destination protocol.

Note: Data preparation tasks are performed in the source protocol. You must set the current protocol to the source protocol to perform these tasks.

To prepare data for transfer, you must perform the following tasks:

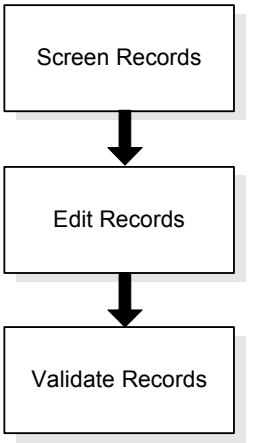
- Screen the records.
- Validate the records.

You can also perform the following optional tasks:

- Edit the records.
- Delete unscreened records.

Data preparation workflow

The following workflow shows how the data preparation tasks relate to each other:



Screening records

Screening is a combination of several processes performed as one single task. You screen records after data is batch loaded into the source protocol. When you screen records, Lab Loader performs the following tasks:

- **Updates the system items.** The system items in records that were successfully batch loaded into the database table are given values. The values assigned are equivalent to those assigned when you interactively enter records through Enter. A *system item* is an internal item used by the Clintrial software to uniquely identify records. System items are automatically attached to each record.
- **Groups the records into observations**, if grouping items are indicated in Design. Grouping the records organizes batch-loaded records into observations. An *observation* is a group of records in a page section that contains repeating items, or a group of records in a non-subject study book that has been configured for grouping. For example, you might group multiple blood tests that were taken on one sample into a single observation. Observations will succeed or fail the transfer as a group. Records grouped into a single observation are displayed as a repeating group in a study page in Enter, and exist collectively in the update and data tables.

  Note: It is not recommended that you group items in a Lab Loader protocol unless absolutely necessary. System performance will be negatively effected.
- **Applies data checks to batch-loaded data**. When data checks are applied to batch-loaded data, the same checks that are applied to interactively entered data are applied. The data checks are:
  - Confirming that subjects are enrolled.
  - Confirming that subject keys, block keys, and page keys are defined.
  - Confirming that subset keys (if used) are defined.
  - Confirming that a master record exists for a set of detail records.
  - Confirming that the master key is unique.
  - Confirming that grouping items have values, if grouping items are defined.
  - Confirming that values are provided for mandatory items.
  - Confirming that a code or value for an item with an attached codelist exists in the codelist.
  - Applying the range checks (upper and lower limits) that are defined for items.
  - Confirming that a value exists in the checklist for an item with an attached checklist.

For more information on specifying grouping items, see the *Design* section in *Admin and Design*.

System item values

When you screen records in a source protocol, the Clintrial software assigns the following values to the system items:

- Sets CT_RECID to a unique system number for each record.

  This CT_RECID is used only in the source protocol. The Clintrial software assigns a new CT_RECID automatically during data transfer.
- Sets ENTRY_DATETIME to the system date at the time of the screening.
- Sets ENTRY_ID to the user account that screened the records.
- Sets DB_ID to the correct database instance.
- Assigns a value of "0" to SUBJECT_ID.

  All panels in Lab Loader are Type 0 panels. Therefore, in the source protocol, the SUBJECT_ID item is merely a placeholder. It is not referenced in Lab Loader. The Clintrial software assigns a valid SUBJECT_ID automatically during data transfer, using data from the destination protocol's enrollment panel.

How screening affects the record status

When you batch load records, the Clintrial software assigns the status Unscreened (3) to all records that are successfully loaded into the update table.

During screening, if you release records for validation and the records pass screening, then the Clintrial software changes the records' status from Unscreened (3) to Verified (1). You can then validate and transfer the records.

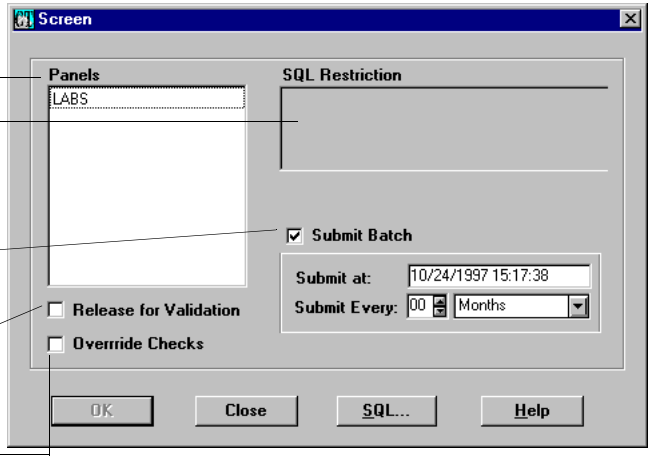
If a record fails screening, the record status changes to Failed Screening (-3). An entry is also made in the Error Log. You must edit the failed record and screen the record again.

If you do not release records for validation, then the record status does not change. However, Error Log entries are created for records that fail screening.

For more information on the Error Log, see Chapter 27.

How to start screening

From the **Load** menu, select **Screen**. The Screen dialog box opens, in which you specify the criteria for screening:



Select the panel or panels that you want to screen.

Optionally, specify a SQL restriction.

Check or clear Submit Batch.

Check or clear Release for Validation.

Check or clear Override Checks.

To select records for screening, select the panel or panels that store the batch-loaded records. You can also specify a SQL restriction to restrict the records within the selected panels.

If you want to release the records for validation, check Release for Validation. If you check this option, the record status changes to Verified (1) when the records are screened successfully.

Note: You can prescreen records by clearing this check box. However, if you do not release the records for validation, you must screen the records again before you can validate them.

If you do not want to check the records against checklists or upper and lower bounds, check Override Checks. Records that normally would not pass these checks will be screened successfully.

Note: The screening process always checks values against codelists, and checks to see if a value is required.

To screen the records, click **OK**.

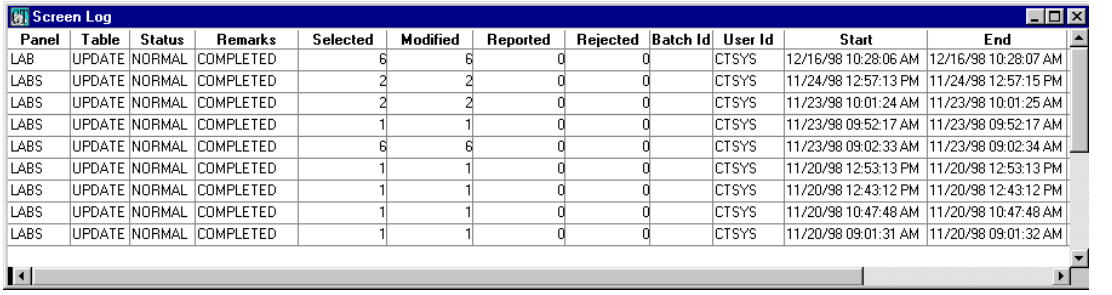
For more information on specifying SQL restrictions, see the *Common Information* section in the *Reference Guide*.

The *Screen Log* is a cumulative report that describes the screening results for screened panels.

You can view the Screen Log, purge all entries from it, or purge selected entries from it based on the following criteria:

- Panel
- User
- Status (NORMAL or ERROR)
- Type of database table (UPDATE or DATA)
- Start date
- End date

To view the Screen Log, from the **Reports** menu, select **Screen Log >> View**. The Screen Log opens:



Screen Log

Panel	Table	Status	Remarks	Selected	Modified	Reported	Rejected	Batch Id	User Id	Start	End
LAB	UPDATE	NORMAL	COMPLETED	6	6	0	0		CTSYS	12/16/98 10:28:06 AM	12/16/98 10:28:07 AM
LABS	UPDATE	NORMAL	COMPLETED	2	2	0	0		CTSYS	11/24/98 12:57:13 PM	11/24/98 12:57:15 PM
LABS	UPDATE	NORMAL	COMPLETED	2	2	0	0		CTSYS	11/23/98 10:01:24 AM	11/23/98 10:01:25 AM
LABS	UPDATE	NORMAL	COMPLETED	1	1	0	0		CTSYS	11/23/98 09:52:17 AM	11/23/98 09:52:17 AM
LABS	UPDATE	NORMAL	COMPLETED	6	6	0	0		CTSYS	11/23/98 09:02:33 AM	11/23/98 09:02:34 AM
LABS	UPDATE	NORMAL	COMPLETED	1	1	0	0		CTSYS	11/20/98 12:53:13 PM	11/20/98 12:53:13 PM
LABS	UPDATE	NORMAL	COMPLETED	1	1	0	0		CTSYS	11/20/98 12:43:12 PM	11/20/98 12:43:12 PM
LABS	UPDATE	NORMAL	COMPLETED	1	1	0	0		CTSYS	11/20/98 10:47:48 AM	11/20/98 10:47:48 AM
LABS	UPDATE	NORMAL	COMPLETED	1	1	0	0		CTSYS	11/20/98 09:01:31 AM	11/20/98 09:01:32 AM

You can use the **View** menu commands to filter or sort a displayed Screen Log, and the **File** menu to save or print the log.

The following table describes the information in the Screen Log:

Report column:	**Description:**
Panel	Source panel for which batch-loaded records were screened.
Table	Oracle table in which batch-loaded records were screened.

Report column:	Description:
Status	Indication of whether screening completed successfully. • NORMAL indicates screening completed successfully. • ERROR indicates that an error occurred during screening, although some records may have been successfully screened before the failure.
Remarks	Information about the status of the screening. • If the screening was successful, this column displays COMPLETED. • If the screening was unsuccessful, this column displays an error message.
Selected	Number of records for which screening was attempted.
Modified	Number of item checks that were successful.
Reported	If you are overriding data checks during screening, the number of items that failed checks, but passed screening because checks were overridden.
Rejected	Number of item checks that failed screening.
Batch Id	Oracle batch job queue ID of a process submitted to the batch job queue. This column displays information only if the screening was submitted as a batch job.
User Id	User ID of the user who submitted or ran the screening.
Start	Date and time the screening began.
End	Date and time the screening completed.
Restriction	SQL restriction used to select records for screening.

Editing records

If you have the appropriate access rights and the designer has defined a study page for the source protocol, then you can use Enter and the default study book to edit the data in a source protocol. However, you cannot use navigator-style editing to edit data; source protocols do not support enrollment panels.

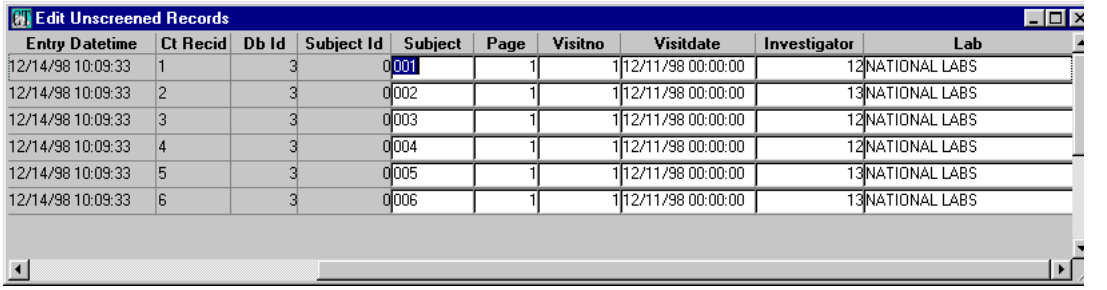
You can also edit data in Lab Loader. There are two ways to edit records in Lab Loader:

- You can edit records with the status Unscreened (3) or Failed Screen (-3) in the Edit Unscreened Records window.
- If the designer has defined a study page for the panel, you can edit records for which an Error Log entry was generated using Error Log editing. The records must have enough context information to be identifiable to Enter.

How to edit unscreened records

You can edit any unscreened records from within Lab Loader. To edit unscreened records, from the **Load** menu, select **Unscreened Records >> Edit**.

After you select a panel and table for which you want to edit unscreened records, the Edit Unscreened Records window opens, in which you can edit clinical data values:



Entry Datetime	Ct Recid	Db Id	Subject Id	Subject	Page	Visitno	Visitdate	Investigator	Lab
12/14/98 10:09:33	1	3	0	001	1	1	12/11/98 00:00:00	12	NATIONAL LABS
12/14/98 10:09:33	2	3	0	002	1	1	12/11/98 00:00:00	13	NATIONAL LABS
12/14/98 10:09:33	3	3	0	003	1	1	12/11/98 00:00:00	12	NATIONAL LABS
12/14/98 10:09:33	4	3	0	004	1	1	12/11/98 00:00:00	12	NATIONAL LABS
12/14/98 10:09:33	5	3	0	005	1	1	12/11/98 00:00:00	13	NATIONAL LABS
12/14/98 10:09:33	6	3	0	006	1	1	12/11/98 00:00:00	13	NATIONAL LABS

When you edit unscreened records in Lab Loader, you are editing the raw database records. The editor does not provide editing features such as range checking or codelist support. To use these features, you must edit the records using Enter.

Note: You cannot edit the system items in the unscreened records.

About Error Log editing

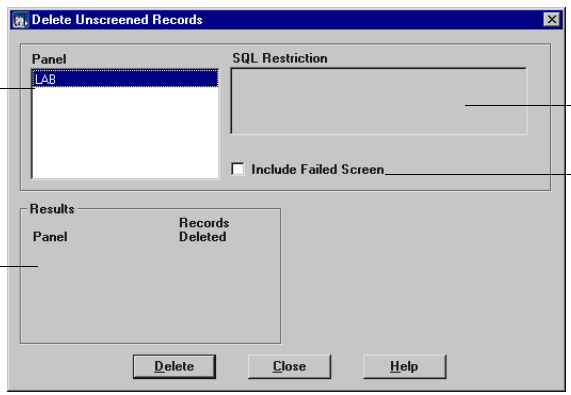
You can use the Error Log to edit records that have an error reported against them if you have the required access rights and if your designer has defined a study page and study book for the panel that contains the record that you want to edit. The records must contain valid context information for them to be identifiable in Enter.

For more information on Error Log editing, see Chapter 27.

Deleting unscreened records

You can delete records for a panel that have the status Unscreened (3) or Failed Screen (-3). For example, you may want to delete the records that you have batch loaded incorrectly, and then batch load the records again using a different control file.

To delete unscreened records, from the **Load** menu, select **Unscreened Records >> Delete**. The Delete Unscreened Records dialog box opens:



Select the panel for which you want to delete unscreened records.

The results of the deletion appear in this box.

Optionally, specify a SQL restriction.

Check Include Failed Screen if you want to delete records with the status -3.

Clear this check box if you do not want to delete those records.

Note: In the Delete Unscreened Records dialog box, you select the panel for which you want to delete unscreened records. Optionally, you can specify a SQL restriction to restrict the records that will be deleted. If you do not specify a SQL restriction, all unscreened records for the selected panel will be deleted.

Click **Delete** to delete all unscreened records for the selected panel.

Validating records

Validation is the process of running a validation procedure on clinical data to ensure that the data meets the requirements of the clinical trial for logical and consistent data.

Using Lab Loader, you can only validate records in a source protocol. If your current protocol is not set to a Lab Loader protocol, then the menu command for validation will not be available.

What is a validation procedure?

Each panel has one validation procedure associated with it. A *validation procedure* is a PL/SQL procedure that is built automatically in Design from the derivations and rules associated with the panel:

- *Derivations* calculate values of items or temporary variables that the designer has set up based on constants or on the values of other items.
- *Rules* are part of PL/SQL statements that evaluate to True or False. Rules can automatically flag data that fails validation.

For more information on the order in which derivations and rules are processed at validation, see the *Design* section of *Admin and Design*.

Results of validation

Records either pass or fail validation. After a record passes validation, it can be transferred to the destination protocol.

Records that fail validation cannot be transferred to the destination protocol. The records remain in the source protocol until they are edited and pass validation at a later time. Validation errors are recorded in the Error Log.

Note: You must validate records before you can transfer the data to the destination protocol.

For more information on the Error Log, see Chapter 27.

How validation works with observations

You can validate the records in an observation individually or as a group. However, you can only transfer records in an observation if all records in the observation validate successfully. You cannot transfer any records in an observation if one or more records fails validation or has not been validated.

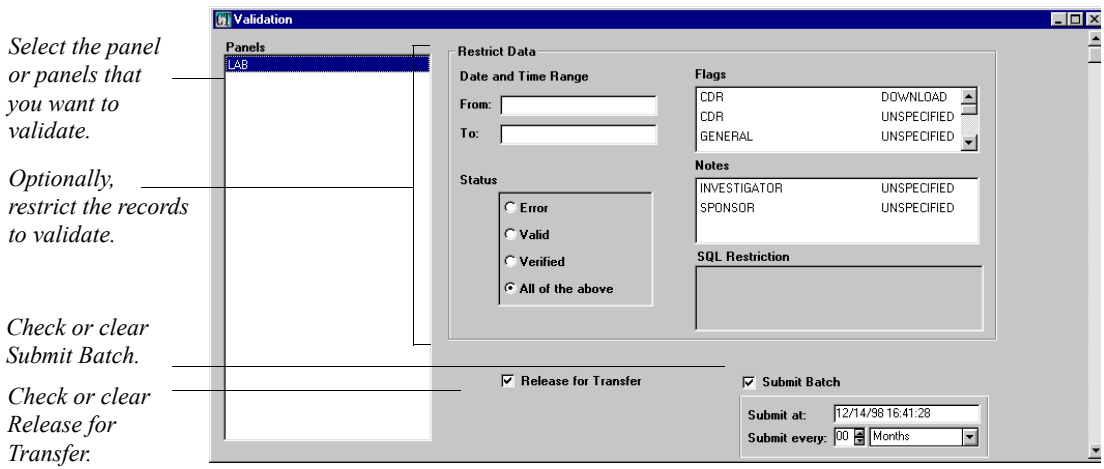
About the record status

When a record passes validation, the Clintrial software changes its status to Validated (0). You can only transfer records with the status Validated.

When a record fails validation, the Clintrial software assigns the status Validation Error (-1).

How to validate records

To start validation, from the **Manage** menu, select **Validate**. The Validation window opens, in which you can select records for validation:



You select the records for validation by selecting one or more panels, and optionally specifying various restrictions.

You can specify the following types of restrictions:

- SQL
- Flags and notes
- Date and time range
- Status

  You can restrict the records to validate by record status. You can select one or more statuses. The following table describes the statuses on which you can place a restriction:

Status:	Status code:	Description:
Error	-1	The record failed validation.
Valid	0	The record passed validation.
Verified	1	The record passed screening (for batch-loaded data) or verification (for interactively entered data).
All of the above	-1, 0, 1	All relevant records. ***Note:*** Also includes record status -2 if you check Release for Transfer.

For more information on SQL and flag and note restrictions, see the *Common Information* section in the *Reference Guide*.

About releasing records for transfer

When you run validation, you can specify that you want to:

- Run the validation and release the records for transfer.
- Or, run the validation, but not release the records for transfer.

  This option allows you to generate derived values and review the results of validation without changing the status of the records. You must run the validation again, and check Release for Transfer to transfer the records to the destination protocol.

The following table summarizes how Release for Transfer works:

When you:	If validation succeeds:	If validation fails:
Validate records and release them for transfer	Record status changes to Validated (0). Derived items are updated. You can transfer the records to a destination protocol.	Record status changes to Validation Error (-1). Validation errors are recorded in the Error Log. Flags that are attached automatically during validation are added to records.
Validate records and do not release them for transfer	Record status does not change. Derived items are updated. You cannot transfer the records to a destination protocol.	Record status does not change. Validation errors are recorded in the Error Log. Flags that are attached automatically during validation are added to records.

Note: The record can change when you are testing validation. Therefore, records may be audited, depending on where the audit start point is set. For example, if the validation procedure calculates a derivation, and the audit start point is set to data entry, then records in the update table are audited when you test validation.

To begin the validation procedure, from the **File** menu, select **Run**.

About the Validation Log

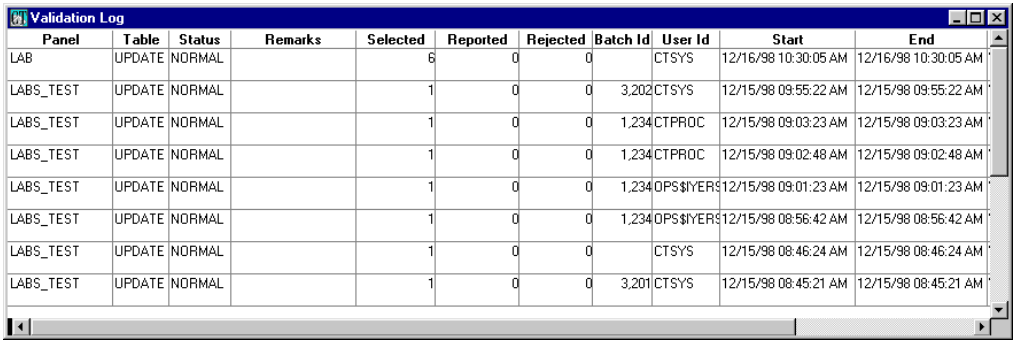
The *Validation Log* is a cumulative report that describes the results of the validation process.

You can view the Validation Log, purge all entries from it, or purge selected entries from it based on the following criteria:

- Panel
- User
- Status (NORMAL or ERROR)
- Type of database table (UPDATE or DATA)
- Start date
- End date

To view the Validation Log, from the **Reports** menu, select **Validation Log >> View**.

The Validation Log opens:



Validation Log

Panel	Table	Status	Remarks	Selected	Reported	Rejected	Batch Id	User Id	Start	End
LAB	UPDATE	NORMAL		6	0	0		CTSYS	12/16/98 10:30:05 AM	12/16/98 10:30:05 AM
LABS_TEST	UPDATE	NORMAL		1	0	0	3,202	CTSYS	12/15/98 09:55:22 AM	12/15/98 09:55:22 AM
LABS_TEST	UPDATE	NORMAL		1	0	0	1,234	CTPROC	12/15/98 09:03:23 AM	12/15/98 09:03:23 AM
LABS_TEST	UPDATE	NORMAL		1	0	0	1,234	CTPROC	12/15/98 09:02:48 AM	12/15/98 09:02:48 AM
LABS_TEST	UPDATE	NORMAL		1	0	0	1,234	OPS$IYER	12/15/98 09:01:23 AM	12/15/98 09:01:23 AM
LABS_TEST	UPDATE	NORMAL		1	0	0	1,234	OPS$IYER	12/15/98 08:56:42 AM	12/15/98 08:56:42 AM
LABS_TEST	UPDATE	NORMAL		1	0	0		CTSYS	12/15/98 08:46:24 AM	12/15/98 08:46:24 AM
LABS_TEST	UPDATE	NORMAL		1	0	0	3,201	CTSYS	12/15/98 08:45:21 AM	12/15/98 08:45:21 AM

You can use the **View** menu commands to filter or sort a displayed Validation Log, and the **File** menu to save or print the log.

The following table describes the information in the Validation Log:

Report column:	**Description:**
Panel	Name of the panel for which records were validated.
Table	Type of database table for which records were validated. In a source protocol, this column is always UPDATE.
Status	Indication of whether validation completed successfully. • NORMAL indicates a successful validation. • ERROR indicates an unsuccessful validation.
Remarks	Information about the status of the validation. • If a validation completed successfully, then this column displays COMPLETED. • If a validation was unsuccessful, this column displays an error message.
Selected	Number of records selected for validation.
Reported	Number of items in the records with the rule action REPORT.
Rejected	Number of items in the records with the rule action REJECT.

Report column:	Description:
Batch Id	Oracle batch job queue ID of a process submitted to the batch job queue. This column displays information only if the validation was submitted as a batch job.
User Id	User account that submitted or ran the validation.
Start	Date and time the validation began.
End	Date and time the validation completed.
Restriction	SQL restriction used to select records for validation.

25 Transferring Records

Overview

After you have batch loaded lab data into a source protocol and prepared the data for transfer, you can transfer the data to the destination protocol.

Note: You cannot transfer data into Enrollment (Type 5) panels.

What is data transfer?

Data transfer moves data from a source protocol to a destination protocol. The transfer is directed by criteria specified in a transfer map.

You can only transfer data from a Type 4 - Lab Loader protocol into a Type 1 - Clinical Data protocol. That is, the source protocol must be a Lab Loader type protocol, and the destination protocol must be a Clinical Data type protocol.

What is a transfer map?

A *transfer map* indicates data to be transferred from a source protocol to a destination protocol by establishing a direct connection from the source items to the destination items. The transfer map specifies which data will be transferred, and indicates the location where you want the data to be stored.

Transfer maps are owned by the source protocol, and must be created before the transfer is performed. Each transfer map can be used for many transfers. Any pair of source panels and destination panels typically has only one transfer map that is used for all transfers between the panels. You can also specify multiple maps for each source-destination pair of panels for greater flexibility.

Transfer maps are uniquely identified by five values:

- The map name
- The source protocol
- The source panel
- The destination protocol
- The destination panel

For example, you can create the following unique transfer maps:

- A map named MAPA that maps items from the STUDY1 panel in the LAB_SRC source protocol to items in the MEDIKA_CLINICAL protocol.

- A map named MAPB that maps items from the STUDY1 panel in the LAB_SRC source protocol to items in the MEDIKA_CLINICAL protocol.
- A map named MAPA that maps items from the STUDY1 panel in the LAB_SRC source protocol to items in the KALURIL protocol.

Transferring records

To transfer records, the current protocol must be set to the destination protocol. For example, if you are transferring data from the LAB_SRC source protocol to the MEDIKA_CLINICAL destination protocol, you would set the current protocol to MEDIKA_CLINICAL before transferring data.

About enrollment

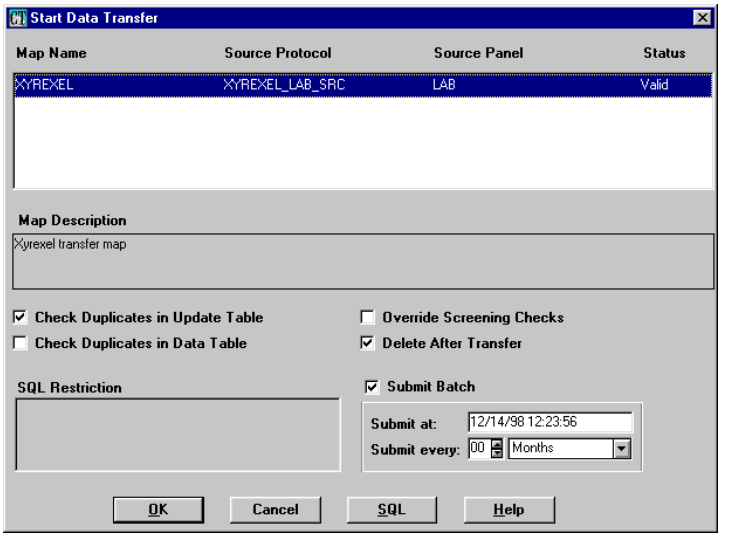
To transfer a record to a Subject type panel (Type 1-4), the subject associated with the record must be enrolled. You may want to add rules to the source protocol's validation procedure to check for enrollment before transferring the records.

Note: You cannot transfer data from a source protocol to an enrollment panel in the destination protocol.

About panel keys

You must have set up panel keys for the panels into which you will transfer data. The items referenced by the panel key definition must be defined as required items. If you do not set up panel keys, you will be unable to transfer repeat records for a specific visit. Lab Loader will transfer one record per visit and treat the other records as duplicates.

To begin the transfer, from the **Transfer** menu, select **Start Data Transfer**. The Start Data Transfer dialog box opens:



In this dialog box, you select the transfer map that will control the data transfer. Only valid maps can be used in the transfer process. You also select several transfer options, which are described in the following table:

Option:	**Description:**
Check Duplicates in Update Table	Check this option to check for duplicates in the update table. Clear this option if the Clintrial software should not check for duplicates in the update table.
Check Duplicates in Data Table	Check this option to check for duplicates in the data table. Clear this option if the Clintrial software should not check for duplicates in the data table.

Option:	Description:
Override Screening Checks	You can choose whether the automatic screening that the Clintrial software performs during data transfer overrides certain screening checks. The screening checks the Clintrial software applies during data transfer are the screening checks defined for the destination panel. If you check Override Screening Checks, then the Clintrial software does not check that the value for an item is within the defined upper or lower bounds and does not check values against checklists attached to items.
Delete after Transfer	You can choose whether to delete the records from the source panel after transferring them to the destination panel. • Check Delete After Transfer to delete the records from the source panel after transferring them to the destination panel. • Clear Delete After Transfer to keep the records in the source panel after the transfer is complete. ***Note:*** This option appears only if you set the system parameter and user preference CTL_TEST_MODE to Yes. If the system parameter or user preference is set to No, then the records are always deleted.
SQL Restriction	Allows you to specify a SQL restriction to restrict the records that are selected for transfer to the destination protocol.

The transfer process

During the data transfer, the Clintrial software performs the following actions for each record:

1. Checks the record in the source protocol against the SQL restriction to see whether it should be transferred.
2. Checks the record for necessary destination protocol key items and mandatory items.
3. Updates the CT_RECID.

4. Updates the SUBJECT_ID using information from the destination protocol's enrollment panel.
5. Screens the record using the screening checks defined for the destination panel.
6. If duplicate detection is specified, checks for duplicates in the destination protocol.

If the Clintrial software:	Then the Clintrial software:
Finds a duplicate in the update table	a. Updates the record in the destination protocol. b. Automatically validates the record if the original record had a status of 0 or -1.
Finds a duplicate in the data table	a. Inserts the record into the update table of the destination protocol. b. Adds a flag to either the record in the update table or the record in the data table.
Does not find a duplicate	Inserts the record into the update table of the destination protocol.

7. If duplicate detection is not specified, inserts the record into the update table of the destination protocol.
8. Regroups the records, using the subject item, block key item, block repeat key item (if defined), page key item, and page repeat key item (if defined) as the grouping items, if they are in a Type 2 or Type 4 panel. If they are in a Type 0 panel, the Clintrial software groups the records using the predefined grouping items and subset key item.
9. Deletes the records that transferred successfully from the source panel, if appropriate.

If any of the preceding actions results in a REJECT error, then a copy of the record is added to the Error Log in the source protocol, and the record is not transferred.

Note: If a REPORT error occurs during screening, then the record is still transferred to the destination protocol, and the error is reported in the Error Log of the destination protocol.

About the transfer map status

When you begin the transfer, Lab Loader checks that the source protocol and destination protocol referenced in the selected transfer map exist, and that the source panel and destination panels exist and are installed. If any of these checks fails, the transfer map status becomes Invalid, and the transfer does not occur.

Lab Loader then checks that the last modification date of the map is later than the last modification date of the source panel and the destination panels. If the source panel and the destination panels were modified and the transfer map was not updated, then the map is marked Old, and the transfer is rejected.

The following table summarizes the possible statuses for transfer maps:

Status:	Description:
Valid (0)	The map was valid the last time it was edited or used for transfer.
Invalid (1)	The map is invalid. This status can occur when the destination protocol, destination panel, source protocol, or source panel has been deleted after the map was created, or if the data types for mapped items no longer match.
Old (2)	One of the source or destination protocols or panels has been edited more recently than the map.
Incomplete (3)	The map was saved before all required items were mapped. For example, the map was saved, but not all key items were mapped.

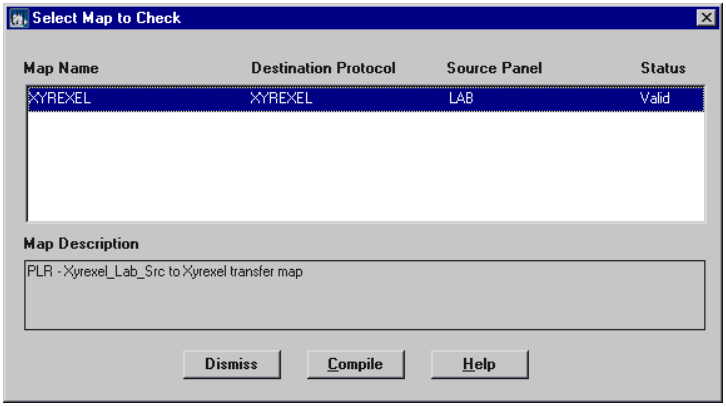
To change the status of a transfer map, you open the transfer map, make any necessary modifications, and save the map. You can also compile the map, which changes the map status of Old to a status of Valid if the map is still valid.

Note: You must set the protocol to the source protocol to edit the transfer map.

About compiling the transfer map

You can compile a transfer map to ensure the map is valid. Compiling the map checks that the source and destination panels are still installed, and that source and destination items still exist. In this manner, you can easily see if something has changed.

To compile a transfer map, from the **Transfer** menu, select **Map >> Check**. The Select Map to Check dialog box opens:



Select a map name and click **Compile**. To close the dialog box, click **Dismiss**.

About duplicate records

When you transfer data from the source panel, you may be transferring a record that already exists in the destination panel. For example, a lab may send you data that is identical to data it sent you in a previous dataset, or data that is an update of previous data.

Lab Loader can check for duplicate records during data transfer. A *duplicate record* is a record for which the following keys are identical:

- Subject item
- Block key item
- Block repeat key item
- Page key item
- Page repeat key item
- Subset key item
- Panel key items
- User-defined panel keys

For example, look at the following three records:

Record number	Subject ID (subject key)	Visit No. (block key)	Visit No. (block repeat key)	Page No. (page key)	Page No. (page repeat key)	Test Name (panel key)	Test Result
1	004	1	2	7	a1	HCT	45.7
2	004	1	2	7	a1	HCT	44.1
3	004	1	2	7	a1	HGB	15.5

Records 1 and 2 are duplicate records. That is, all the key item values match. Record 3 is not a duplicate record because the panel key item (Test Name) values are different.

When you transfer data, you determine the extent to which Lab Loader checks for duplicate records in the destination protocol. You can:

- Check for duplicates in the update table.
- Check for duplicates in the data table.
- Check for duplicates in both the update table and the data table.
- Disregard duplicate checking.

If Lab Loader detects a duplicate record in the update table, then Lab Loader updates the record in the update table with the data in the record being transferred. If multiple duplicate records exist in the update table, then Lab Loader updates all of the records.

If Lab Loader detects a duplicate record in the data table but not in the update table, then Lab Loader inserts the new record in the update table, and flags either the newly created record in the update table, or the duplicate record in the data table. The location for the flag is determined by the system parameter CTL_DUPFLAG_LOC. For more information on this system parameter, see page 403.

If there is a duplicate record in both the update table and the data table, Lab Loader updates the record in the update table, but no flag is attached to the record. Either a flag already exists for the duplicate record, or the record in the update table was entered interactively and is outside the scope of Lab Loader duplicate detection.

About transfer errors and the Error Log

When errors occur during data transfer, entries are added to the Error Log for the record. However, the location of the Error Log entry depends on when the error occurs:

- If the error prevents the record from being transferred, then the record remains in the source protocol, and an entry is added to the source protocol's Error Log.

  For example, a record for a subject who is not enrolled in the destination protocol's study book results in an error in the source protocol's Error Log.
- If the error occurs after the record is inserted into the update table, an entry is added to the destination protocol's Error Log.

  For example, a screening error would generate an entry in the destination protocol's Error Log.

For errors that occur during data transfer in Lab Loader, the ERRTYPE column in the Error Log has the following value:

TRANSFER — The error occurred during the transfer.

For more information on the Error Log, see Chapter 27.

Transfer reports

The *Transfer Log* is a cumulative log that describes the results of the transfer process.

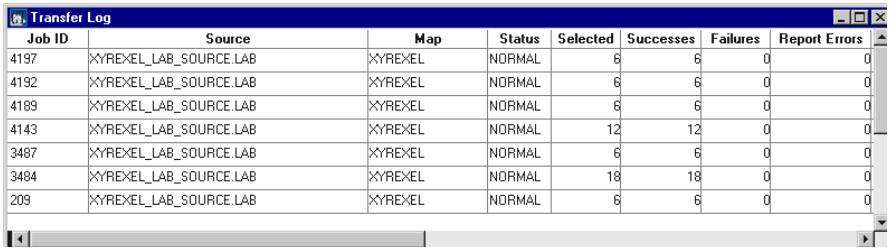
You can view the Transfer Log, purge all entries from it, or purge selected entries from it based on the following criteria:

- Source panel, source protocol, and transfer map
- User
- Status (NORMAL or ERROR)
- Start date
- End date

To view the Transfer Log, from the **Reports** menu, select **Transfer Log >> View**.

Note: If the current protocol is not set to the destination protocol, then the Transfer Log menu command is unavailable.

The Transfer Log opens:



You can use the **View** menu commands to filter or sort a displayed Transfer Log, and the **File** menu to save or print the log.

The following table describes the information in the Transfer Log:

Report column:	**Description:**
Job ID	The Clintrial software job number assigned to the transfer process. You can use this number to match transfers between the Transfer Log and the Duplicates Summary Report.
Source	Name of the source protocol and source panel from which the records were transferred.
Map	Name of the transfer map used to perform the transfer.

Report column:	Description:
Status	Indication of whether the transfer completed successfully. • NORMAL indicates that the transfer completed successfully. • ERROR indicates that an error occurred during the transfer.
Selected	Number of records for which the transfer was attempted.
Successes	Number of records that transferred successfully.
Failures	Number of records that failed the transfer.
Report Errors	Number of destination protocol Error Log entries generated by the transfer.
Remarks	Information about the transfer.
Start	Date and time the transfer started.
End	Date and time the transfer completed.
Batch ID	Oracle batch job queue ID of a process submitted to the batch job queue. This column only displays information if the transfer was submitted as a batch job.
User ID	User account that submitted or ran the transfer.
Restriction	SQL restriction applied to records to determine if they should be transferred.

Note: The Batch ID is an Oracle ID assigned to processes submitted as a batch job. The Job ID is a Clintrial software ID assigned to all processes regardless of whether they were submitted as a batch job.

About the Duplicates Summary Report

The *Duplicates Summary Report* is a cumulative report that contains general information about the number of duplicate records detected during the transfer process.

Note: A duplicate record in this situation is a record in the source protocol that is a duplicate of a record in either the update table or the data table of the destination protocol.

The following table describes the information in the Duplicates Summary Report:

Report field:	**Description:**
Map	Name of the transfer map used to perform the transfer.
Job Number	The Clintrial software job number assigned to the transfer process. You can use this number to match transfers between the Transfer Log and the Duplicates Summary Report.
User	User account that submitted or ran the transfer. ***Note***: If you purge entries from the Transfer Log, the corresponding entries in the Duplicates Summary Report do not have a value for User.
Source protocol	Name of the protocol from which records were transferred.
Source panel	Name of the panel from which records were transferred.
Started	Date and time the transfer began. *Note*: If you purge entries from the Transfer Log, then the corresponding entries in the Duplicates Summary Report do not have a value for Started or Ended.
Ended	Date and time the transfer completed.
Destination Panels	Destination panel to which records were transferred.
Update Table	Number of duplicates detected in the update table for the panel.
Data Table	Number of duplicates detected in the data table for the panel.

Note: If a source protocol record is the duplicate of both a record in the update table and a record in the data table, then the record is included only in the count of the number of duplicates detected in the update table.

The *Detail Duplicates Report* is a cumulative tabular report that provides identification information for the duplicate records detected during the most recent transfers.

The report includes the following columns:

- The table in which the duplicate record is located
- The job ID assigned to the transfer process
- The CT_RECID
- A column for keys associated with the destination panel (for example, subject item and block key item)

If you transfer a duplicate of a record that is already recorded in the Detail Duplicates Report, then another entry is made in the Duplicates Summary Report and the Detail Duplicates Report.

26 Lab Loader Setup

Overview

A *protocol account* (or *protocol*) is an Oracle account that consists of database tables that hold the clinical data, flags, and notes associated with clinical data, audit and error log information, and one or more views of the clinical data stored in the protocol.

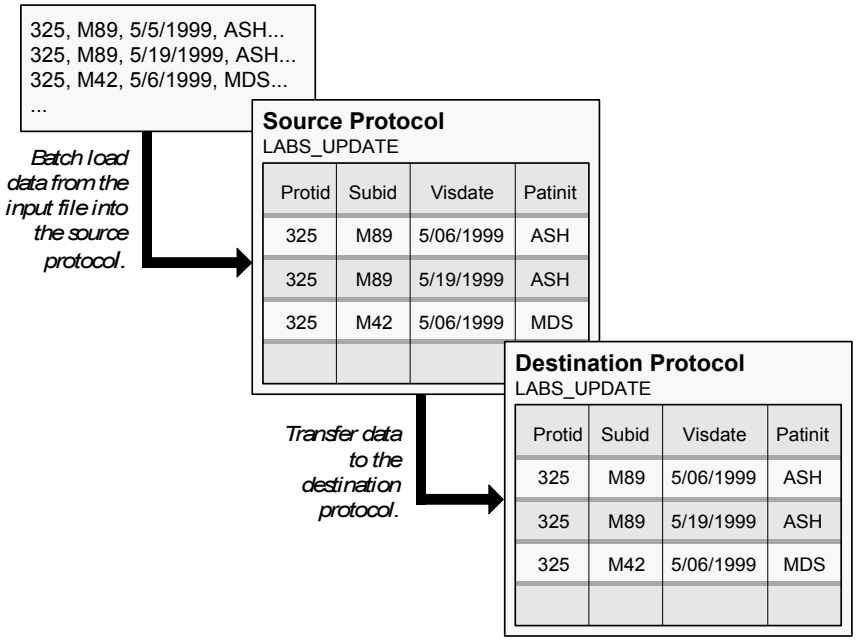
What are source and destination protocols?

When you use Lab Loader to load and transfer lab data, you work with two different types of protocols:

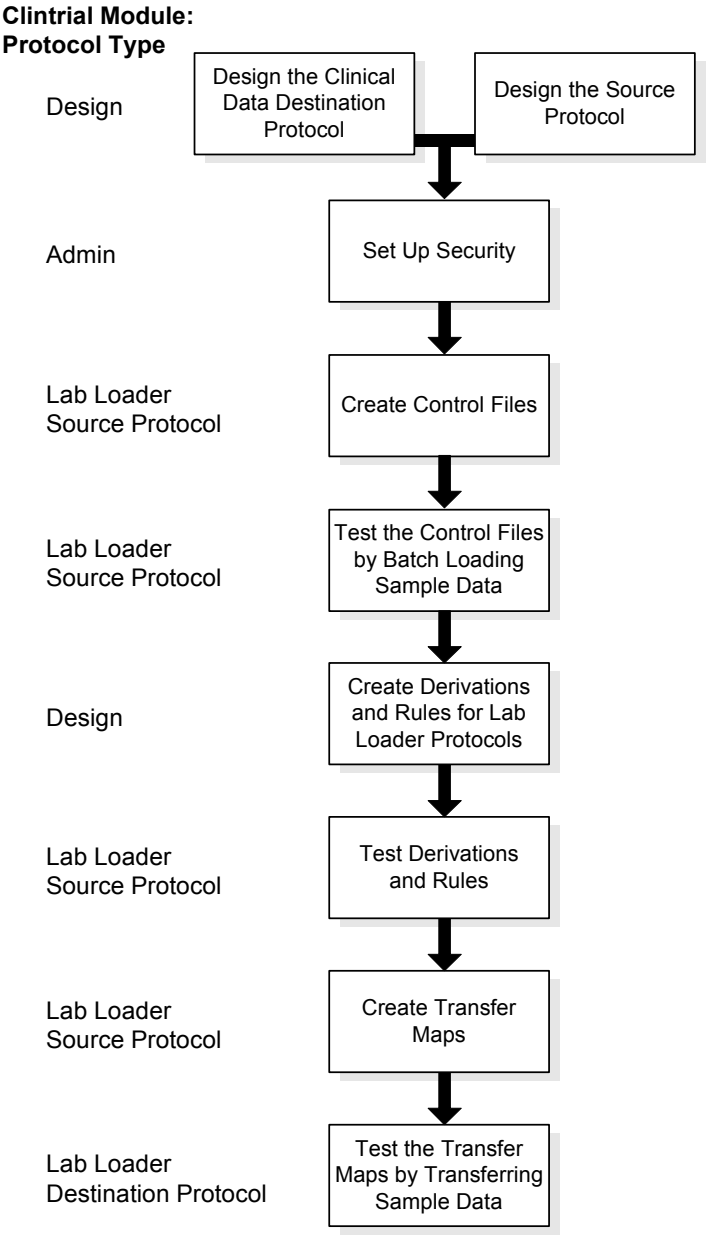
- The *source protocol* is a Lab Loader protocol (Type 4) into which you batch load lab data. You work with the lab data in this protocol to prepare it for transfer to the destination protocol.
- The *destination protocol* is a clinical data protocol (Type 1) that contains the clinical data for a study. You transfer data into this protocol after preparing it in the source protocol. The destination protocol must *not* be a Lab Loader protocol (Type 4).

You also work with an *input file*, which is an ASCII file that contains lab data to be batch loaded into the Clintrial software. You receive the input file from the lab analyzing the specimens or samples. Using Lab Loader, you batch load the data from the input file into the source protocol, prepare the data, and then transfer the data to the destination protocol.

The following figure shows the interaction between the input file, source protocol, and destination protocol:



The following figure shows the workflow you should use to set up Lab Loader:



Setting up the destination protocols

A *destination protocol* is a clinical data protocol (Type 1) that contains the clinical data for a study. The destination protocols are the same clinical data protocols that you use to perform all other Clintrial software data management tasks. You set up these protocols as described in the *Design* section in *Admin and Design*.

However, when you are designing the destination panels that will contain the transferred data, you should consider the following:

- The way that you will map the transfer.
- The structure of the input files that you will batch load.
- The structure of the source protocol and source panels.

Caution: You must also set up panel keys for the panels into which you will transfer data. The items referenced by the panel key definition must be defined as required items. If you do not set up panel keys, then you will be unable to transfer repeat records for a specific visit. Lab Loader will transfer one record per visit and treat the other records as duplicates.

Creating a source protocol

A *source protocol* is a Lab Loader protocol (Type 4) into which you batch load lab data. You work with the lab data in this protocol to prepare it for transfer to the destination protocol.

Source protocols contain the source panels from which you transfer lab data into the clinical data panels.

Before you create a source protocol, you should determine how you want to organize the data that will be batch loaded into Lab Loader, and what you need to do to transfer the batch-loaded data into the destination protocol.

How to determine protocol hierarchy

When you batch load data, you place it in the source protocol, which serves as a holding and processing area before you transfer the data to the destination protocol. The structure of this holding and processing area is determined by the protocol hierarchy that you create.

You can use one source protocol to contain all of the data that you batch load. Alternatively, you can use multiple source protocols. For example, you may want a separate source protocol for each lab that sends you data, or you may want a separate source protocol for each study for which you are processing lab data.

The following questions may help you decide how to structure your source protocols:

- Do you want to create a data dictionary protocol to hold standardized items?

  If you create a protocol with the Dictionary attribute to hold standardized items, then the source protocols that you create must include this protocol in their searchlist. The data dictionary protocol should be a Lab Loader protocol (Type 4). Only Type 4 protocols can own control files and transfer maps.
- How many destination protocols will you transfer the data to? How are these clinical data protocols structured?

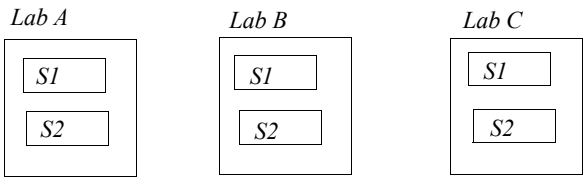
  The structure and items of the destination protocols determine which items you need to create in your source protocol. If the destination protocols have many differences, then you may want to create separate source protocols and source panels to accommodate these differences. You may also want to include the destination protocols in the search list for the source protocol.
- How many labs send you data? Is the structure of the input file the same for each lab?

  If the input files from different labs are different in structure, you may need to use separate control files to batch load data, and you may need different items to contain the data once it is batch loaded. Therefore, you may want to use separate source protocols or source panels.
- How many studies will you be obtaining data for? Is the data for the studies similar in structure and type, or does the structure change between studies?

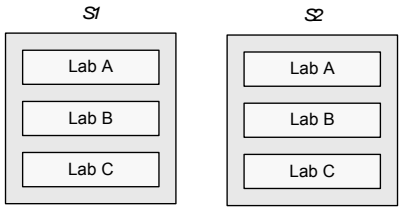
  If the data for the studies is different, you may need to create different items in the source panels to contain the data.
- Will data for a single study come in as a separate input file, or will it be in the same file as data for another study?

Suppose you receive data from three central labs for two separate studies. You can structure your source protocol hierarchy in any one of the following ways:

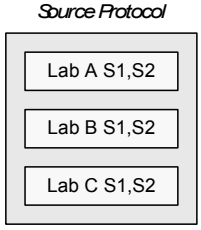
- Create three source protocols, one for each lab. Each protocol has two panels, one for each study:



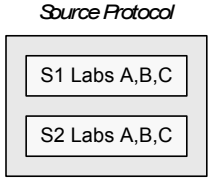
- Create two source protocols, one for each study. Each protocol has three panels, one for each lab:



- Create one source protocol with three panels, one for each lab. Each panel contains data for both studies:

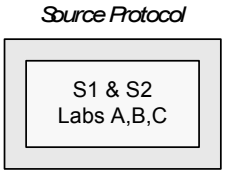


- Create one source protocol with two panels, one for each study. Each panel contains data from all three labs:



- Create one source protocol with six panels, one for each lab/study combination:

- Create one source protocol with one panel. All the data will be batch-loaded into the same panel:



Characteristics of the Lab Loader protocol type

Lab Loader protocols (Type 4) differ from other Clintrial software protocols in the following ways:

- A Lab Loader protocol can contain only Type 0 panels. It does not allow the creation of enrollment panels, and does not use a context panel.
- Records in a Lab Loader protocol stay in the update table. They cannot be merged into the data table.
- A Lab Loader protocol can never be used as a destination protocol during data transfer.
- Only a Lab Loader protocol can be used as a source protocol during data transfer.
- When you delete a Lab Loader protocol, any transfer maps and control files owned by that protocol are also deleted, even if the destination protocols are still active.
- When you import a Lab Loader protocol, any transfer maps and control files owned by that protocol are also imported.
- When you export a Lab Loader protocol, any transfer maps and control files owned by that protocol are also exported.
- A Lab Loader protocol cannot be Resolve-enabled. That is, a Lab Loader protocol cannot be used in conjunction with Resolve in working with discrepancies.

How to create a source protocol

You create source protocols using Design. Source protocols must be Lab Loader protocols (Type 4).

The following table describes some of the protocol attributes that may affect the setup of source protocols:

Attribute:	Description:
Protocol	The name of the protocol. You may want to create a naming convention that immediately identifies a protocol as a source protocol.
Type	The protocol type. Source protocols must be Type 4 – Lab Loader protocols. If the Lab Loader module is not installed, then Type 4 will not be an option.
Dictionary	Specifies whether the protocol is a data dictionary protocol. The Clintrial software cannot create associated clinical data tables for a protocol with the dictionary attribute.
Parent Protocol	The protocol that defines the default searchlist for the current protocol as the combination of the parent protocol and the parent protocol's searchlist. If you are using a data dictionary protocol to contain standardized items, then you may want to use that protocol as the parent protocol.
Modify Searchlist	An indication of whether searchlist modification is allowed. The searchlist for a protocol is defined by the parent protocol; if you want to be able to copy panels and items from other protocols, such as the destination protocol, then you should check this option.
Audit Start	The default point at which auditing begins in each panel created in this protocol. In Lab Loader protocols (Type 4), the Audit Start point is set to Merge by default. You can change this attribute.
Error Log item	An item optionally displayed for each record in the Error Log to uniquely identify the record. This item must be a context item. It cannot be used in Lab Loader protocols (Type 4) as Lab Loader protocols do not have CONTEXT panels. You can use the Manage system parameter or user preference ERRLOG_DISPLAY_ITEM to generate the same behavior. For more information on this parameter, see "Manage system parameters" on page 403.

For information on other protocol attributes, see the *Design* section of *Admin and Design* or the Design Help.

Creating source panels and items

After you have created a source protocol, you need to create the panels and items for that protocol.

The panels and items you create depend on the protocol hierarchy you have set up, the format and structure of the data you intend to batch load into the protocol, and the format and structure of the panels into which you want to transfer the data.

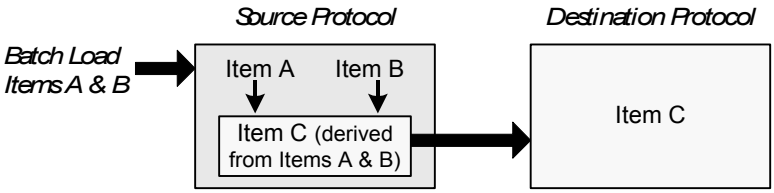
How to determine the source panel structure

The structure of the destination protocol helps to determine how you design the panels in your source protocols. For example, when you transfer records, each nonderived item in a destination panel that you want to populate at transfer time must have a corresponding item in the source panel.

The design of the panels in the source protocol is also influenced by the format and structure of the data in the input files.

The source protocol is similar in structure to both the destination protocol and the input file. The source protocol design must take these structures into account to facilitate both batch loading and data transfer.

For example, an item in the destination protocol may not have a corresponding item in the input file, but may be a derivation resulting from two other items in the input file. The source protocol could have three items: two items to store the values batch loaded from the input file, and one item to hold the derived value, which will then be transferred to the destination protocol:



Or, you may want to batch load all data from the input file as ASCII text, and then use derivations in the source panel to convert certain item values to numeric values before transferring them to the destination panel. The source panel could have two items for each item in the input file and destination protocol: one item to hold the character value, and one item to hold the derived numeric value.

How to determine the needed source items

You determine the items you need to create in the source panels by looking at the structure of the input file and the destination panels, and by anticipating the mapping of the transfer records.

First, look at the format of the input file and assess the structure by asking the following questions:

- What fields can you batch load directly into the Clintrial software? These fields need corresponding items in the source panel.
- What fields must be converted? For example, you cannot use conversions such as TO_NUMBER() when transferring data in the Clintrial software. These conversions must be handled during batch loading through the control file. You can also use derivations to convert the data by setting up items to hold the derived values.

Then, look at the format of the destination panel and assess the structure by asking the following questions:

- What items have a corresponding field in the input file? These values can be batch loaded into the source file, and then transferred directly to the destination panel without any processing. The source panel can contain one item to handle the value.
- What are the subject, block, block repeat, page, page repeat, and subset keys? Are other keys, such as panel keys, defined for the panel? All keys need a corresponding item in the source panel to permit transfer into the destination panel.
- What are the required items for the destination panel?

Keep in mind the following requirements when you are defining the source panel items:

- The underlying types of source and destination items must be the same. If the data types are different, you can use derivations in the source panel to derive an item of the correct type, and then transfer the derived item.
- If the item sizes of the source and destination items do not match, then the destination item length must be larger.
- A subject item, block key item, and page key item must be mapped for Type 1-4 destination panels. In addition, if defined, a block repeat key item, page repeat key item, and subset key item must be mapped for Type 1-4 destination panels. Therefore, you need corresponding items in the source panel.
- If additional keys are defined on the destination panel, then these keys must have corresponding items in the source panel. For example, if you are transferring data into a Type 4 panel, then the destination panel should have a

panel key defined to help uniquely identify the records during duplicate detection.

- If a key item is a derived item in the destination panel, then all items that are used for the derivation must have a corresponding item in the source panel. Otherwise, the key item value will change during validation.
- All required items in the destination panel must be mapped. They must have corresponding items in the source panel.
- If data for more than one destination protocol is stored in a source panel, then there must be a protocol destination item defined in the source panel to differentiate the data.

About key items

When you transfer data from a source panel to a Type 1 - 4 panel, you must map the subject item, block key item, and page key item. Therefore, you must ensure that these items exist in the source panel.

If any other keys for the destination panel have been defined, then there must be a corresponding key item in the source panel for them.

About derived items

Lab Loader does not support type conversions during record transfer. The underlying types of source and destination items must be the same for the map to be valid.

One method you can use to manage type conversions is to have an extra item in the source panel, and then use derivations to populate the item with the type-converted data.

You can also use derivations to create items in the source panel that exist in the destination panel, but that do not have a corresponding field in the input file.

About the destination protocol item

When you transfer data, Lab Loader transfers all of the records from a source panel into the panels of the destination protocol. However, if you are storing records for multiple destination protocols in one source panel, then you should transfer only the records for one specific destination protocol at a time.

Lab Loader provides a transfer map item called [Destination Protocol] to differentiate records belonging to different protocols. You can map the transfer map item to a source item that contains the name of the destination protocol.

- If the destination protocol name exactly matches the source item value in a record, then the record is transferred.
- If the destination protocol name does not match the source item value, then the record is not transferred.
- If you do not map the [Destination Protocol] item, then all records in the source panel are transferred.

Data integrity checks

One of the main functions of Lab Loader is to enable you to process the lab data after batch loading before placing the data in the data tables. This ensures that the data will be logical and consistent with the standards of your clinical trial.

You can create several data integrity checks to help you process and evaluate the data before transferring it.

About validation procedures

A *derivation* is a PL/SQL statement that calculates the value of an item or temporary variable. You can use derivations in the source protocol to convert data types, supply item values, or change the format of data to match the destination protocol.

A *rule* is a PL/SQL expression that checks the value of an item against certain conditions, and evaluates to either TRUE or FALSE. For example, a rule could check that the subject ID item for a record has a value.

The *validation procedure* is the combination of all the derivations and rules that have been set up and attached to the panel. When records are validated, the Clintrial software runs the validation procedure for the records. Each record can either pass or fail validation. Whether a record passes validation depends on whether the rules that make up the validation evaluate to TRUE for that record.

Note: For a record to transfer successfully, the record must be valid and the subject associated with the record must be enrolled. You may want to add checks to the validation procedure to check for enrollment before transferring the records.

About codelists and checklists

A *codelist* is a set of codes and a corresponding set of values. Codelists are associated with items.

By associating a codelist with an item, you can limit valid data to the codes or values that are in the codelist. The Clintrial software stores the entered code, or encodes the entered value as the corresponding code. You can also allow for the entry of more than one value for the same code.

Codelists are available to all protocols within the database instance. You can attach the same codelist to both an item in the source protocol and an item in the destination protocol.

A *checklist* is a type of codelist used to view suggested entries for a field. No encoding is performed. That is, the codelist value is stored, rather than the codelist code. Entered values are checked against the checklist to see if they are valid.

For example, if you use standard names for all of the lab tests, then you may want to place these names in a checklist to ensure that the batch-loaded data corresponds to the correct tests. You can also use codelists or checklists to ensure consistency in units of measure.

For more information on codelists and checklists, see the *Design* section in *Admin and Design*.

About flags

Lab Loader uses flags to help identify records that do not meet certain data integrity checks. For example, Lab Loader automatically attaches a flag to a record in the destination protocol during transfer if a duplicate record is detected during data transfer.

You also can associate a flag with rules created for use during validation. These flags are attached automatically to records if the rule evaluates to FALSE.

When you transfer records, only item level flags are transferred to the destination protocol. Record or observation level flags are not transferred:

- If there is a one-to-many mapping of an item from source to destination panels, then the flag is duplicated and transferred to each relevant item in the destination panel.
- If the flag already exists for a record in the destination panel, then the text of the newly transferred flag is appended to the text of the existing flag.

In most places where a restriction clause can be used to access records (for example, validation), a flag or note restriction can also be used. A flag or note restriction enables the user to request only records to which specified flags or notes are attached. For example, a user might want to edit or delete only records with a duplicate detection flag attached.

For more information on flag and note restrictions, see the *Enter* section in *Enter, Resolve, and Retrieve*.

Data navigation

If you define a study page that corresponds to the Lab Loader protocol (Type 4), then you can use Enter and the default study book for the panel to edit the data.

About Error Log editing

If you plan to use Error Log editing, you must define a study page that corresponds to the Lab Loader protocol (Type 4).

For more information

For information on creating study pages, see the *Design* section in *Admin and Design*.

For information on editing data using the default study book, see the *Enter* section in *Enter, Resolve, and Retrieve*.

For information on editing data using the Error Log, see Chapter 27.

27 The Error Log

Overview

The *Error Log* is a cumulative log of errors that occurred during screening, validation, and transfer operations in Lab Loader. It is also a cumulative log of errors that occurred during screening, validation, merging, global change, and global delete operations in Manage. You use the Error Log to view and correct records that failed these processes. There is one Error Log for each protocol.

Where is the Error Log found?

When errors occur in Lab Loader during screening, validation, or transferring, entries are added to the Error Log. However, the location of the Error Log entry depends on when the error occurs:

- If the error occurs during screening, then an entry is added to the source protocol's Error Log.

  For example, if a mandatory item is missing a value, an error will be generated and added to the source protocol's Error Log.

- If the error occurs during transfer and prevents the record from being transferred, then the record remains in the source protocol, and an entry is added to the source protocol's Error Log. A flag is attached to the record in the source protocol.

  For example, if a record contains a subject who is not enrolled in the destination protocol's study book, an error will be generated and added to the source protocol's Error Log.

- If the error occurs during transfer and occurs after the record is inserted into the update table of the destination protocol, an entry is added to the destination protocol's Error Log.

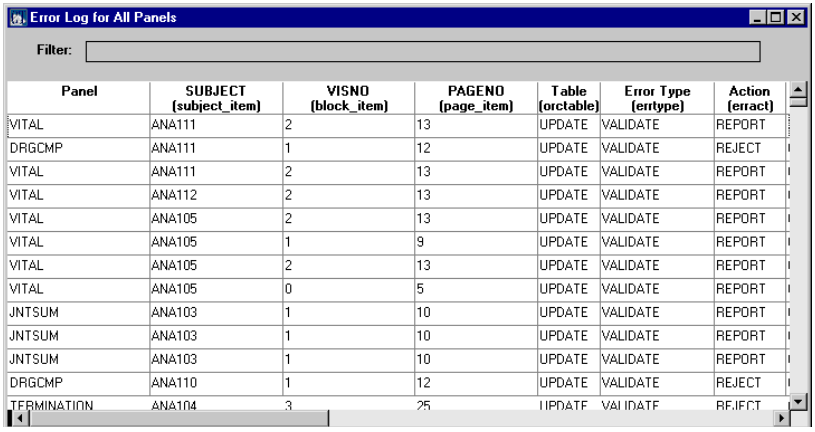
  For example, if a screening error occurs during the transfer process, then an error will be generated and added to the destination protocol's Error Log.

Viewing the Error Log

View the Error Log for all panels

To view the Error Log for all panels in a protocol, from the **Reports** menu, select **Error Log >> View All**.

The Error Log opens:



Panel	SUBJECT (subject_item)	VISNO (block_item)	PAGENO (page_item)	Table (orctable)	Error Type (errtype)	Action (erract)
VITAL	ANA111	2	13	UPDATE	VALIDATE	REPORT
DRGCMP	ANA111	1	12	UPDATE	VALIDATE	REJECT
VITAL	ANA111	2	13	UPDATE	VALIDATE	REPORT
VITAL	ANA112	2	13	UPDATE	VALIDATE	REPORT
VITAL	ANA105	2	13	UPDATE	VALIDATE	REPORT
VITAL	ANA105	1	9	UPDATE	VALIDATE	REPORT
VITAL	ANA105	2	13	UPDATE	VALIDATE	REPORT
VITAL	ANA105	0	5	UPDATE	VALIDATE	REPORT
JNTSUM	ANA103	1	10	UPDATE	VALIDATE	REPORT
JNTSUM	ANA103	1	10	UPDATE	VALIDATE	REPORT
JNTSUM	ANA103	1	10	UPDATE	VALIDATE	REPORT
DRGCMP	ANA110	1	12	UPDATE	VALIDATE	REJECT
TERMINATION	ANA104	3	25	UPDATE	VALIDATE	REJECT

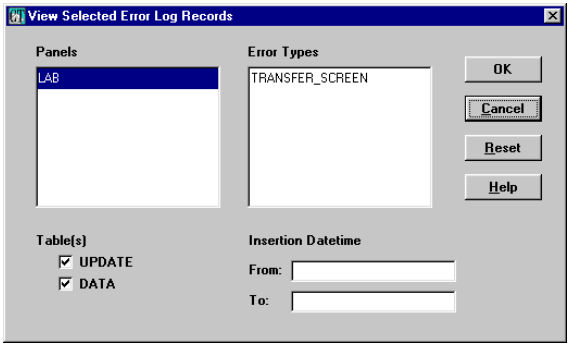
If you are working with more than one page of records, you can view records by page by using:

- The **View** menu's **First Page**, **Prior Page**, **Next Page**, **Last Page** commands.
- The arrow buttons on the Task toolbar.

View the Error Log for selected panels

To view the Error Log for selected panels, from the **Reports** menu, select **Error Log >> View By Panel**.

The View Selected Error Log Records dialog box opens:

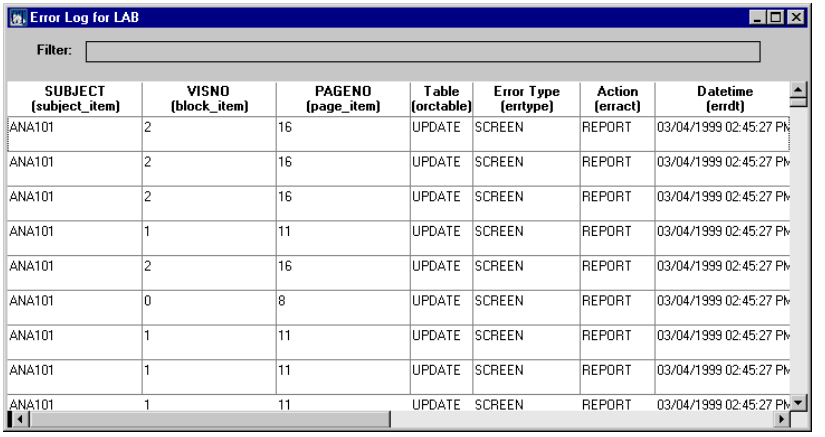


Select the panels for which you want to view the Error Log. Then, select the error types for which you want records to be displayed on the Error Log. If you do not select an error type, then records containing all error types will display on the log.

Select the type of database table for which you want to display the Error Log. You can select the update table, the data table, or both types of database tables.

You can further restrict the records that display in the log by entering a range of dates and times that the records were generated on the Error Log.

The Error Log opens:



SUBJECT (subject_item)	VISNO (block_item)	PAGENO (page_item)	Table (orctable)	Error Type (errtype)	Action (erract)	Datetime (errdt)
ANA101	2	16	UPDATE	SCREEN	REPORT	03/04/1999 02:45:27 PM
ANA101	2	16	UPDATE	SCREEN	REPORT	03/04/1999 02:45:27 PM
ANA101	2	16	UPDATE	SCREEN	REPORT	03/04/1999 02:45:27 PM
ANA101	1	11	UPDATE	SCREEN	REPORT	03/04/1999 02:45:27 PM
ANA101	2	16	UPDATE	SCREEN	REPORT	03/04/1999 02:45:27 PM
ANA101	0	8	UPDATE	SCREEN	REPORT	03/04/1999 02:45:27 PM
ANA101	1	11	UPDATE	SCREEN	REPORT	03/04/1999 02:45:27 PM
ANA101	1	11	UPDATE	SCREEN	REPORT	03/04/1999 02:45:27 PM
ANA101	1	11	UPDATE	SCREEN	REPORT	03/04/1999 02:45:27 PM

When you view the Error Log for a specific panel, the Error Log may display an additional item, defined by the ERRLOG_DISPLAY_ITEM user parameter. Your designer determines if this additional item is used.

If you are working with more than one page of records, then you can view records by page by using:

- The **View** menu's **First Page**, **Prior Page**, **Next Page**, **Last Page** commands.
- The arrow buttons on the Task toolbar.

Error Log options

You can view the Error Log, purge all entries from it, or purge selected entries from it based on the following criteria:

- Panel
- Error type

- Type of database table (UPDATE or DATA)
- Date and time the entries were added to the log
- SQL Restriction (Double-click the SQL Restriction box.)

You can use the **View** menu to filter or sort a displayed Error Log, and the **File** menu to save or print the log.

Error Log contents

Information displays for each record in which an error occurs. The following table describes the information in the Error Log:

Report column:	**Description:**
Panel	If you select the **View All** command, name of the panel containing the record with the error.
Subject Item	For Types 1 through 5 panels. The column heading is the subject item. The value in the column is the value of the record's subject item. ***Note:*** This column only displays in View By Panel mode.
Block Item	For Types 1 through 4 panels. The column heading is the block item name. The value in the column is the value of the record's block item.
Block Repeat Item	For Types 1 through 4 panels. The value of the block repeat key item if the context panel for the protocol has a block repeat key item.
Page Item	For Types 1 through 4 panels. The column heading is the page item. The value in the column is the value of the record's page item.
Page Repeat Item	For Types 1 through 4 panels. The value of the page repeat key item if the context panel for the protocol has a page repeat key item.
Table	Type of database table (UPDATE or DATA) containing the record.

Report column:	Description:
Error Type	• SCREEN — The error occurred during screening. • VALIDATE — The error occurred during validation. • TRANSFER — The error occurred during data transfer. For error types GLOBCH, GLOBDEL, and MGLOBCH, see the *Manage* section of this book.
Action	For error type SCREEN: REPORT — There is an error with the study book. For example, a study page is not defined for the visit. REJECT — There is an error with the data. For example, a mandatory item is missing a value. For error type VALIDATE: REPORT — A rule with the error action REPORT evaluated to FALSE. REJECT — A rule with the error action REJECT evaluated to FALSE. For error type TRANSFER: REPORT — There is an error with the study book. For example, a page is not defined for the visit. Or, there is an error with the screening checks on the destination items. REJECT — There is an error with the data. For example, a mandatory item is missing a value.
Datetime	Date and time the error occurred.
Remarks	Description of the error, as determined by the error type.
Rule Name	For error type SCREEN, the name of the item that failed a screen check. For example, if there was no subject identifier for the record that you tried to screen, then this value is SUBJECT_ID. For error type VALIDATE, the name of the rule that evaluated to FALSE. For error type TRANSFER, the name of the item that failed a screen check.

Report column:	Description:
Ct Recid	Value of the CT_RECID system item for the record in the protocol where the record exists.

Note: If an additional Error Log item is defined for the protocol, the error log item will also display on the Error Log. The Error Log item is determined by the designer and is defined by the ERRLOG_DISPLAY_ITEM user parameter. Error Log items are only displayed if you select **Error Log >>View By Panel** to view the Error Log.

Editing records from the Error Log

When a record fails a process in Lab Loader, you may need to edit the record and repeat the process. For example, if a record fails validation, you may need to edit the record and validate the record again. You can edit records directly from the Error Log. You do not need to use Enter to edit the records.

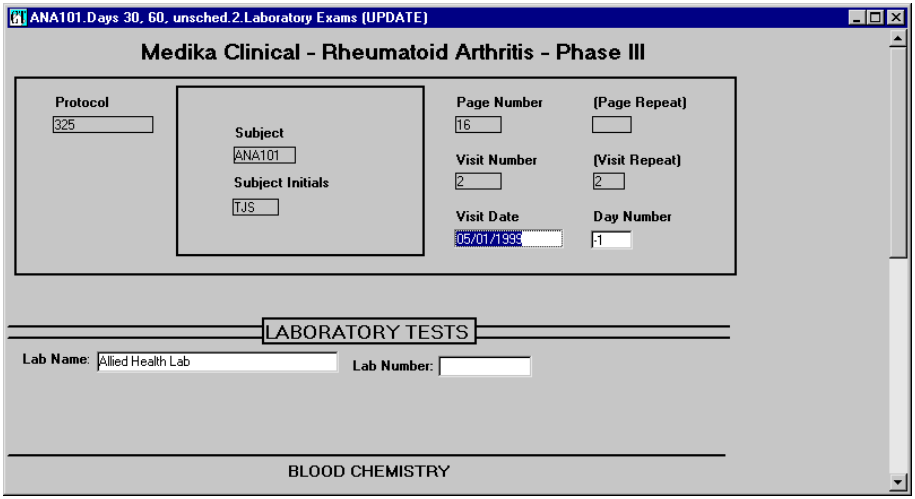
You can use the Error Log to edit records that have an error reported against them if you have the required access rights and if your designer has defined a study page and study book for the panel that contains the record that you want to edit. There must also be enough context information in the record for the record to be identifiable to Enter.

When you select a record in the Error Log, a study page opens in which you can edit the records and save the new values to the database. You can also:

- Supply a reason for change.
- Attach flags and notes to records.
- Work with discrepancies in the destination protocol.

Note: You must set the study book to use when editing from the Error Log. From the **File** menu, select **Set Study Book**. A dialog box opens in which you can select the study book.

To select a record in the Error Log for editing, double-click the record. The Clintrial software opens the study page that contains the record. The following example shows a portion of the study page that opens for a record from the LAB panel of the MEDIKA_CLINICAL protocol that was selected in the Error Log:



You edit the record in the same way that you edit records in a study page in Enter. However, you can only perform a subset of the editing and the navigation functions available in Enter:

- You can only edit one study page at a time; you cannot navigate to other study pages or subjects in the study book.
- You cannot add or insert repeating items.
- You cannot delete records.

After you make the corrections and save the record, you can perform the activity, such as validation, that the record had previously failed.

For more information on access rights, see the *Admin* section of *Admin and Design.*

28 *Lab Loader System Administration*

Overview

After you define your source protocol, you need to perform the following system administration tasks:

- Manage access to the Lab Loader protocol by defining access rights and access levels.
- Define system parameters to customize Lab Loader behavior.

You perform system administration tasks in Admin.

For more information on system administration tasks, see *Admin and Design*.

Access rights and access levels

After you set up a source protocol, you assign access rights to the source protocol in Admin. An *access right* is a predefined set of Clintrial software activities that can be associated with a user or a usergroup.

Access levels determine what type of access users have to the activities defined by an access right. By selecting an appropriate access level, you grant users or usergroups the ability to perform certain activities.

For more information on access rights and access levels, see *Admin and Design*.

Design access rights

To set up source and destination protocols, users must be assigned access to the appropriate Design protocol access rights.

Lab Loader access rights

To perform setup and data-processing tasks within Lab Loader, such as creating control files and transfer maps, batch loading data, processing the batch-loaded data, and transferring records, users must be assigned the appropriate access level to the following Lab Loader access rights:

Protocol access right:	**User can:**	**Access level:**
Design	Work on control files and transfer maps.	Full — Can perform all actions on control files and transfer maps. Read — Can view attributes of control files and transfer maps. None — Cannot access control files or transfer maps. ***Note***: The Design access right can be applied to only a Lab Loader protocol.
Transfer	Transfer records from a Lab Loader protocol into the clinical data protocol on which this right will be set, and manage duplicates. Granting this option allows the user to transfer data to any panel.	Full — Can transfer records, view and purge the Transfer Log, and view maps and reports. Read — Can view transfer maps, the Transfer Log, and duplicates. None — Cannot transfer records. ***Note***: The Transfer access right cannot be applied to a view protocol or Lab Loader protocol.

Manage access rights

Manage access rights control access to Lab Loader activities that are also accessible from Manage.

Enter access rights

To perform Error Log editing in a source protocol, the user must have at least NoDelete access to the Enter Unmerged protocol access right, as well as Full access to the Manage Other access right.

System parameters and user preferences

System parameters define characteristics of the work environment for all users of an Oracle database instance to which the users connect through the Clintrial software.

You set system parameters in Admin.

What are user preferences?

User preferences are a subset of system parameters. Each user can change the default values of the parameters for use in their account by changing the user preferences. Default values for user preferences come from corresponding system parameters.

Your Clintrial software administrator will set default user preferences in Admin when the Clintrial software is installed. You can change the default Lab Loader user preferences in Lab Loader.

Lab Loader system parameters

Lab Loader has two system parameters that affect the behavior of Lab Loader. The following table describes these system parameters:

System parameter:	Description:
CTL_DUPFLAG-_LOC	Indicates the record to which a duplicate flag should be attached. DATA — The flag should be attached to the duplicate record in the DATA table of the destination protocol when duplicate records are found during data transfer. UPDATE — The flag should be attached to the duplicate record in the UPDATE table of the destination protocol when duplicate records are found during data transfer.
CTL_TEST_MODE	This system parameter affects the action Lab Loader takes with records in the source panel after a successful transfer. Yes — The Start Data Transfer window displays a check box labeled Delete Records After Transfer. If you check this check box, records that are successfully transferred from the source protocol to the destination protocol are deleted from the source protocol. If you clear this check box, the records remain in the source protocol. No — The Delete Records After Transfer check box is not displayed and records are always deleted after transfer. This system parameter also sets the default user preference.

Manage system parameters

The Manage user parameter ERRLOG_DISPLAY_ITEM allows you to indicate an additional item to be displayed on the Error Log. It is used for non-context items. That is, items in Type 0 panels. This additional item is only displayed on the Error Log when the Error Log is viewed by panel.

This user parameter is also available as a user preference, and can be changed by any user at any time during a session without restarting the Clintrial software.

This user parameter performs the same function as the ERRORLOG_ITEM item attribute used for context items. That is, items in Type 1-4 panels.

29 Lab Normals

Overview

What are lab normal ranges?

Lab normal ranges (also called reference values) are laboratory test values that serve as reference values for subsequent laboratory test results. Lab normal ranges are laboratory test results that are indicative of a healthy state, or are average, typical, or usual. Laboratory test results that are outside of the lab normal ranges may be considered abnormal, unusual, or unhealthy.

You use lab normal ranges as a basis for comparison when you evaluate lab data for a subject. For example, consider the following lab normal ranges:

Age:	Hemoglobin Level:	Unit:
Adult males	14 to 18	g/dL
Elderly males	12.4 to 14.9	g/dL
Adult females	12 to 16	g/dL
Elderly females	11.7 to 13.8	g/dL

Now, consider the following test results:

Subject:	Age:	Age Unit:	Sex:	Hemoglobin Level:	Unit:
ANA101	52	YR	M	15.2	g/dL
ANA102	47	YR	F	14.7	g/dL
ANA103	68	YR	M	11.7	g/dL
ANA104	65	YR	M	12.8	g/dL
ANA105	70	YR	F	13.1	g/dL

In comparison to the lab normals, subject ANA103 has a hemoglobin level that is outside of the normal range.

Storing lab normal ranges

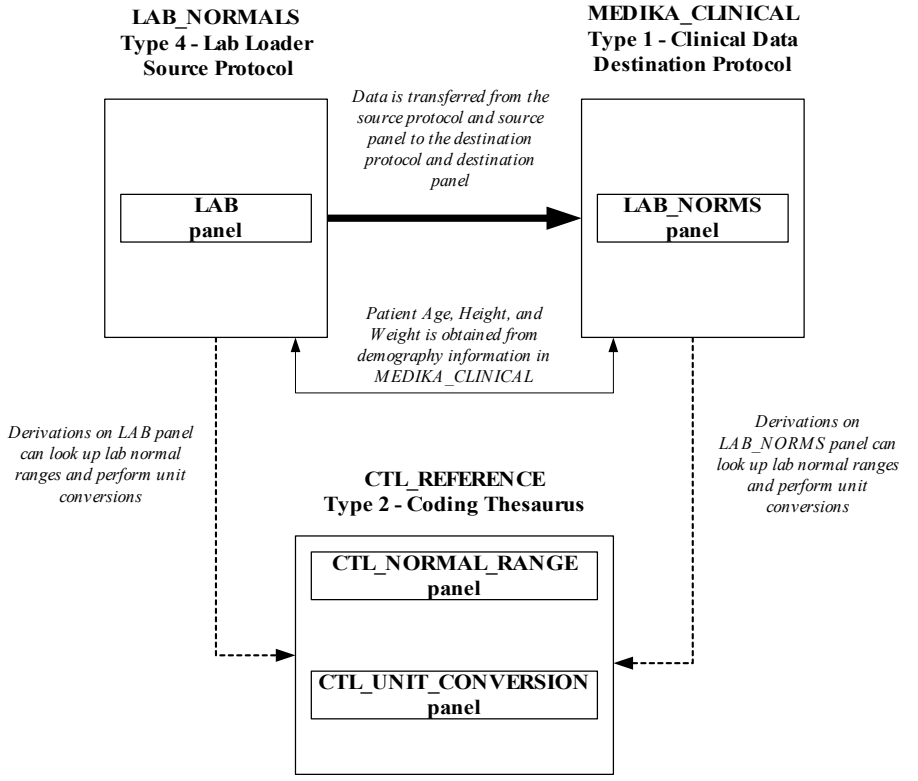
Lab normal ranges are typically stored in a Type 0 panel. A Type 0 panel stores data that is not related to a particular subject or visit. Neither a subject identifier nor a visit identifier is required for a Type 0 panel.

Using Lab Loader, you must first batch load lab normal ranges into a Type 0 panel. You can then validate and merge the data. You edit and maintain the lab normal ranges using Enter.

How do you use lab normals?

Using the Clintrial software, you can perform the following tasks associated with lab normals:

- Batch load, validate, and merge lab normal ranges that vary by age, sex, and weight
- Compare clinical data to lab normal ranges to determine the normalcy status of test results
- Convert test results into Système International (SI) units



Sample lab normals protocols

In addition to the MEDIKA_CLINICAL sample study protocol, the following protocols are provided with the Clintrial software to help you set up and maintain lab normal ranges:

- CTL_REFERENCE — Thesaurus protocol set up to contain lab normal ranges and SI unit conversion factors.
- LAB_NORMALS — Source protocol containing clinical data to be prepared, and then transferred into MEDIKA_CLINICAL.

The protocols must be imported before you perform the Lab Loader server installation. When you import CTL_REFERENCE, you must ensure that the protocol remains named CTL_REFERENCE, as the PL/SQL functions provided refer to the CTL_REFERENCE protocol.

For more information on importing CTL_REFERENCE and LAB_NORMALS, see the *Server Installation* section in *Getting Started*.

CTL_REFERENCE protocol

CTL_REFERENCE is intended as an example of a thesaurus (Type 2) protocol to assist you in setting up lab normal ranges. The derivations on the source protocol (LAB_NORMALS) and the destination protocol (MEDIKA_CLINICAL) perform lab normal range lookups on CTL_REFERENCE. However, you can also use CTL_REFERENCE as a thesaurus protocol for your own source protocol and destination protocol.

CTL_REFERENCE contains two study books:

- CTL_NORMAL_RANGE — Set up to contain lab normal ranges.
- CTL_UNIT_CONVERSION — Set up to contain units, multiplication factors, and additive constants for converting the normalcy status into SI units.

The following table describes the fields provided in the CTL_NORMAL_RANGE study book:

Item:	Description:
Lab ID	A unique laboratory identifier, such as the lab name.
Test	The name of the lab test.
Start Date	The date after which the associated lab normal ranges are effective.
High	The highest acceptable value for the test result.
Low	The lowest acceptable value for the test result.
Unit	The unit of measure for the test.
Sex	The sex for which the lab normal range is applicable.
Age Low	The lowest age value for which the lab normal range is applicable.

Item:	Description:
Age High	The highest age value for which the lab normal range is applicable.
Age Unit	The unit of measure for the age.
Wt Low	The lowest weight value for which the lab normal range is applicable.
Wt High	The highest weight value for which the lab normal range is applicable.
Wt Unit	The unit of measure for the weight.

Batch loading lab normal ranges

Sample control files for batch loading data are provided with the Clintrial software to help you batch load lab normal ranges into CTL_REFERENCE. You can also modify the control files as necessary to batch load lab normal ranges into your own thesaurus protocol. You must batch load data into CTL_REFERENCE through Manage.

Additionally, sample lab normal ranges are provided with the Clintrial software. The data is intended as an example of a valid set of lab normal ranges. You can import the sample lab normal ranges using Design.

You must batch load the sample data or your own data using Manage.

LAB_NORMALS protocol

LAB_NORMALS is a Lab Loader (Type 4) source protocol provided with the Clintrial software. You batch load lab data into LAB_NORMALS, manipulate the data, and then transfer the data into the MEDIKA_CLINICAL destination protocol. The derivations on LAB_NORMALS and on MEDIKA_CLINICAL (also provided with the Clintrial software) perform lab normal range lookups on CTL_REFERENCE.

Developing lab normal ranges

Lab normal ranges are often dependent upon one or more items, such as age, sex, and weight. If the lab normal range is dependent upon an item, then the item is a factor in determining the normal range of values for a test result. For example, the age of the subject is a factor in determining the lab normal ranges for blood pressure. Blood pressure results in adults differ significantly from blood pressure results in children. Therefore, age is a factor in determining lab normal ranges for blood pressure.

Lab normal ranges can also be dependent upon the specific lab from which they are obtained. Each lab may have a slightly different methodology for obtaining a set of lab normal ranges. As such, a lab may provide values that differ slightly in comparison to lab normal ranges provided by other labs. Therefore, the lab from which the lab normal ranges are obtained can be a factor.

In CTL_REFERENCE, you can maintain lab normal ranges that vary for the following items:

- Lab
- Lab test
- Effective date
- Sex
- Age
- Weight

Consider the following set of lab normal ranges:

Age:	Sex:	Hemoglobin Level:	Unit:
Less then 7 days	M/F	17 to 22	g/dL
1 week	M/F	15 to 20	g/dL
1 month	M/F	11 to 15	g/dL
Children	M/F	11 to 13	g/dL
Adult	M	14 to 18	g/dL
Elderly	M	12.4 to 14.9	g/dL
Adult	F	12 to 16	g/dL

Age:	Sex:	Hemoglobin Level:	Unit:
Elderly	F	11.7 to 13.8	g/dL

As shown, age and sex are factors for hemoglobin. Using the Clintrial software, you can then enter a set of lab normal ranges that vary by age and sex.

In CTL_REFERENCE, you can enter the following lab normal ranges:

Lab ID	Test	Start Date	High	Low	Unit	Sex	AgeL	AgeH	AgeU	WtL	WtH	WtU
NATIONAL	HEMG	12/01/01	22	17	g/dL	.	0	0.019	YR	0		LB
NATIONAL	HEMG	12/01/01	20	15	g/dL	.	0.019	0.082	YR	0		LB
NATIONAL	HEMG	12/01/01	15	11	g/dL	.	0.082	3.000	YR	0		LB
NATIONAL	HEMG	12/01/01	13	11	g/dL	.	3.000	18.000	YR	0		LB
NATIONAL	HEMG	12/01/01	18	14	g/dL	M	18.000	65.000	YR	0		LB
NATIONAL	HEMG	12/01/01	14.9	12.4	g/dL	M	65.000		YR	0		LB
NATIONAL	HEMG	12/01/01	16	12	g/dL	F	18.000	65.000	YR	0		LB
NATIONAL	HEMG	12/01/01	13.8	11.7	g/dL	F	65.000		YR	0		LB

Conditions

The following section describes the conditions that must be met when you develop lab normal ranges.

Same test unit must be used

You must enter the same test unit for all records for the same lab ID, test, and start date. If the test unit is not the same for all records containing the same lab ID, test, and start date, then you should not enter a unit.

Age must be entered for all records

If age is a factor, then you must enter an age for all records containing the same lab ID, test, and start date. If age is not a factor, then you must enter 0 in the Age low field.

Weight must be entered for all records

If weight is a factor, then you must enter a weight for all records containing the same lab ID, test, and start date. If weight is not a factor, then you must enter 0 in the Wt low field.

Sex must be entered for all records

If sex is a factor, then you must enter a sex for all records containing the same lab ID, test, and start date. If sex is not a factor, then you must enter a period (‘.’) in the Sex field.

Complete set of lab normal ranges must be entered

You must provide a complete set of lab normal ranges for every lab ID, test, and start date. That is, if age, sex, or weight are factors, then you must ensure that data for all possible ranges of age, sex, and weight is entered for every lab ID, test, and start date.

For example, if the age range is 18-25 years, then you must enter data for the following year ranges:

- 0-18 years
- 18-25 years
- 25 years and up

Next low value must equal previous high value

For age and weight, the next low value must be equal to the previous high value.

Consider the following partial example:

AgeL	AgeH	AgeU	WtL	WtH	WtU
3.000	18.000	YR	0		LB
18.000	65.000	YR	0		LB

In the example, the AgeL in record two is equal to the AgeH in record one.

For more information on conditions, see the next section.

Validating lab normals

When you have batch loaded or interactively entered a set of lab normal ranges, you must validate and then merge the data. To be a valid set of lab normal ranges, all records must have passed validation, and all records must have been merged into the DATA table.

CTL_REFERENCE contains a set of rules and derivations that are applied to data during validation. The following table describes the rules that are applied to the data during validation:

Rule Name:	Rule Action:	Description:
CTL$CHK_OVERLAP_RANGES	REJECT	Ensures that there are no overlapping lab normal ranges.
CTL$CHK_MISSING_RANGES	REPORT	Ensures that there are no missing lab normal ranges.
CTL$CHK_AGE_RANGE	REJECT	Ensures that the high age value is greater than the low age value.
CTL$CHK_WT_RANGE	REJECT	Ensures that the high weight value is greater than the low weight value.
CTL$CHK_TEST_RANGE	REJECT	Ensures that the high test value is greater than the low test value.
CTL$CHK_TEST_UNIT	REPORT	Ensures that the test unit of a record is the same as the test unit in other records containing the same lab ID, test code, and start date.

CTL$CHK_OVERLAP_RANGE

The CTL$CHK_OVERLAP_RANGE rule ensures that no overlapping lab normal ranges exist. An overlapping range exists when at least one of the following conditions is met:

- More then one record exists in which the Lab ID, Test, Start Date, Age Low, and Weight Low are the same, and:

– One record contains '.' for Sex, and another record contains M or F for Sex.

- More than one record exists in which the Lab ID, Test, and Start Date are the same, and the age ranges overlap each other
- More than one record exists in which the Lab ID, Test, and Start Date are the same, and the weight ranges overlap each other

Consider the following examples:

Example 1

The following example shows two records in which the sex overlaps, where the lab ID, test, start date, age low, and weight low are the same, and two nondistinct values are entered for sex:

Lab ID	Test	Start Date	High	Low	Unit	Sex	AgeL	AgeH	AgeU	WtL	WtH	WtU
NATIONAL	HEMG	12/01/01	18	14	g/dL	.	18.000	65.000	YR	0		LB
NATIONAL	HEMG	12/01/01	18	14	g/dL	M	18.000	65.000	YR	0		LB

Example 2

The following example shows two records in which the age overlaps:

Lab ID	Test	Start Date	High	Low	Unit	Sex	AgeL	AgeH	AgeU	WtL	WtH	WtU
NATIONAL	HEMG	12/01/01	18	14	g/dL	M	18.000	65.000	YR	0		LB
NATIONAL	HEMG	12/01/01	18	14	g/dL	M	20.000	70.000	YR	0		LB

Example 3

In the following example, the weight range in record 2 overlaps the weight range in record 1:

Lab ID	Test	Start Date	High	Low	Unit	Sex	AgeL	AgeH	AgeU	WtL	WtH	WtU
NATIONAL	HEMG	12/01/01	14.9	12.4	g/dL	M	65.000		YR	0	150	LB
NATIONAL	HEMG	12/01/01	14.9	12.4	g/dL	M	65.000		YR	130	200	LB

Lab ID	Test	Start Date	High	Low	Unit	Sex	AgeL	AgeH	AgeU	WtL	WtH	WtU
NATIONAL	HEMG	12/01/01	14.9	12.4	g/dL	M	65.000		YR	200		LB

CTL$CHK_MISSING_RANGES

The CTL$CHK_MISSING_RANGES rule ensures that a complete set of lab normal ranges exists. Lab normal ranges are missing when one or more of the following conditions are met:

- No value is entered for Sex.
- Sex is a factor, and both sexes are not represented.
- No value is entered for Age.
- Age is a factor, and not all age ranges are entered.
- No value is entered for weight.
- Weight is a factor, and not all weight ranges are entered.

Consider the following examples:

Example 1

In the following example, not all weight ranges are entered:

Lab ID	Test	Start Date	High	Low	Unit	Sex	AgeL	AgeH	AgeU	WtL	WtH	WtU
NATIONAL	HEMG	12/01/01	16	12	g/dL	F	18.000	65.000	YR	100	140	LB
NATIONAL	HEMG	12/01/01	16	12	g/dL	F	18.000	65.000	YR	140	180	LB
NATIONAL	HEMG	12/01/01	16	12	g/dL	F	18.000	65.000	YR	180	240	LB

To be complete, the weight ranges for Females, aged 18 to 65, must also include:

- 0-100 LB
- 240 LB and above

Example 2

In the following example, no value is entered for Age Low:

Lab ID	Test	Start Date	High	Low	Unit	Sex	AgeL	AgeH	AgeU	WtL	WtH	WtU
NATIONAL	HEMG	12/01/01	13	11	g/dL	F		18.000	YR	0		LB
NATIONAL	HEMG	12/01/01	16	12	g/dL	F	18.000	65.000	YR	0		LB
NATIONAL	HEMG	12/01/01	16	12	g/dL	F	65.000		YR	0		LB

CTL$CHK_AGE_RANGE

The CTL$CHK_AGE_RANGE rule ensures that the Age High value in all records is greater than the associated Age Low value.

Consider the following example:

Lab ID	Test	Start Date	High	Low	Unit	Sex	AgeL	AgeH	AgeU	WtL	WtH	WtU
NATIONAL	HEMG	12/01/01	16	12	g/dL	F	18.000	0				
NATIONAL	HEMG	12/01/01	16	12	g/dL	F	18.000	65.000	YR	0		LB
NATIONAL	HEMG	12/01/01	16	12	g/dL	F	65.000		YR	0		LB

In record one, the Age high value is not greater than the associated Age Low value.

CTL$CHK_WT_RANGE

The CTL$CHK_WT_RANGE rule ensures that the Weight High value in all records is greater than the associated Weight Low value.

Consider the following example:

Lab ID	Test	Start Date	High	Low	Unit	Sex	AgeL	AgeH	AgeU	WtL	WtH	WtU
NATIONAL	HEMG	12/01/01	16	12	g/dL	F	18.000	65.000	YR	140	100	LB

Lab ID	Test	Start Date	High	Low	Unit	Sex	AgeL	AgeH	AgeU	WtL	WtH	WtU
NATIONAL	HEMG	12/01/01	16	12	g/dL	F	18.000	65.000	YR	140	180	LB

In record one, the Weight High value is not greater than the associated weight low value.

CTL$CHK_TEST_RANGE

The CTL$CHK_TEST_RANGE rule ensures that the test High value is greater than the associated test Low value.

Consider the following example:

Lab ID	Test	Start Date	High	Low	Unit	Sex	AgeL	AgeH	AgeU	WtL	WtH	WtU
NATIONAL	HEMG	12/01/01	12	16	g/dL	F	18.000	65.000	YR	100	140	LB
NATIONAL	HEMG	12/01/01	16	12	g/dL	F	18.000	65.000	YR	140	180	LB
NATIONAL	HEMG	12/01/01	16	12	g/dL	F	18.000	65.000	YR	180	240	LB

In record one, the High value is not greater than the low value.

CTL$CHK_TEST_UNIT

The CTL$CHK_TEST_UNIT rule ensures that all records with the same Lab ID, Test, and Start Date contain the same Unit value.

Consider the following example:

Lab ID	Test	Start Date	High	Low	Unit	Sex	AgeL	AgeH	AgeU	WtL	WtH	WtU
NATIONAL	HEMG	12/01/01	16	12	g/dL	F	18.000	65.000	YR	100	140	LB
NATIONAL	HEMG	12/01/01	16	12	g/L	F	18.000	65.000	YR	140	180	LB
NATIONAL	HEMG	12/01/01	16	12	g/dL	F	18.000	65.000	YR	180	240	LB

In record two, the test unit is not the same as the test unit in record one and in record three.

Using lab normal ranges

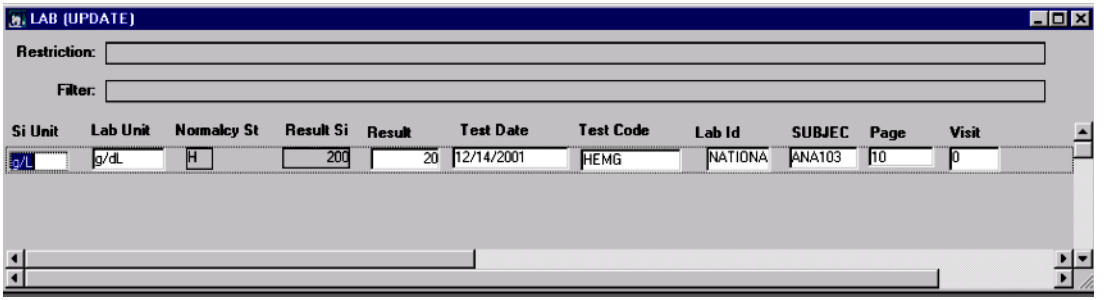
You use lab normal ranges to determine the normalcy status of test results. The *normalcy status* is a value that indicates the measure of normality of the test result as compared to the lab normal ranges.

The following table describes the normalcy statuses:

Status:	Full Status:	Description:
L	Below normal	The test result is below the lowest acceptable value in the lab normal ranges.
H	Above normal	The test result is above the highest acceptable value in the lab normal ranges.
N	Normal	The test result is within the lowest acceptable value and the highest acceptable value in the lab normal ranges.
Null	Null	A Null normalcy status indicates either: • No lab normal range is defined for this test, or • Lab normal ranges do not apply to this test.

Normalcy statuses are returned during validation when validation is run on clinical data in LAB_NORMALS. Derivations that are executed during validation compare the test results in the clinical data to the lab normal ranges in CTL_REFERENCE, and then return a normalcy status based on the comparison. If the patient's age, height, or weight are factors, then the patient's demography information is obtained from the DMG panel in MEDIKA_CLINICAL before determining a normalcy status. Derivations are provided with LAB_NORMALS.

The following example shows the normalcy status, as calculated during validation:



Calculating normalcy status

You can calculate a normalcy status for all records in your own source protocol. To calculate normalcy status, you must first create a source protocol and a destination protocol. If test results will vary by age, sex, and weight, then you must create the following items:

- Sex
- Age
- Age units
- Weight
- Weight units

These items must exist on the same panel.

Converting units into SI units

You can convert test results from standard units into Système International (SI) units during validation. An *SI unit* is a standardized unit of measure from the International System of Units. The *International System of Units* is a system of presenting units of measure in universally recognized formats.

To convert test results, you must first enter the Units, Test, Multiplication Factor, and Additive Constant in the CTL_UNIT_CONVERSION study book of the CTL_REFERENCE protocol. During validation, the derivations in LAB_NORMALS look up the appropriate unit to be converted, and then return the test results in SI units. The conversions must be in the following format:

a * X + b

where a and b are constants, and X is the value to be converted.

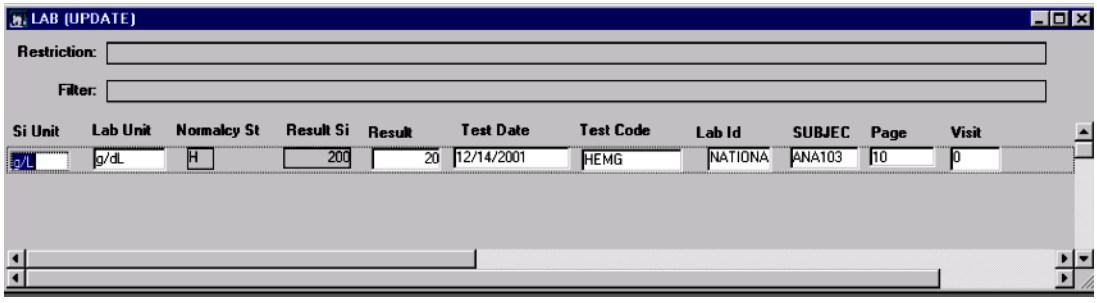
The following table describes the fields provided in the CTL_UNIT_CONVERSION study book:

Item:	Description:
From	The standard unit to be converted from.
To	The SI unit to be converted to.
Test Code	The name of the lab test.
Multiplication Factor	The factor by which to multiply the test results. (a, in the preceding example.)
Additive Constant	The constant to add to the product. (b, in the preceding example.)

For example, to convert hemoglobin results from standard units (g/dL) into SI units (g/L), you would enter the following:

From:	To:	Test Code:	Multiplication Factor:	Additive Constant:
g/dL	g/L	HEMG	10	0

After validation, the following results would be visible in Enter:



In the example, the test result in standard units is 20 g/dL. When converted during validation, the result in SI units is 200 g/L.

30 Control Files

Overview

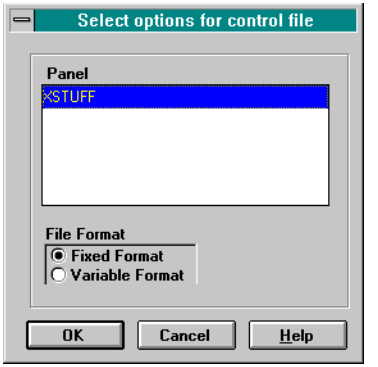
When you start the batch load, you must select a control file for the Clintrial software to use during the batch load. A *control file* is a file that describes how data from an input file will be batch loaded into the source protocol. It functions as the interface between the input file and the Clintrial software database tables, and specifies the location where the Clintrial software should store the data. In Lab Loader, this initial storage location is a panel in a source protocol.

The Clintrial software creates a default control file, which you use as a starting point for creating your own control file.

Note: You can also create your own control file using any text editor. You are not required to use the Clintrial software default control file.

Creating control files

To create a control file, from the **Load** menu, select **Control File >> New**. The Clintrial software displays the Select options for control file dialog box. In the Select options for control file dialog box, select the panel for which you are creating the control file, and the file format for the corresponding data input file. The panels must be installed to appear in this dialog box:



There are two types of input file formats:

- Fixed format

  In a fixed format input file, the data values have a specified length, and each value begins at a fixed location in the record. No delimiters separate the values.

- Variable format

  In a variable format input file, the data values do not have to be a specified length, and may not begin at the same location in each record. Delimiters that you specify, such as commas, separate the values.

After you specify the panel and file format, the Clintrial software uses the information to create a default control file.

Note: The default control file is a starting point. You must revise the control file to match the structure of your input file.

The default control file lists all of the items in the selected panel. If the control file is in fixed format, the default control file also estimates the fixed location for the item values based on the item length.

You must edit the default control file to correspond to the structure of the input file rather than to the structure of the Clintrial software panel. For example, you may need to:

- Rearrange the order of the items in the control file.
- Change the delimiter in a variable format control file.
- Change an item's fixed size in a fixed format control file.
- Add conversion instructions, such as instructions for converting date formats.
- Adjust the ENCLOSED BY clause to change the character used to indicate character strings.
- Delete items for which the input file does not contain values.

The following sections provide examples of the default control files the Clintrial software creates, and describe ways you can edit these files.

For more information on creating control files, see the Oracle SQL*Loader documentation.

In a *fixed format* input file, each data value begins at a fixed location in the record. The corresponding fixed format control file must specify the location of the data value, so that the correct values are stored in the corresponding items.

When you create a default fixed format control file, the Clintrial software assumes that every item will be used. Thus, the Clintrial software lists all of the items in the panel, and provides a default location for the data value, based on the item length.

The following example shows a fixed format control file for the LAB panel in the XYREXEL_LAB_SOURCE protocol:

```
------------------------------------------------------------------------
--
-- Control file for loading data into:
--      XYREXEL_LAB_SOURCE.LAB_UPDATE
------------------------------------------------------------------------
LOAD DATA

APPEND
INTO TABLE XYREXEL_LAB_SOURCE.LAB_UPDATE

TRAILING NULLCOLS

(STATUS              constant     3,
CT_RECID             sequence     (count),
SUBJECT_ID           constant     0,
SUBJECT              position(1:8)       NULLIF SUBJECT=BLANKS,
LAB                  position(11:20)     "RTRIM(LTRIM(:LAB))",
TEST                 position(21:28)     "RTRIM(LTRIM(:TEST))",
INVESTIGATOR         position(29:36)
"RTRIM(LTRIM(:INVESTIGATOR))",

AGE                  position(37:44)     NULLIF PAGE=BLANKS,
VISITNO              position(45:54)     NULLIF VISITNO=BLANKS

VISITDATE            position(55:68)     DATE "YYYYMMDDHH24MISS"
NULLIF VISITDATE=BLANKS,
TEMPERATURE          position(69:77)     NULLIF TEMPERATURE=BLANKS
)
```

Note: You do not need to batch load every character from an input file into the Clintrial software source protocol. To skip a character, adjust the position numbers so that the character's position is not specified.

Variable format control files

In a *variable format* input file, no item has a fixed length, so the item values may occur at a different location in every record. Variable format records use a delimiter, such as a comma, to separate the item values.

When you create a default variable format control file, the Clintrial software lists all of the items in the panel, and specifies a default delimiter.

The following example shows a variable format control file for the LAB panel in the XYREXEL_LAB_SOURCE protocol:

```
--------------------------------------------------------------------------
--
-- Control file for loading data into:
--      XYREXEL_LAB_SOURCE.LAB_UPDATE
--------------------------------------------------------------------------

LOAD DATA

APPEND
INTO TABLE XYREXEL_LAB_SOURCE.LAB_UPDATE

-- Note: Change @ to your file's separator character and adjust the 'ENCLOSED BY' clause
FIELDS TERMINATED BY ',' OPTIONALLY ENCLOSED BY ""

TRAILING NULLCOLS

(STATUS              constant     3,
CT_RECID             sequence     (count),
SUBJECT_ID           constant     0,
SUBJECT              "RTRIM(LTRIM(:SUBJECT))",
LAB                  "RTRIM(LTRIM(:LAB))",
TEST                 "RTRIM(LTRIM(:TEST))",
INVESTIGATOR         NULLIF INVESTIGATOR=BLANKS,
PAGE                 NULLIF PAGE=BLANKS,
```

```
VISITNO          NULLIF VISITNO=BLANKS,
VISITDATE          DATE "MM/DD/YYYY" NULLIF VISITDATE=BLANKS,
TEMPERATURE          NULLIF TEMPERATURE=BLANKS
)
```

Delimiters

A variable format control file must indicate the delimiter that is used in the input file.

For example, if the input file is a comma-separated (.csv) file, then the delimiter is a comma. In the control file, you must replace the default delimiter (@) with a comma:

FIELDS TERMINATED by ‘,’

Trailing null values

By default, a control file includes the following line:

TRAILING NULLCOLS

This line indicates that if the control file includes more items than are in the input file, then those items should be given the value Null when the record is batch-loaded.

Date format

The control file must specify the date format that is used in the input file.

For example, if the input file contains the date 03-17-1999 00:00:00, then the control file must specify the date format of the item as:

DATE “MM-DD-YYYY HH24:MI:SS”

Character strings

The control file must specify the character that is used to indicate character strings in the input file. In the control file, enclose the character in single quotation marks.

For example, if the double quotation mark is used to indicate character strings in the input file, then the control file must specify:

OPTIONALLY ENCLOSED by ‘”’

NULLIF clause

For items of the data type NUMBER or DATE, the default control file contains a NULLIF clause. The default NULLIF clause treats an item as Null if the value in the input file is blank.

You can edit the NULLIF clause in the control file so that an item is treated as Null if the value in the input file is another value; for example, a period (.).

LTRIM and RTRIM clauses

For items of the data type TEXT, the default control file includes the following:

- An LTRIM clause, which trims leading blanks
- An RTRIM clause, which trims trailing blanks

Saving control files

During the course of a clinical study, you may receive data multiple times from a lab. This data will most likely be in the same format each time, and you can use the same control file to batch load the data. You can create control files to batch load this data once, and then store the control files in a database table, referred to as the control file library.

After the files are saved to the control file library, you and other users with the correct privileges can use these control files to batch load data. You do not have to recreate the control files each time you receive data from a specific lab.

To save a control file to the control file library, from the **File** menu, select **Save to Library**.

The NLS_LANG setting of Windows operating system on the computer you are using for the Clintrial Client is set as either ANSI or Unicode. The Oracle database uses the client's NLS_LANG setting to determine the character set of control files and scripts that the client is sending and to determine if character set conversion is necessary. If the NLS_LANG client setting is not the same as the control file, data integrity and consistency might be compromised.

By default, the Windows NLS_LANG setting is in ANSI format. However, by default, Lab Loader saves control files in Unicode format.

The ANSI NLS_LANG settings for the Windows English and Japanese clients are:

- AMERICAN_AMERICA.WE8MSWIN1252
- JAPANESE_JAPAN.JA16SJIS or
- JAPANESE_JAPAN.JA16SJISTILDE

To save the control file to your computer when you are not using Unicode, open the control file, and then from the **File** menu, select **Save as…** and choose ANSI format.

If the Oracle client is not configured to use Unicode format, to use a control file it must be saved as a file on your computer in ANSI format. You cannot directly access control files in the control file library during a batch load.

Note: The default Save behavior in Lab Loader saves the control file to the control file library.

If you have a control file or data file saved in UTF-8 format, the client NLS_LANG must be configured to use Unicode. Otherwise, data can't be loaded to Source Protocol.

The Unicode NLS_LANG settings for the Windows English and Japanese clients are:

- UTF-8 - AMERICAN_AMERICA.AL32UTF8
- UTF-8 - JAPANESE_JAPAN.AL32UTF8

Copying control files

You can copy an existing control file from the control file library to serve as the starting point for creating a new control file. All control files that exist in the control file library for protocols in the current protocol's searchlist are available to copy.

To copy a control file, from the **Load** menu, select **Control File >> Copy**.

31 Transfer Maps

Overview

A *transfer map* indicates data to be transferred from a source protocol to a destination protocol by establishing a direct connection from the source items to the destination items. A transfer map specifies which data will be transferred, and indicates the location where you want the data to be stored.

Lab Loader stores the transfer maps you create in a table in the database. These maps are available to any user with the correct access rights to use when transferring data.

Note: The transfer map is owned by the source protocol in which it is created. If you delete the source protocol, then any transfer maps owned by the protocol are also deleted.

How transfer maps are identified

Transfer maps are uniquely identified by five values:

- The map name
- The source protocol
- The source panel
- The destination protocol
- The destination panel

Each transfer map references the data in a specific source panel and a specific destination panel. You cannot:

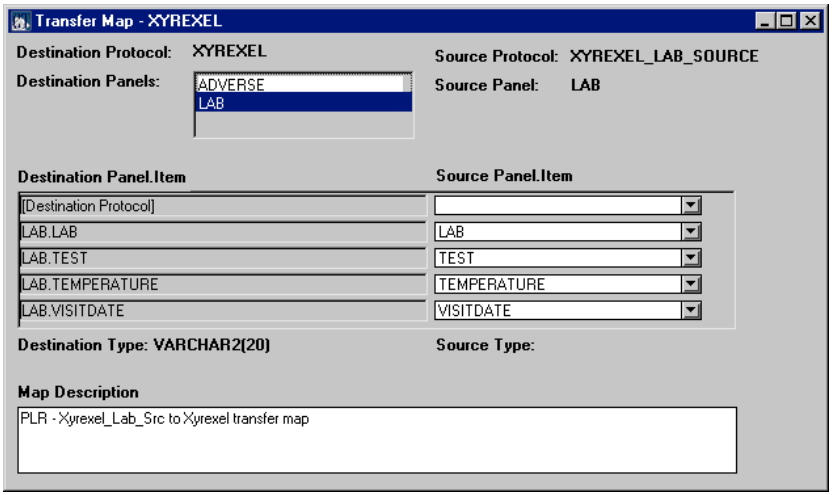
- Transfer data from more than one source panel at a time.
- Transfer data to more than one destination panel at a time.
- Transfer data into different destination protocols at the same time.

Creating transfer maps

To create a transfer map, from the **Transfer** menu, select **Map >> New**. In the Select Source and Destination dialog box, specify the transfer map identification information, and then click **OK**.

Note: To create a transfer map, the current protocol must be set to the source protocol. The source protocol must be Type 4 - Lab Loader.

A Transfer Map window opens, in which you indicate the mapping of the destination and source items:



If the destination panel and source panel are similar in structure, then you can use the Auto Map command to map the source items to the destination items automatically. The Clintrial software chooses a source item for each destination panel item by matching data types and item names. To automap the items, from the **Edit** menu, select **Auto Map**.

To clear the selections you made and begin again, from the **Edit** menu, select **Clear**.

When you are mapping the items, consider the following:

- The underlying types of source and destination items must be the same.
- A source panel item cannot be larger than the destination panel item to which it is mapped. However, the destination panel item can be larger than the source panel item.

  If the source panel item is larger than the destination panel item, then the source item will not be available for selection in the Source Panel Item drop-down list.
- The subject item, block key item, and page key item for the destination protocol must be mapped, if any of the destination panels is Type 1-4.
- All items marked Mandatory in the destination panels must be mapped.

How to transfer data to multiple protocols

When you transfer data, Lab Loader transfers all of the records from a source panel into the destination panels referenced in the transfer map. However, if you are storing records for multiple destination protocols in one source panel, then you must transfer only the records for one destination protocol at a time.

The transfer map contains a transfer map item called [Destination Protocol] that allows you to differentiate records belonging to different protocols. You can map this transfer map item to a source item that contains the name of the destination protocol. If the destination protocol name matches the source item value in a record, then the record is transferred. If the destination protocol name does not match the source item value, then the record is not transferred.

If you do not map the [Destination Protocol] item, then all records in the source panel are transferred.

How to transfer job ID data

When you transfer data, the Clintrial software assigns an internal job ID number to the records that are transferred as part of a specific process. You may want to store this job ID in the destination panel to help identify records transferred at the same time.

The transfer map includes a source item called [Job ID], which you can map to an item in the destination protocol. The [Job ID] item is a TEXT data item.

For example, if you map the [Job ID] source item to an item in the destination panel called JOB_ID, and the Clintrial software assigns the job ID 72 to the transfer process, then all records that transfer successfully will have the value 72 in the JOB_ID item.

Copying transfer maps

The Clintrial software allows you to copy existing transfer maps and use the copy as the basis for creating a new map. You can copy a transfer map from the current protocol or from any protocol in the current protocol's searchlist.

Copying transfer maps is helpful when:

- You have two source panels with similar structures, and you want to transfer data from these panels into a destination panel.

- You want to use the same mapping of items from a source panel to context items of different destination protocols.

How transfer maps are copied

When you copy a transfer map, the amount of mapping information that is preserved in the new map depends on the destination panel:

- If the destination panel for the original map and the newly copied map is the same, then mappings for which source items exist are carried over from the original map to the new map.
- If the destination panel for the original map and the newly copied map are different, then only mappings for context items are preserved. All other mapping expressions are deleted from the new map.

Transfer map status

When you save a transfer map, Lab Loader checks to see if the map is valid. A map is valid if:

- The source and destination protocols both exist.
- All source and destination panels referenced by the map exist and are installed.
- Each of the items mapped from source panels and items mapped to destination panels exist within their panels.
- All items match in size and type. Destination items can be larger than source items, but source items cannot be larger than destination items.
- The subject item, block item, and page item are mapped, if any of the destination panels is Type 1-4.
- All mandatory items in the destination panels are mapped.

You can save transfer maps before you have completed editing them. For example, you can save a transfer map before you have mapped all of the mandatory items in the destination panel. These transfer maps are assigned the status Incomplete. You must finish editing incomplete transfer maps before you can use them to transfer data.

Maps can also have a status of Old. This status can occur if the source panel or the destination panels have been modified since the map was last saved. When you open an Old map, Lab Loader checks to see that the items referenced by the

map still exist and still match in size and data type. You can edit Old transfer maps before you use them, or you can compile the map, which changes the map status of Old to a status of Valid if the map is still valid.

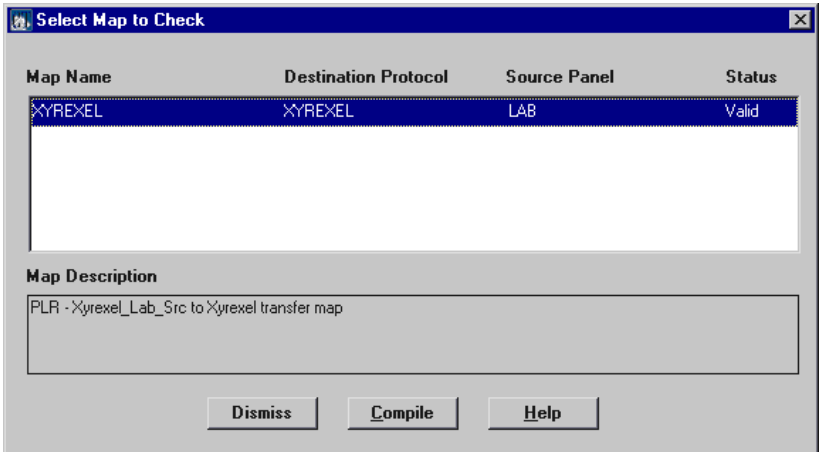
Note: You must set the protocol to the source protocol to edit the transfer map.

Maps must have the status Valid or Old to be used for transferring data.

About compiling the transfer map

You can compile a transfer map to ensure that the map is valid. Compiling the map checks that the source and destination panels are still installed, and that source and destination items still exist. In this manner, you can easily see if something has changed.

To compile a transfer map, from the **Transfer** menu, select **Map >> Check**. The Select Map to Check dialog box opens:



Select a map name and click **Compile**.

Transfer Map statuses

The following table summarizes the possible statuses for transfer maps:

Status:	**Description:**
Valid (0)	The map was valid when it was last edited or used for data transfer.

Status:	Description:
Invalid (1)	The map is invalid. This status can occur when: • The destination protocol, destination panel, source protocol, or source panel has been deleted after the map was created • The data types for mapped items no longer match • A mapped item has been deleted
Old (2)	One of the source or destination protocols or panels has been edited more recently than the map.
Incomplete (3)	The map was saved before it was completed. For example, the map was saved, but not all key items were mapped.

32 Lab Loader and Multisite

Overview

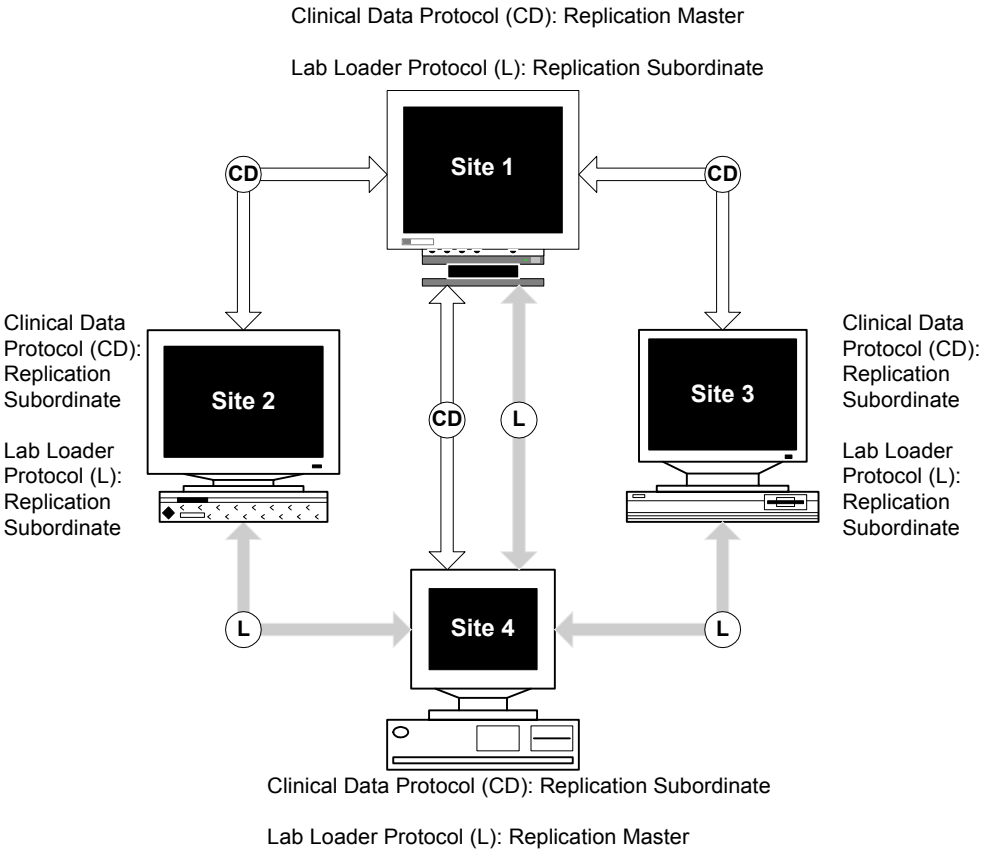
This chapter describes how Lab Loader works differently in a Multisite environment, and contains the following sections:

- 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 *Multisite*.

Note: If you try to distribute a Lab Loader protocol to a site that does not have Lab Loader installed, the distribution fails.

Note: We strongly recommend 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 more information on opening a protocol for revision, see *Multisite*.

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

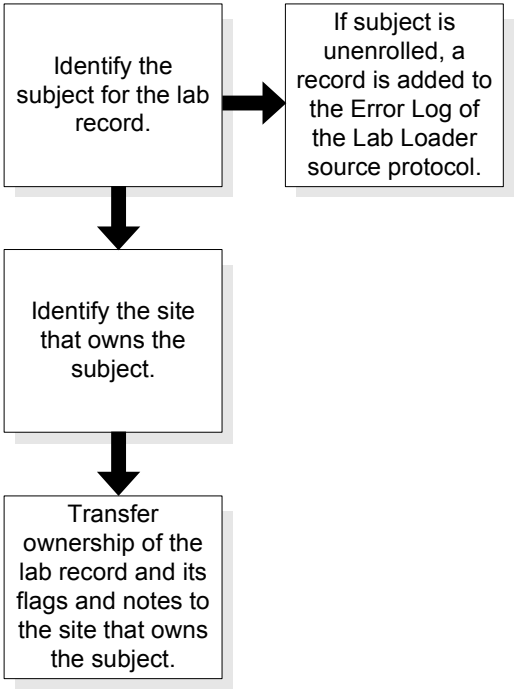
For destination panels of Type 1-4, the validation process:

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:



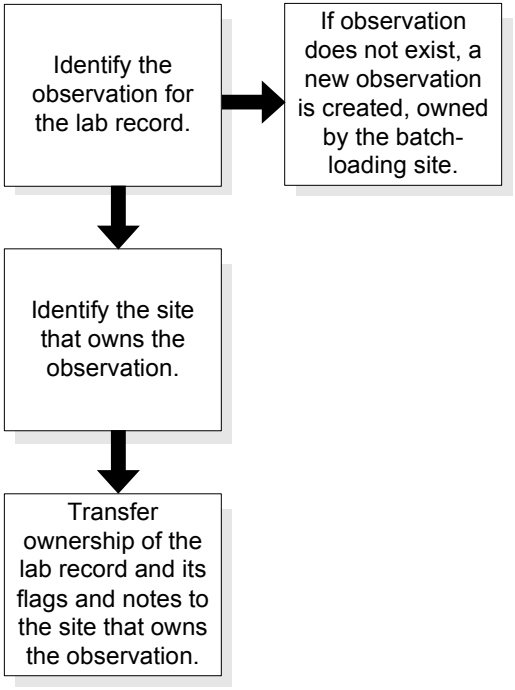
Type 0 panels

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

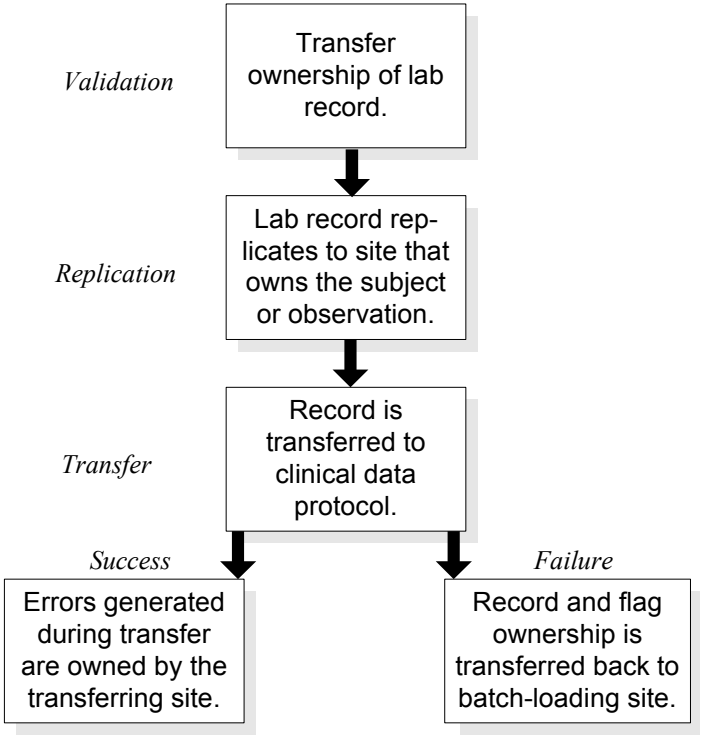
When the ownership of a subject in a clinical data protocol changes between the times of validation and the transfer of lab data, the lab records for that subject fail to transfer, and ownership of these records is returned to the batch-loading site.

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.

Workflow

The following figure shows the workflow for transferring replicated lab data:



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