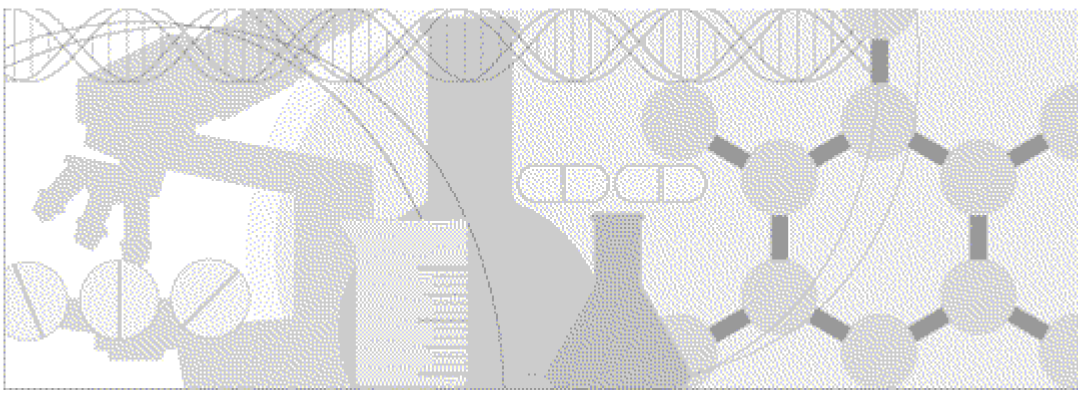
User Guide

Oracle® Health Sciences Central Coding
Release 3.0.4



Part Number: E58686-01

Contents

About this guide

In this preface

Overview of this guide

This guide provides an architectural overview of the Central Coding application, descriptions of all system functions, and step-by-step instructions for using the Central Coding application and managing the coding dictionaries.

Audience

This guide is for everyone who uses the Central Coding application. This includes the coders and approvers who use the Central Coding application to code items, as well as the Central Coding administrators who are responsible for configuring the application; managing the coding dictionaries, coding algorithms, coding definitions, assignment rules, synonym lists, stopword lists, adapters, study information, and job schedules; using impact analysis; and performing on-going user and work team administration.

Documentation

The product documentation is available from the following locations:

- **Oracle Software Delivery Cloud** (https://edelivery.oracle.com)—The complete documentation set.
- **My Oracle Support** (https://support.oracle.com)—*Release Notes* and *Known Issues*.
- **Oracle Technology Network** (http://www.oracle.com/technetwork/documentation)—The most current documentation set, excluding the *Release Notes* and *Known Issues*.

All documents may not be updated for every Central Coding release. Therefore, the version numbers for the documents in a release may differ.

Title	Description
Release Notes	The *Release Notes* document presents information about new features, enhancements, and updates for the current release.
Known Issues	The *Known Issues* document presents information about known issues for the current release.
Secure Configuration Guide	The *Secure Configuration Guide* provides an overview of the security features provided with the Oracle® Health Sciences Central Coding application, including details about the general principles of application security, and how to install, configure, and use the Central Coding application securely.
Installation Guide	The *Installation Guide* provides the following: • Architectural overview of the Central Coding application • Step-by-step instructions for installing, upgrading, and uninstalling the Central Coding software • Descriptions of system functions • Step-by-step instructions for managing the Central Coding application at the server level, including loading coding dictionaries, adding studies and adapters using the command line, and producing performance metrics.
User Guide	The *User Guide* provides an architectural overview of the Central Coding application, descriptions of all system functions, and step-by-step instructions for using the Central Coding application and managing the coding dictionaries.
Quick Start for Coders and Approvers	The *Quick Start for Coders and Approvers* provides a brief overview of the tasks that coders and approvers perform in the Central Coding user interface, including step-by-step instructions for coding and approving requests, and working with queries.
Page-level Help	The page-level Help describes the function(s) and fields for each page in the user interface.

Note: **If you are integrating with the InForm application, in addition to the items in the Central Coding documentation set, you must refer to the InForm Adapter Installation Guide for information about installing the InForm Adapter software.**

Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc.

If you need assistance

Oracle customers have access to support through My Oracle Support. For information, visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info, or if you are hearing impaired, visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs.

Finding Central Coding information and patches on My Oracle Support

The latest information about the Central Coding application is on the Oracle Support self-service website, My Oracle Support. Before you install and use the Central Coding application, check My Oracle Support for the latest information, including *Release Notes* and *Known Issues*, alerts, white papers, bulletins, and patches.

Creating a My Oracle Support account

You must register at My Oracle Support to obtain a user name and password before you can enter the site.

1. Open a browser to https://support.oracle.com.
2. Click the **Register** link.
3. Follow the instructions on the registration page.

Finding information and articles

1. Sign in to My Oracle Support at https://support.oracle.com.
2. If you know the ID number of the article you need, enter the number in the text box at the top right of any page, and then click the magnifying glass icon or press **Enter**.
3. To search the knowledge base, click the **Knowledge** tab, and then use the options on the page to search by:
   - Product name or family.
   - Keywords or exact terms.

Finding patches

You can search for patches by patch ID or number, product, or family.

1. Sign in to My Oracle Support at https://support.oracle.com.
2. Click the **Patches & Updates** tab.
3. Enter your search criteria and click **Search**.
4. Click the patch ID number.

   The system displays details about the patch. You can view the Read Me file before downloading the patch.
5. Click **Download**, and then follow the instructions on the screen to download, save, and install the patch files.

Finding Oracle documentation

The Oracle website contains links to Oracle user and reference documentation. You can view or download a single document or an entire product library.

Finding Oracle Health Sciences documentation

For Oracle Health Sciences applications, go to the Oracle Health Sciences Documentation page at http://www.oracle.com/technetwork/documentation/hsgbu-clinical-407519.html.

> **Note: Always check the Oracle Health Sciences Documentation page to ensure you have the most up-to-date documentation.**

Finding other Oracle documentation

1 Do one of the following:

- Go to http://www.oracle.com/technology/documentation/index.html.
- Go to http://www.oracle.com, point to the **Support** tab, and then click **Product Documentation**.

2 Scroll to the product you need, and click the link.

Finding prerequisite software for Oracle Health Sciences applications

Prerequisite software for Oracle Health Sciences applications is available from the following locations:

- Download the latest major or minor release from the Oracle Software Delivery Cloud (https://edelivery.oracle.com/).

  For information on the credentials that are required for authorized downloads, click **FAQs** on the main page of the Oracle Software Delivery Cloud portal.

- Download subsequent patch sets and patches from My Oracle Support (https://support.oracle.com).

  To find patch sets or patches, select the **Patches & Updates** tab.

If a previous version of prerequisite software is no longer available on the Oracle Software Delivery Cloud, log a software media request Service Request (SR). Previous versions of prerequisite software are archived and can usually be downloaded. After you open an SR, you can check its status:

- US customers: Call 1-800-223-1711.
- Outside the US: Check www.oracle.com/us/support/contact/index.html for your local Oracle Support phone number.

For more information on logging a media request SR, go to My Oracle Support for Document 1071023.1: Requesting Physical Shipment or Download URL for Software Media (https://support.oracle.com/epmos/faces/DocumentDisplay?id=1071023.1).

PART 1: INTRODUCTION

CHAPTER 1

Central Coding overview

In this chapter

Central Coding overview

The Central Coding software is a web-based application that integrates with the Oracle Clintrial software or the Oracle InForm software to provide centralized coding for all studies within an organization. Because the Central Coding software works independently from the Clintrial or InForm software, you can have parallel work paths for the clinical study teams and the clinical coding 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.

Coding is the process of mapping a standardized term and code from a given level of a standard coding dictionary to a verbatim. You can code adverse events, drugs, diseases, and other items using consistent terminology defined in industry-standard and customer-defined dictionaries.

The Central Coding software streamlines the coding process with features such as autocoding, customizable synonym and stopword lists, code and propagate functionality, and configurable workflow for the efficient review, resolution, and approval of coded terms—all of which can occur simultaneously and across staff, sites, studies, and locations.

The Central Coding software is FDA 21 CFR Part 11 compliant and provides:

- Remote connectivity, enabling simultaneous access for multiple, decentralized users.
- Global, multi-study/multi-center connectivity.
- Link-through and single sign-on capabilities to the InForm application.
- Centralized, multi-version, multi-dictionary support including support for MedDRA, MedDRA-J, WHO-DD, and JDrug.
- Customizable algorithms to increase high auto-hit rates.
- Configurable synonym lists for use across different studies.
- Definable stopword lists to increase the speed and accuracy of autocoding.
- Autocoding and automatic approval to reduce the manual coding effort.
- Code and propagate to eliminate the need to manually code identical verbatims.
- Configurable role-based workflow and approval.
- Query creation for use in the InForm application.
- Reports for coding consistency, coded items, updated codes, and users.
- Exports for coding consistency, coded items, and queries.
- Full audit history.
- Impact analysis to view MedDRA, MedDRA-J, WHO-DD, or JDrug dictionary changes to evaluate their impact on study data, and to reconcile any differences to existing terms, codes, and synonyms.

Central Coding users

- **Coder**—An end user with rights to perform coding tasks.

  A coder can manage the autocoding process or interactively code requests using the coding browser.

- **Approver**—An end user with rights to examine coded requests and to approve or disapprove the code, or mark a request as needing further action.

  The Central Coding application can be configured to apply approvals to coded requests automatically or to require manual approval.

- **Dictionary manager**—A user with rights to perform dictionary maintenance tasks.

  These include the tasks required for on-going administration of the Central Coding application, such as managing synonym lists, stopword lists, coding algorithms, coding definitions, assignment rules and the coding dictionaries.

- **System Administrator**—A user with rights to perform system setup and maintenance tasks.

  These include the tasks required for the initial setup and on-going administration of the Central Coding application including managing users, roles, and work teams; configuring synonym lists, stopword lists, coding algorithms, coding definitions, and assignment rules; managing adapters, study information, and job schedules; using impact analysis; and managing the coding dictionaries.

  System administration roles can be generalized, with many tasks being performed by a single administrator, or they can be specialized, with various people performing specific types of administrative tasks.

- **Production user**—A user with access to the Central Coding application server.

  This user performs tasks outside of the Central Coding user interface at the server level including performing troubleshooting tasks; modifying system settings; loading, configuring, and deleting coding dictionaries; adding adapters and studies using the command line; and updating data using the Data Installer utility.

Supported coding dictionaries

The Central Coding application supports:

- The use of the following industry-standard coding dictionaries.
    - **MedDRA and MedDRA-J**—Medical Dictionary for Regulatory Activities.
    - **WHO-DD (C format)**—World Health Organization Drug Dictionary.

      When using WHO-DD you can configure the Central Coding application to autocode to the Trade Name (default) or to the Medicinal Product. With either configuration option, you can report (return) the Trade Name, Preferred Name, and Ingredients to the source application.
    - **JDrug**—Data File for Ethical Drugs (Coding Table) from Iyaku-Joho-Kenkyujo, Inc.
- Any number and combination of standard and custom dictionaries.

  Contact Oracle for information on any dictionary other than MedDRA, MedDRA-J, WHO-DD, or JDrug.
- Any number and combination of dictionary versions, such as multiple versions of MedDRA or WHO-DD.

  Contact Oracle for a list of the supported dictionary versions.

Multilingual data

The Central Coding application can accept both English and Japanese verbatims (multilingual data).

- When you install the Central Coding application on an English operating system, you can choose whether to use multilingual data.
- When you install the Central Coding application on a Japanese operating system, the installation program assumes that there will be multilingual data.

If you choose to use multilingual data, the Central Coding installation program:

- Loads the Japanese report templates. These reports contain the MS Mincho or MS UI Gothic font so that Japanese text appears correctly in the reports. These reports can contain both Japanese and English data.
- Sets the default date format to YYYY/MON/DD HH24:MI:SS. You can modify this setting as needed on the System Configuration page.

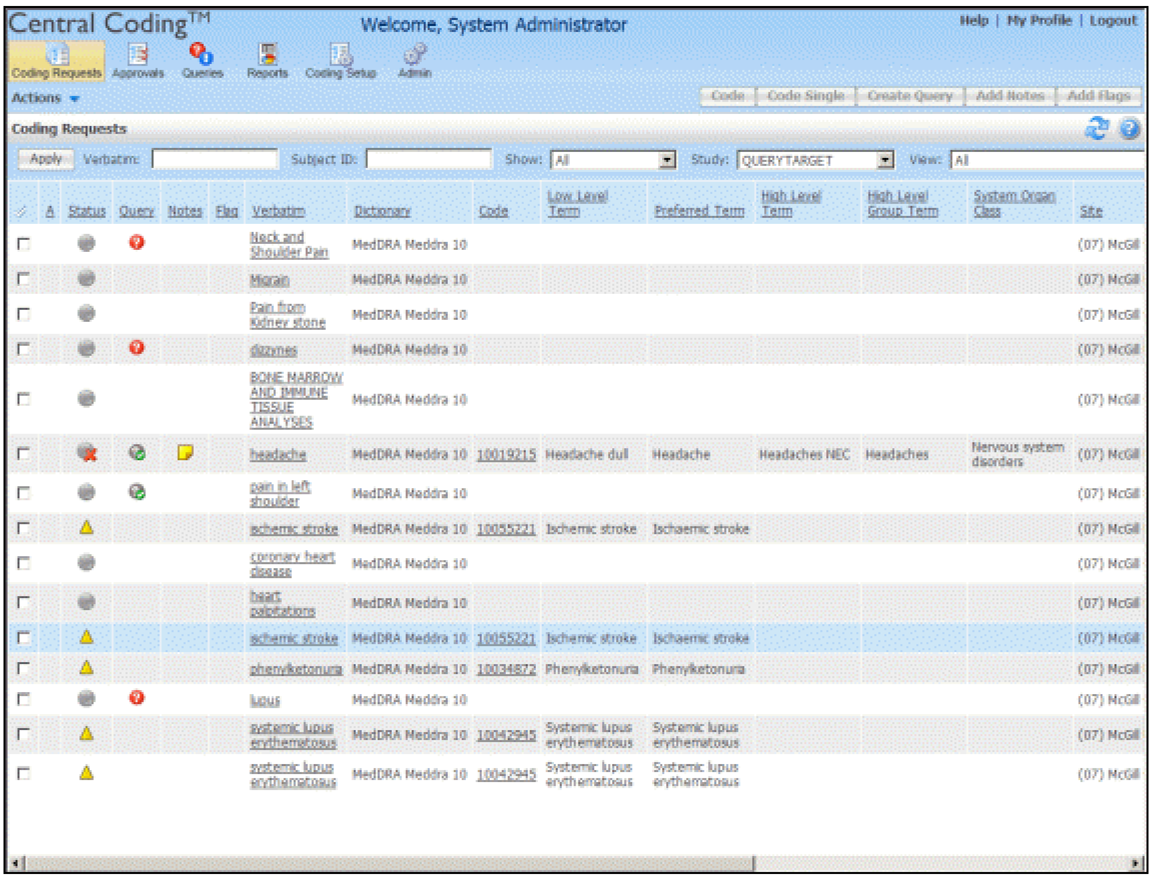
Note: You cannot perform an upgrade to support the Japanese language.

The Central Coding user interface

The main Central Coding application window

The main Central Coding user interface appears in a browser window and allows you to access all the features of the Central Coding application. You can navigate through the user interface from within the browser window unless otherwise noted. The same user can view and edit data in multiple browser windows.

In the user interface, required fields appear pink. Make sure that your display is set to more than 256 colors for proper viewing of highlighted fields.



Components of the user interface

> **Note: The components that appear in the user interface depend on your user profile, roles, and rights, which are defined by an administrator.**

- **Folders**—Contain a set of pages that are grouped by a particular function.

  Only the folders to which your assigned role(s) give you access rights appear in the window. After you log in to the application, the user interface opens and displays all the folders that you are allowed to access based on your user profile, roles, and rights. The first folder is selected and its contents are visible by default. The folders are Coding Requests, Approvals, Queries, Reports, Coding Setup, and Administration.

- **Pages**—Contain specific fields for entering or viewing data.

  Pages are grouped together in a folder. Only the pages for which your assigned roles give you access rights appear in a folder. The page name appears in the title bar of the window. Page-level online help is available for each page.

  Pages that permit user data entry notify you of missing or incorrect required fields before you can save changes. Fields that do not permit data entry have a gray background and are read only.

- **Actions menu**—Located at the top left of the page, the **Actions** menu appears on most pages and lists tasks that initiate specific functions related to the page.

  Each listed action consists of a link and a set of rights required to perform that action. Only the actions to which you have access rights are active in the Actions menu. Keyboard shortcuts are available for many Actions menu items.

- **Buttons**—Located at the top right of the page, buttons appear on most pages and initiate specific functions related to the page or common actions such as **Previous** and **Save**.

  Each button is controlled by a set of rights required to perform the action, and might include a link to navigate to another part of the user interface. Only the button actions to which you have access rights are active. Keyboard shortcuts are available for many buttons.

- **Page Controls**—Appear if the page contains more data than can be viewed without scrolling.

  The page control allows you to advance to the first, previous, next, or last page or to jump to a specific page number. Both vertical and horizontal scroll bars appear in the main user interface window and the Coding Browser for oversized pages.

- **Status Bar**—Located at the bottom of the user interface window, the Internet Explorer status bar displays information about an action.

- **Central Coding Help Center**—Provides access to the Central Coding documentation from the user interface.

  To open the Central Coding Help Center page, click the **Documentation** link in the top right corner of the main application window. The page appears in a second browser window that you can resize and move for easy viewing.

- **Page-level help**—Describes the page function(s) and fields for each page in the user interface.

  To open a help page, click the **Help ( )** button in the top right corner of any page or dialog box. The page-level help is part of the *User Guide*. The page-level help opens in a second browser window that you can resize and move for easy side-by-side viewing with other pages.

  > **Note:** **The popup blocker in your browser may prevent the help pages from opening. If this occurs, either turn off the popup blocker or press the Ctrl key before you click the Help button.**

- **Hover help**—Provides a brief description of what the selected menu item, action, button, or icon does, and what, if any, keyboard shortcuts exist for the item.

  To display hover Help hold your mouse pointer over the item and the hover Help text appears in a popup window. When you move your mouse pointer off the item, the hover Help disappears.

Folders

Each folder contains the pages that are used by a function in the application. Only the folders to which you have access rights appear in the Central Coding user interface window.

The folders that are available in the Central Coding user interface are:

- **Verbatims**—Provides access to the coding requests assigned to the work teams of the logged in user.
- **Approvals**—Provides access to the coding requests assigned to the work teams of the logged in user that are waiting for an approval or that have been approved.
- **Queries**—Provides access to information about queries created in the Central Coding application for use with the InForm application.
- **Reports**—Provides access to the reporting and exporting functions.
- **Coding Setup**—Provides access for viewing the coding dictionaries; managing the synonym lists, stopword lists, coding algorithms, coding definitions, and assignment rules; and for using impact analysis.
- **Administration**—Provides access for managing users, roles and rights, work teams, system configuration options, communication with the InForm application, and all the requests in the system regardless of their work team assignments.

Status icons in the user interface

You can view the status of a coding request or a query in the Central Coding user interface by viewing the associated icon. The following is a complete list of the status icons for coding requests and queries, and the icons' associated meanings.

Icon	Status	Description
Coding requests		
	Uncoded	The item is not coded.
	Partially coded	If coding to a primary autocode target and a secondary autocode target, the application found a single match for the primary target and multiple matches for the secondary target. You must manually select the code you want to use.
	Needs review	The request is successfully autocoded but must be reviewed.
	Recode	The request must be recoded. Requests with this status have been disapproved by an approver. By default, the disapproval reason appears in a note associated with the request.
	Coded, awaiting approval	The request is successfully coded but needs an approval.
	Completed, awaiting delivery	The request is successfully coded and approved, but is not yet delivered to the source application.
	Autocoded	The request was successfully autocoded.

Icon	Status	Description
	Completed, delivered	The request is successfully coded, approved, and delivered to the source application.
	Undeliverable, retry	The request may be successfully coded and approved, but the Central Coding application cannot deliver the request to the source application because of a communication issue.
Queries		
	Open/Open Pending	Entered in the Central Coding application by a Central Coding user to be addressed by an InForm user. • A query can enter the Open state if it is manually created by a Central Coding user or automatically created by the Central Coding application using the Allow Auto Query setting. • A query can enter the Open Pending state if the query is opened in the Central Coding application, but the change has not yet been transferred to the InForm application.
	Candidate	Entered by a Central Coding user. A Central Coding administrator can assign a Candidate query to the Open or Deleted state.
	Answered	Open query that was addressed by an InForm user.
	Closed/Closed Pending	Query on a verbatim that was successfully coded. • A query can enter the Closed state if it is manually closed by a Central Coding user or automatically closed by the Central Coding application using the Allow Auto Close Query setting. • A query can enter the Closed Pending state if the query is closed in the Central Coding application, but the change has not yet been transferred to the InForm application.
	Deleted	Candidate query that was deleted by a Central Coding user with the Issue Candidate Query right. **Note:** Only queries in the Candidate state can be deleted.
	Undeliverable, retry	The Central Coding application cannot deliver the query data to the source application because of a communication issue. The Central Coding application will retry delivery when the next Get Requests job runs.
	Undeliverable, cannot retry	The Central Coding application cannot deliver the query data to the InForm application because the form is unable to accept queries. This could happen if a form is locked or deleted in the InForm application. As a result, the query is closed in the Central Coding application.
Note: For each query, the hover Help displays the state of the query, the state of the query's delivery process to the InForm application, and the reason associated with the query.		

List display

Pages that display lists of items support the following functionality:

- **Pagination**—For the manageable display of long lists. For more information, see ***Setting the list page size*** (on page 49).
- **Sorting**—Ascending and descending sorting by any sortable column in the list; sortable column headings are underlined.
- **Inclusion**—Of only those items that you have rights to view.
- **Filtering**—Based on page-specific criteria; your filter settings are saved across sessions.
- **Return**—List pages that you access from a parent page support a return operation to navigate back to the parent page.

Date formats

The Central Coding user interface supports:

- One format for data entry and data display.
- The input and display of partial and imprecise dates.

  For example, "January 1, 2002", "January 2002," or "2002."

> **Note:** You must include the year in all partial dates.

The default date format depends on the type of operating system. The date format is set during the installation and can be modified on the System Configuration page.

- For an English operating system, the default date format is DD/MON/YYYY HH24:MI:SS.
- For a Japanese operating system, the default date format is YYYY/MON/DD HH24:MI:SS.

Keyboards shortcuts

To facilitate rapid data entry, you can use keyboard shortcuts instead of using the mouse to select folder pages, actions, and buttons. Keyboard shortcuts appear next to the corresponding command in the hover Help text. Information about additional keyboard shortcuts is also included in the page-level Help. For more information, see ***Getting help*** (on page 41).

Date or search fields	
Shortcut	Description
=	**Current date**—Populates a date field with the current date.
*	**Asterisk**—Matches any sequence of characters when used in a search field. For example, if you type ***aceta*** in the Verbatim field, the search returns any word that contains **aceta**, such as acetaminophen.
%	**Percent sign**—Matches any sequence of characters when used in a search field. For example, if you type **%aceta%** in the Verbatim field, the search returns any word that contains **aceta**, such as acetaminophen.

Admin folder	
Shortcut	**Description**
Alt+1	Opens the Users page, from which you can view information about the users that are defined in the application, and activate, deactivate, and terminate users.
Alt+2	Opens the Roles page, from which you can view information about the roles defined in the application, and remove roles from the application.
Alt+3	Opens the Work Teams page, from which you can view information about the work teams defined in the application, and remove work teams from the application.
Alt+4	Opens the All Requests page, from which you can view the complete list of coding requests in the Central Coding application, view the work teams assigned to requests, and run an audit history report for a request.
Alt+5	Opens the Study Information page, from which you can view and manage information about the adapters in the application and their associated studies.
Alt+6	Opens the Study Group List page, from which you can create and edit study groups.
Alt+7	Opens the View Job Log page, from which you can view detailed information about the get verbatims or return codes jobs, and to stop a running job.
Alt+8	Opens the Locks page, from which you can view the list of items in the application that are locked.
Alt+9	Opens the Adapters page, from which you can view information about the InForm Adapters that are defined in the application.
Alt+0	Opens the Reconciliation Options page, from which you can view the default selection options that appear on the Reconcile Verbatims page, which you use to reconcile the verbatims after running impact analysis.
Ctrl+1	Opens the System Configuration page, from which you can view the authentication, application, lock management, and impact analysis configuration options.
Ctrl+2	Opens the System Information page, from which you can view version information for the Central Coding product, the Oracle database, and the Windows system. You can also view copyright information for the software products used with the Central Coding application.
Ctrl+3	Opens the Query Standard Reason List page, from which you can manage the reasons that appear in the Reason drop-down list in the Create Query, Cancel Query, Close Query, and Reissue Query dialog boxes.
Ctrl+4	Opens the Coding Flags page, from which you can view the definitions associated with each coding flag.

The coding browser

The coding browser is a system component that allows you to code events, diseases, drugs, and other items by matching entered terms against the terminology in industry-standard or custom coding dictionaries. All coding requests that require interactive coding and those that fail autocoding must be interactively coded using the coding browser.

There are two methods of interactive coding:

- **Search**—Allows you to search selected fields in a dictionary for text that begins with or contains the verbatim text.
- **Browse**—Allows you to examine the target coding dictionary, from level to level, and select relevant terms. When you find an appropriate term, you can apply the term and code to the verbatim.

The coding browser appears in a separate, popup window, which you must manually close before you can navigate anywhere else within the application or perform any other tasks.

Information in the coding browser

The information that appears in the coding browser varies with the coding method you select (search or browse), the type of item being coded, the configured dictionary elements, and the related system configuration setting for the coding browser. The coding browser displays the hierarchy levels that support the selected dictionary.

- For information on the dictionary elements, see ***Dictionary elements and the element configuration options*** (on page 24).
- For information on using the **Show Non Current Terms During Browser Search** setting to configure the coding browser, see ***Displaying only current terms in the coding browser*** (on page 121).
- For examples of how the coding browser appears, see ***Examples: Search mode displays*** (on page 14) and ***Examples: Browse mode displays*** (on page 17).

Interactive coding tasks

Use the coding browser to perform the following interactive coding tasks:

- Manually run the autocode algorithm for a supplied text.
- Search selected fields (that equate to a configured element) in a dictionary for text that begins with or contains the verbatim text, and review possible codings that contain the results.

  The coding browser supports ascending and descending sorting on the dictionary element columns in the Results section in the coding browser when it is in the Search mode. The sortable column headings are underlined.
- Browse the hierarchy of a dictionary and manually select codes.
- Suggest synonyms for a code.
- Create a query for a verbatim. The query appears in the Central Coding and InForm applications.

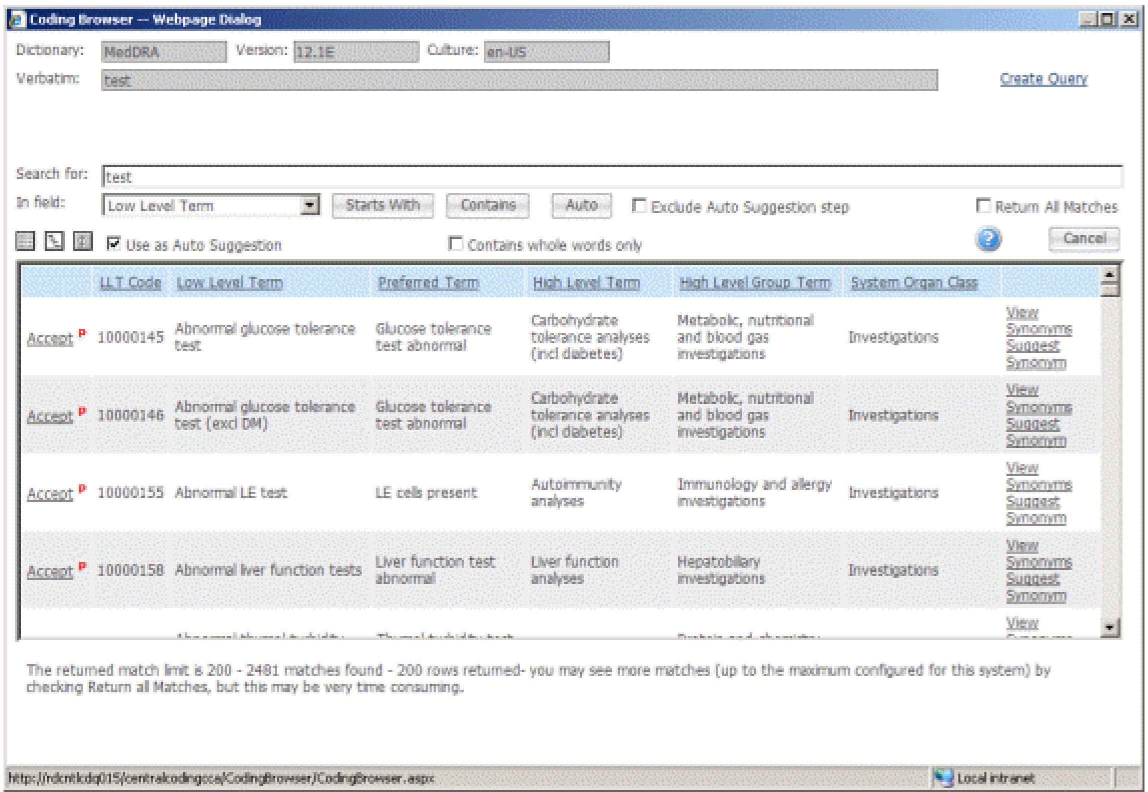
Examples: Search mode displays

See the following examples of how the coding browser Search mode display appears for the different coding dictionaries.

- *MedDRA or MedDRA-J* (on page 15)
- *WHO-DD* (on page 16)
- *JDrug* (on page 17)

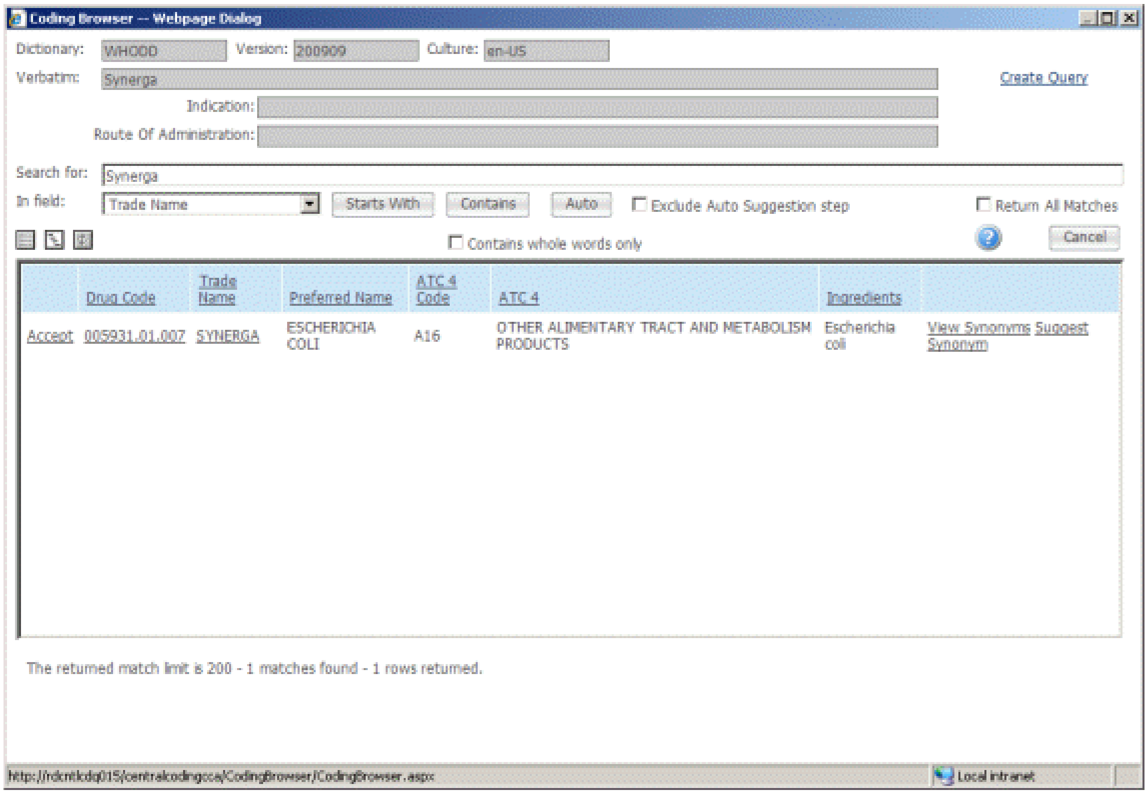
Search mode—MedDRA or MedDRA-J

The following example shows how the coding browser appears when you are coding events, diseases, or other items in the Search mode using a MedDRA or MedDRA-J dictionary.



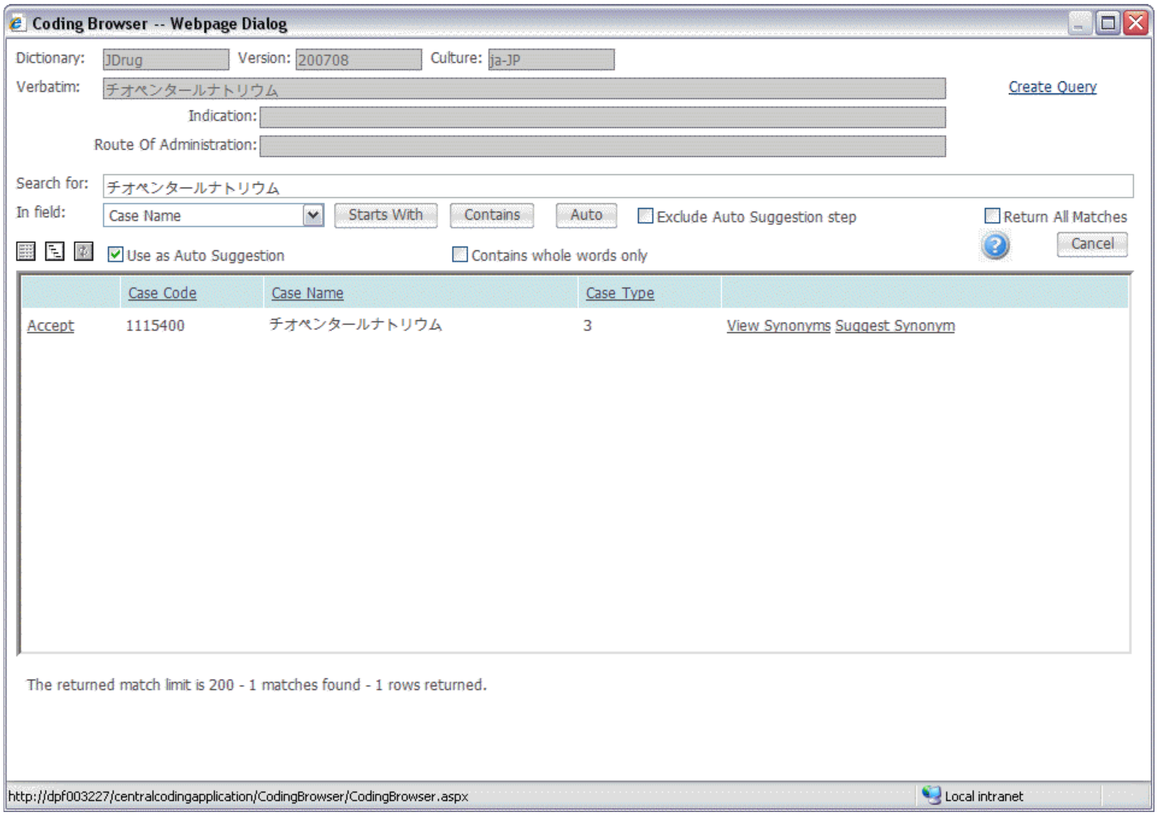
Search mode—WHO-DD

The following example shows how the coding browser appears when you are coding drugs in the Search mode using a WHO-DD dictionary.



Search mode—JDrug

The following example shows how the coding browser appears when you are coding drugs in the Search mode using a JDrug dictionary.



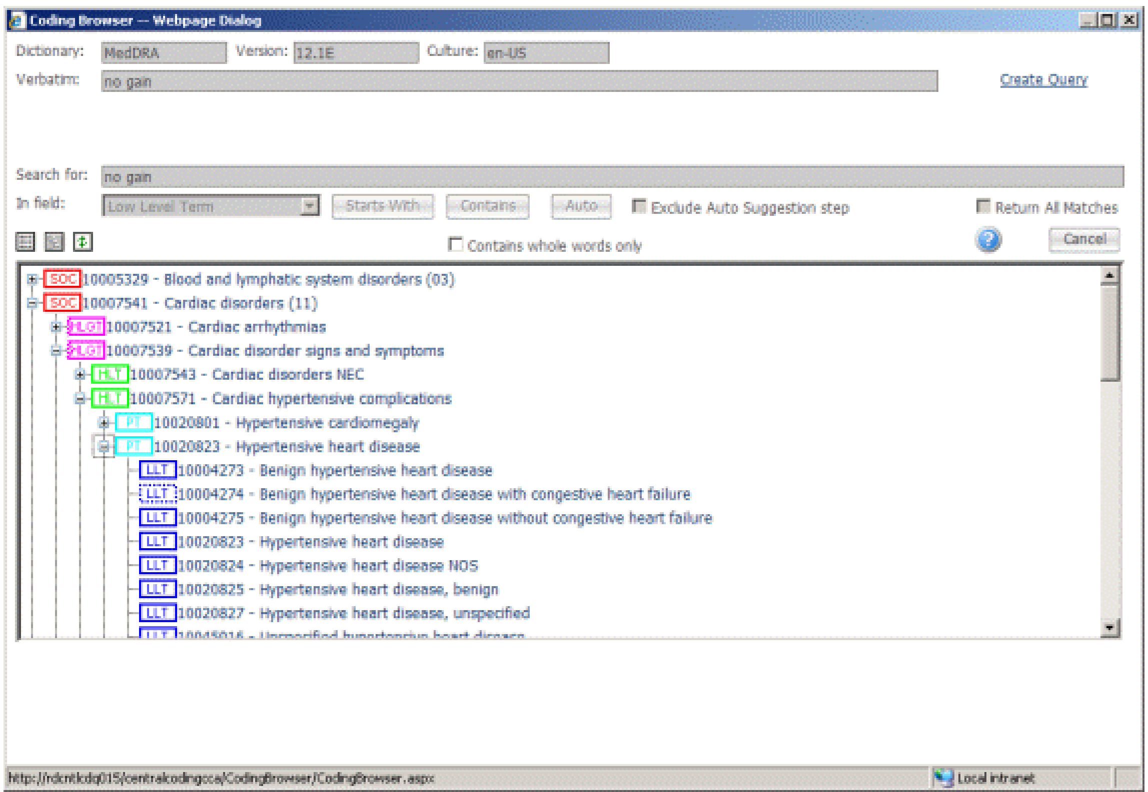
Examples: Browse mode displays

See the following examples of how the coding browser Browse mode display appears for the different coding dictionaries.

- *MedDRA or MedDRA-J* (on page 18)
- *WHO-DD* (on page 19)
- *JDrug* (on page 20)

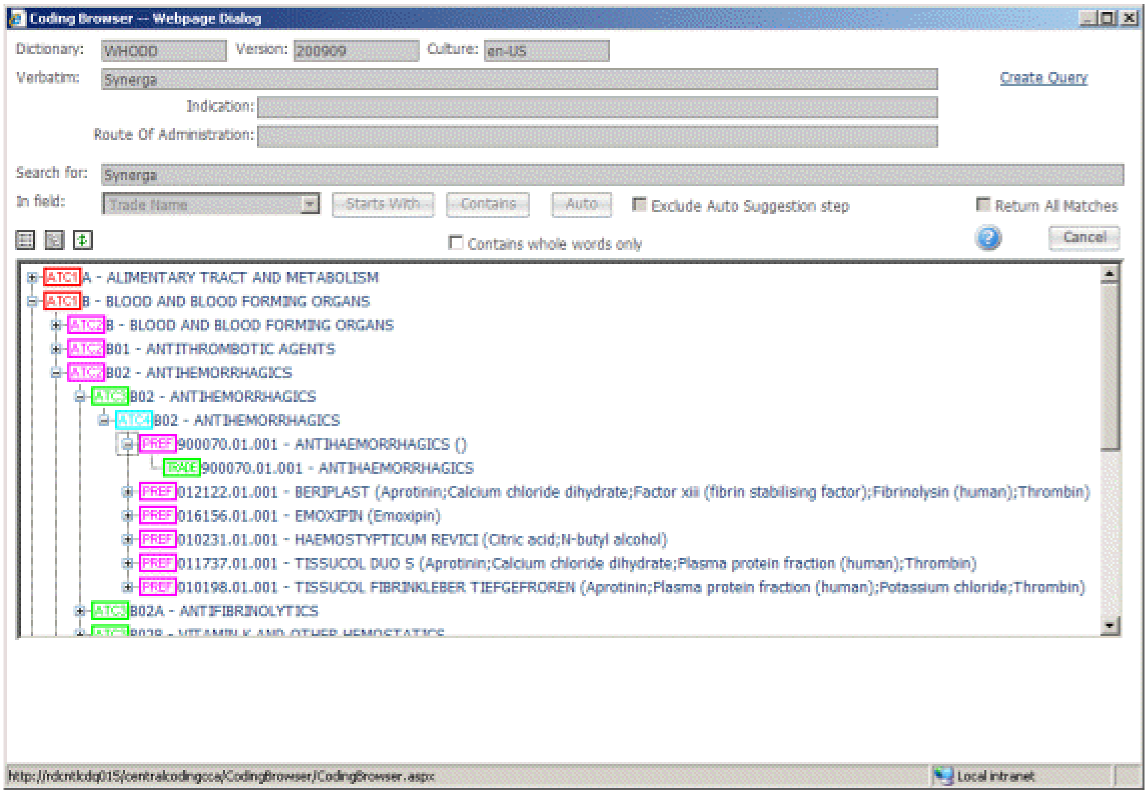
Browse mode—MedDRA or MedDRA-J

The following example shows how the coding browser appears when you are coding events, diseases, or other items in the Browse mode using a MedDRA or MedDRA-J dictionary.



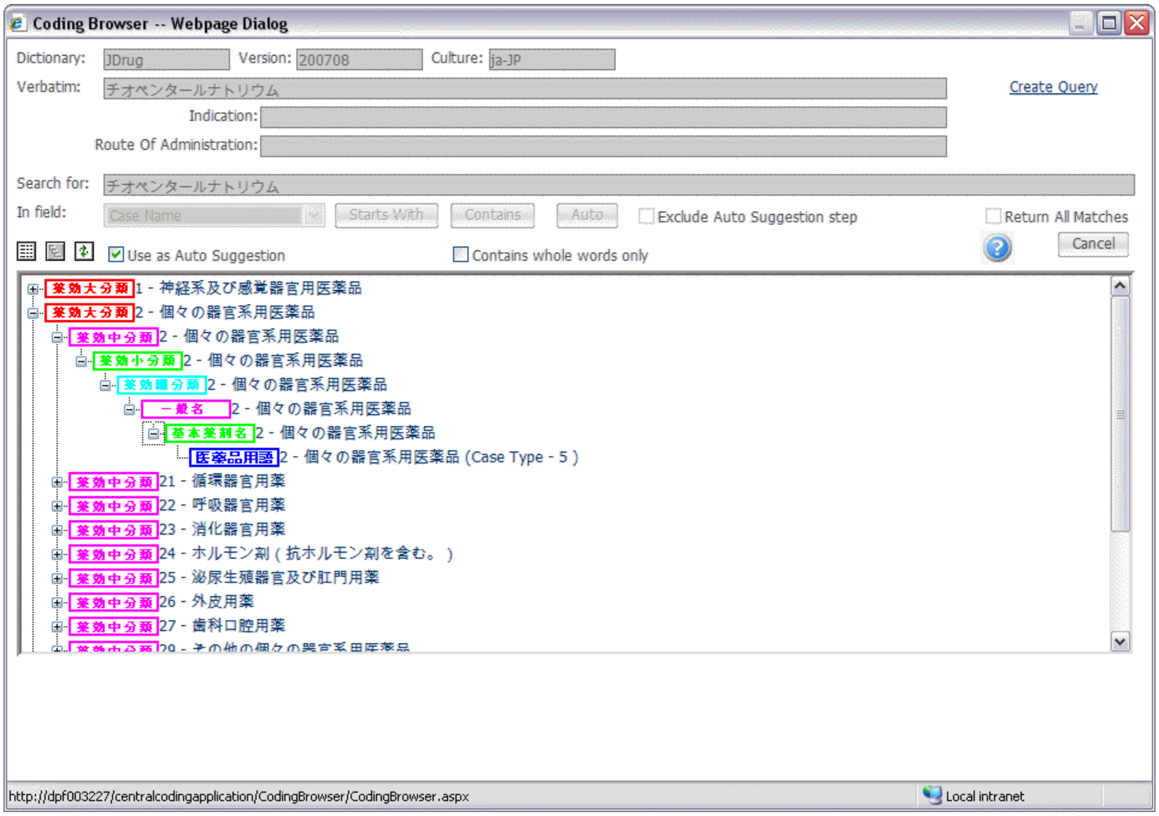
Browse mode—WHO-DD

The following example shows how the coding browser appears when you are coding drugs in the Browse mode using a WHO-DD dictionary.



Browse mode—JDrug

The following example shows how the coding browser appears when you are coding drugs in the Browse mode using a JDrug dictionary.



Coding and coding requests

Coding

Coding is the process of mapping a standardized term and code from a given level of a standard coding dictionary to a verbatim. You can code adverse events, drugs, diseases, and other items using consistent terminology defined in industry-standard and customer-defined dictionaries.

Autocoding

Autocoding (also called *automatic coding*) is a type of coding that uses an algorithm to select an appropriate code value for a term.

When the Central Coding application receives a coding request from the Clintrial application or retrieves a coding request from the InForm application, it evaluates a set of rules to determine, among other things, whether to autocode the request. 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 returns coded information to the Clintrial or InForm application and stores the information in the Central Coding database.

If autocoding fails, a coder must interactively code the request.

An administrator configures whether autocoded requests are automatically approved by the system or if they require manual approval by an approver. An administrator also configures whether autocoded requests require review by a coder.

Interactive coding

Interactive coding is a type of coding that you perform manually using the coding browser to select a code value for a term. You must use interactive coding to:

- Code any request that is not configured for autocoding.
- Select a coding value when autocoding returns multiple matches or no matches.
- Change an existing code.

The coding browser provides the user interface and functionality that allows coders to interactively select codes from coding dictionaries. For more information, see ***The coding browser*** (on page 13).

Search method of interactive coding

The search method of interactive coding allows you to search selected fields in a coding dictionary for text that begins with or contains the verbatim text.

Browse method of interactive coding

The browse method of interactive coding allows you to examine the target coding dictionary, from level to level, and select relevant terms. When you find an appropriate term, you can apply the term and code to the verbatim.

Coding definitions

A coding definition is a set of information that is used in conjunction with assignment rules to control the Central Coding application request-processing workflow, and to make sure that requests are coded correctly. For more information, see *Assignment rules* (on page 23).

A coding definition:

- Is associated with a coding dictionary and consists of a synonym list, stopword list, and coding algorithm.
- Controls which dictionary elements appear in the user interface and are returned to the source application when coding uses that coding definition.
- Provides a reusable set of parameters for incoming requests without requiring an administrator to select the parameters for each request. Instead, a coding definition is assigned to requests based on the rules defined within an assignment rule.

Synonyms and synonym lists

A synonym is a word or phrase that is equivalent to the classification-level term associated with a code in a coding dictionary. For example, you can add the synonym "High Blood Sugar" for the low level term "Elevated Blood Sugar" in the MedDRA dictionary.

Using synonyms increases the chance that the autocoding algorithm will find a code match for a verbatim.

A synonym list is group of synonyms. Synonyms can only exist within a synonym list. All synonyms in a synonym list are associated with terms in the same dictionary.

There are two ways to create synonyms.

- A coder can propose a synonym and a dictionary manager or administrator approves it for use.
- A dictionary manager or an administrator can create and approve a synonym in a single step.

The coding definition specifies which synonym list should be used by the autocoding algorithm when attempting to find a code match for a verbatim. For more information, see *Coding definitions* (on page 22).

Stopwords and stopword lists

A stopword is a word in verbatim text that can be discarded during autocoding because it does not add significant meaning to the description of a term. Stopwords can include articles, prepositions, and non-medical words such as **subject** or **experienced**. Using stopwords increases the chance that the autocoding algorithm will find a code match for a verbatim.

For example, suppose the following sentence was entered as verbatim text:

> The subject had a bleeding ulcer.

During automatic coding, the stopwords and punctuation are dropped and the text becomes:

> bleeding ulcer

A stopword list is a group of stopwords. Stopwords can exist only within a stopword list. Stopwords are not associated with terms in a particular coding dictionary. Any stopword list can be used with any dictionary.

A dictionary manager or an administrator can create and approve a stopword in a single step from the Stopword Lists page.

The coding definition specifies the stopword list that should be used by the autocoding algorithm to remove stopwords from the verbatim. For more information, see *Coding definitions* (on page 22).

> **Note:** Stopwords for Japanese dictionaries are not supported because they are not used in the Japanese character sets.

Coding algorithms

A coding algorithm is a sequence of steps the Central Coding application performs to determine the most appropriate match for a term during autocoding. Each coding algorithm is identified by a unique name within the Central Coding application. The Central Coding application comes with a default coding algorithm. For more information, see *Default coding algorithm* (on page 163).

Dictionary managers can create new coding algorithms for specific autocoding tasks, and can modify the default coding algorithm by adding or removing steps or by changing the order in which the steps are performed. All the steps that are available for use in an algorithm are predefined in the application; you cannot create new steps through the Central Coding user interface. For more information, see *Available algorithm steps* (on page 162).

To perform autocoding, the Central Coding application attempts to match the verbatim against terms in the classification level of the dictionary to be coded against. If no match is found, the system uses the steps in the algorithm to attempt to find a coding match. For example, the system can attempt to match a synonym, can try to find a term or synonym that contains some or all of the words in the verbatim, or can transform the verbatim by removing punctuation or stopwords, and then attempt one of the matching strategies again.

Assignment rules

An assignment rule is a set of criteria that defines how incoming coding requests are routed in the Central Coding application. Assignment rules are used in conjunction with coding definitions and work teams to provide a high level of control over the Central Coding request-processing workflow.

System administrators create assignment rules to handle specific types of incoming coding requests based on a variety of configurable criteria. Assignment rules allow the system to automatically route coding requests so that administrators do not have to assign a coding definition to each coding request.

Assignment rule properties control:

- Whether an attempt is made to autocode an incoming request.
- How the Central Coding application handles approvals, reviews, and return deliveries to the source application.
- Which work team or work teams are assigned requests.
- Which coding definition is associated with the rule.
- Whether the Central Coding application deletes coding requests after delivery.

The Central Coding application maintains the assignment rules as an ordered list, so that system administrators can control the order in which the rules are run.

Dictionary elements and the element configuration options

A dictionary element is an item in a coding dictionary that corresponds to a code and term and any additional information in each level in the dictionary.

Each coding dictionary has its own set of elements. For more information, see ***Dictionary elements—MedDRA and MedDRA-J*** (on page 30), ***Dictionary elements—WHO-DD*** (on page 31), and ***Dictionary elements—JDrug*** (on page 32).

The element configuration options are the parameters in the Central Coding application that specify the dictionary elements that you want to use to control which coding features and information are available to users in the Central Coding user interface. The Central Coding application provides default element configuration settings for each dictionary. An administrator can change these settings as needed using the options on the Element Configuration page. For more information, see ***Element Configuration page*** (on page 397).

The element configuration settings determine the:

- Autocode target(s).
- Information that appears on the request list view pages and the coding browser displays.
- Dictionary elements that are returned to the source application.
- Dictionary elements that can be exported to the Microsoft Excel spreadsheet software with the request.
- Data items to be reconciled during impact analysis.

Adapters, job schedules, and job queues—Required for InForm integration only

The Central Coding application uses adapters, job schedules, and job queues to communicate with, and transfer data to and from, the InForm application.

Adapters

An adapter is a web services interface that supports the secure transfer of data between the InForm application and the Central Coding application. Each adapter is associated with a specific InForm study or studies.

Jobs and job schedules

A job is a mechanism that the Central Coding application uses to get data from, and return data to, the InForm application. The Central Coding application includes three jobs:

- **Get Requests job**—Retrieves verbatims and associated context items from the InForm application.
- **Exchange Query Updates job**—Synchronizes query data for verbatims in the Central Coding application and the InForm application.
- **Return Codes job**—Returns codes to the InForm application.

A job schedule is a user-defined timetable that specifies when the Central Coding application runs the jobs.

For each adapter and its associated studies, the Central Coding application uses two job schedules for normal request processing.

- **Get Requests job schedule**—Determines when to run the Get Requests job to retrieve coding requests from the InForm application. Each time you choose to run the Get Requests job, the Central Coding application also automatically runs the Exchange Query Updates job to synchronize query data. The Central Coding application runs the jobs serially, beginning the Exchange Query Updates job when the Get Requests job is complete.
- **Return Codes job schedule**—Determines when to run the Return Codes job to return coded requests to the InForm application.

There is one Get Requests job schedule and one Return Codes job schedule for each adapter. The schedules apply to all studies associated with the adapter.

The first time you install the Central Coding software, you must define the Get Requests and Return Codes jobs schedules for each adapter, and then add studies to them. There are no default timetables for the job schedules. The Central Coding application only runs the jobs associated with a study when its adapter is included in the job schedule(s).

You can also choose to run the Get Requests and Return Codes jobs at non-scheduled times. You might want to do this for new adapters for existing studies that have a large amount of uncoded data. Manually running the jobs at an off-peak time allows the data to be transferred without having an impact on performance. After the coding is up to date, you can add the adapter to the job schedules for normal request processing. The Central Coding application runs these manual jobs using separate job queues called *ASAP job queues*. For more information, see ***Job queues*** (on page 26).

Job queues

A job queue is a container for all the requests associated with running scheduled or non-scheduled (manual) jobs. There are three types of job queues for each adapter: Get Requests, Return Codes, and ASAP.

- **Get Requests job queue**—Includes the Get Requests and Exchange Query Updates jobs for all studies included in the Get Requests job schedule when the schedule runs.

  There is one Get Requests job queue for each adapter and its associated studies.

- **Return Codes job queue**—Includes the Return Codes jobs for all studies included in the Return Codes job schedule when the schedule runs.

  There is one Return Codes job queue for each adapter and its associated studies.

- **ASAP job queue(s)**—Includes the Get Requests jobs or Return Codes jobs for studies that are not included in the Get Requests or Return Codes job schedules.

  There is one ASAP job queue for each Get Requests or Return Codes job that you manually run for a study.

For example, if there are 100 studies associated with an adapter that are included in its Get Requests job schedule, the system adds two jobs for each study (a Get Requests job and an Exchange Query Updates job, which totals 200 jobs) to the Get Requests job queue when the schedule runs.

If all 100 studies are also included in the adapter's Return Codes job schedule, 100 jobs are similarly added to the Return Codes job queue.

If you have also run manual Get Requests jobs for 10 additional studies that are associated with the adapter, the system creates an additional 10 ASAP job queues that run synchronously with the scheduled Get Requests and Return Codes job queues. Therefore, running multiple, non-scheduled jobs in a short period of time can affect system performance.

Using adapters in parallel

You can set up multiple adapters and associate them with one or more studies for each instance of the Central Coding application. Then, you define one Get Requests and one Return Codes job schedule *for each adapter*.

- For each adapter, all the job queues run synchronously. The Get Requests, Return Codes, and ASAP job queues run at the same time.
- The jobs in each queue, however, run serially. Each job in a queue starts as soon as the preceding job in the queue completes.
- If you use multiple adapters, the job queues for each adapter run in parallel with those for the other adapters.

Coding request-processing

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 application or retrieves a coding request from the InForm application, the assignment rules determine whether the request is to be automatically or interactively coded, and which coding dictionary to use.

- The Clintrial application initiates all communication to and from the Central Coding application.
- The Central Coding application initiates all communication to and from the InForm 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 returns coded information to the Clintrial or InForm application and stores the information in the Central Coding database. If autocoding fails, a coder must interactively code the request.

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

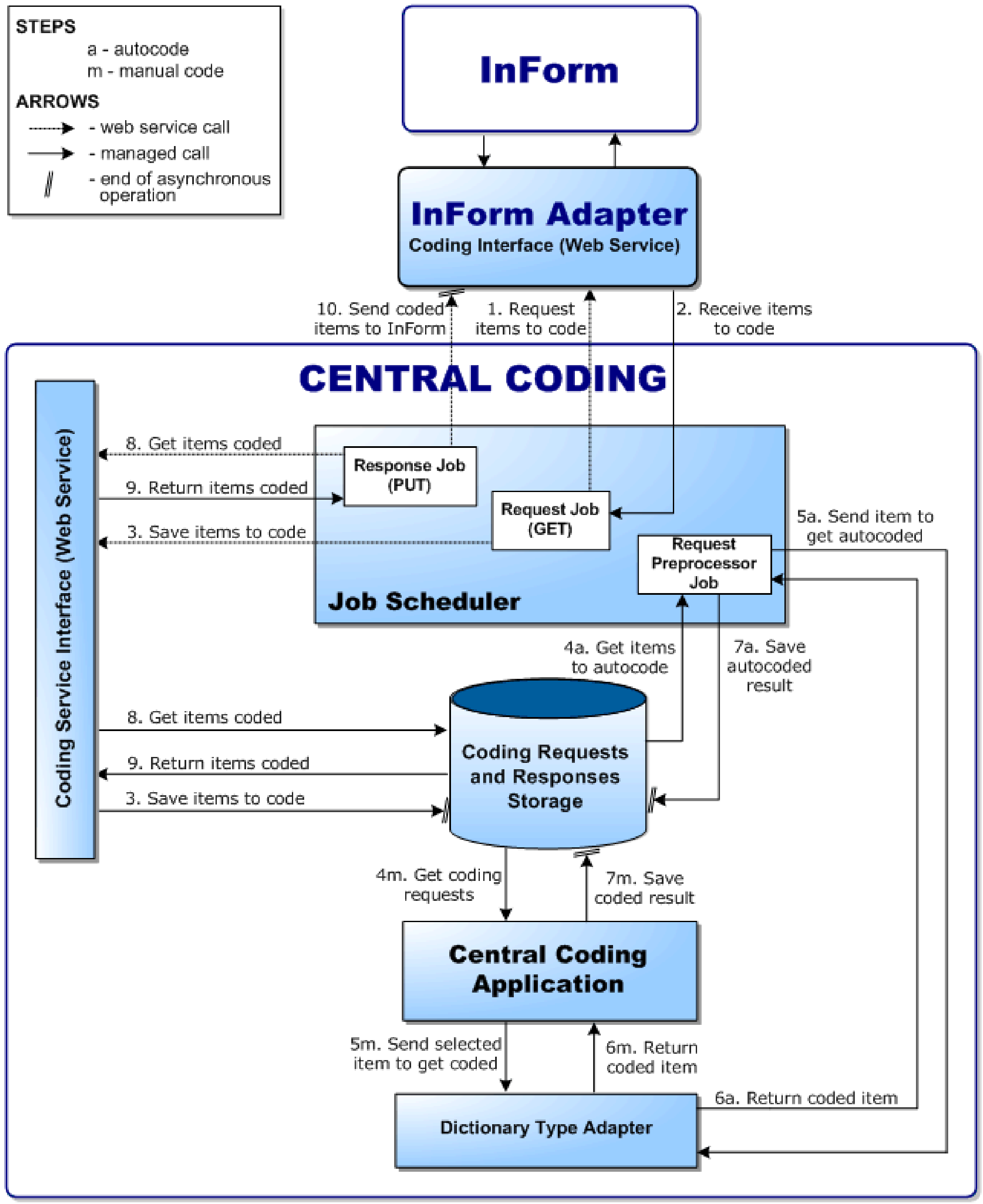
When interactive coding is successful, the application stores the configured elements from the dictionary. An administrator can configure the Central Coding application so that interactively coded requests can be automatically approved or so that they require manual approval by an approver. Approvers may approve or disapprove a coding request, or indicate that more information is required to code the request.

Additional rules are used to determine which work team or work teams are assigned to a coding request. A system administrator defines work teams and work team assignment rules. Work teams consist of coding experts including coders and approvers. Coders and approvers access coding requests through the Central Coding user interface, and use it to approve requests that were coded successfully and require manual approval. Coders and approvers use the coding browser to code requests that require interactive coding and requests that fail autocoding.

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 retrieval by the Clintrial application or delivery to the InForm application. When integrating with the InForm application, the Central Coding job queue picks up the request and delivers it to the InForm application at the next scheduled delivery time.

Coding request-processing workflow—InForm integration



Code and propagate

The code and propagate feature allows the Central Coding application to automatically propagate the selected code value to all other uncoded requests with the same verbatim, coding definition, and context information. Context information is defined in the source application and includes information from the WHO-DD or JDrug dictionary, such as the indication and route of administration.

The code is propagated only to requests associated with studies that are marked as unlocked in the Central Coding application. For more information, see ***Locking a study in the Central Coding application*** (on page 211).

Impact analysis

Impact analysis is the process of evaluating existing terms and code assignments against a new dictionary version, reconciling any differences, and reporting the differences between dictionary versions.

Note: The Central Coding application supports impact analysis for the MedDRA, MedDRA-J, WHO-DD, and JDrug dictionaries. The application does not support impact analysis for custom dictionaries.

Coding dictionaries

About the coding dictionaries

A coding dictionary is a standardized collection of terms and the codes that correspond to those terms. There is usually a code associated with each standardized term.

> **Note:** Coding dictionaries are **not** included as part of the Central Coding installation; you must purchase and install your own coding dictionaries.

MedDRA and MedDRA-J

MedDRA (Medical Dictionary for Regulatory Activities) is a standardized dictionary of medical terminology used to support the classification and communication of medical information throughout the medical product regulatory cycle. MedDRA-J is the Japanese version of MedDRA.

Dictionary elements—MedDRA and MedDRA-J

MedDRA and MedDRA-J are 5-level hierarchy dictionaries that include the following levels and associated additional information. A code and term are associated with each dictionary level.

- **System Organ Class (SOC)**—Available as a secondary autocode target.
  - International Agreement Order
- **High Level Group Term (HLGT)**
- **High Level Term (HLT)**
- **Preferred Term (PT)**—Available as the primary autocode target.
- **Low Level Term (LLT)**—Default primary autocode target.

> **Note:** The primary autocode target can be the Preferred Term or the Lowest Level Term (default), and is configurable. The available secondary autocode target, for either primary target, is the System Organ Class.

WHO-DD

WHO-DD (World Health Organization Drug Dictionary) is a comprehensive dictionary of medicinal product information that is used for identifying drug names, their active ingredients, and therapeutic uses.

Dictionary elements—WHO-DD

WHO-DD is a 7-level hierarchy dictionary that includes the following levels and associated additional information.

- **ATC1 code and term**—Available as a secondary autocode target.
- **ATC2 code and term**—Available as a secondary autocode target.
- **ATC3 code and term**—Available as a secondary autocode target.
- **ATC4 code and term**—Available as a secondary autocode target.
- **Preferred Name and code**
  - Ingredients.
  - Base Substance Drug Code.
  - Base Substance Preferred Name.
- **Trade Name and code**—Default primary autocode target.
- **Medicinal Product and code**—Available as the primary autocode target.
  - Name Specifier.
  - Country of Sale.
  - MA Holder.
  - MA Holder Country.
  - Company.
  - Company Country.
  - ICH Med Prod ID.
  - Sequence Number 3.
  - Sequence Number 4.
  - MA Number.
  - MA Date.
  - MA Withdrawal Date.
  - Product Type.
  - Product Group.
  - Pharmaceutical Product (drug form).

> **Note:** The primary autocode target can be the Trade Name (default) or the Medicinal Product, and is configurable. The available secondary autocode targets are the ATC codes (1-4).

WHO-DD C format

The Central Coding application uses the latest format of WHO-DD—the C format. The C format dictionary provides many additional information items, such as country and drug form, that you can use to identify non-unique drugs while continuing to provide the same functionality as the WHO-DD B2 format dictionary.

You can use a utility to convert WHO-DD files in the B2 format to the C format used in the Central Coding application. This allows you to load the WHO-DD into the Central Coding application, which only supports the C format. When you convert the B2 format to the C format, some C dictionary functions are not available. For more information, contact Oracle support.

> **Note:** When using WHO-DD you can configure the Central Coding application to autocode to the Trade Name (default) or to the Medicinal Product. With either configuration option, you can report (return) the Trade Name, Preferred Name, and Ingredients to the source application.

JDrug

JDrug (Data File for Ethical Drugs (Coding Table) from Iyaku-Joho-Kenkyujo, Inc.) is a comprehensive dictionary of medicinal product information that is used for identifying drug names, their active ingredients, and therapeutic uses.

Dictionary elements—JDrug

JDrug is a 7-level straight hierarchy dictionary that includes the following levels and associated additional information.

- **TC 1**
  - TC 1 (Kana).
- **TC 2**
  - TC 2 (Kana).
- **TC 3**
  - TC 3 (Kana).
- **TC 4**
  - TC 4 (Kana).
- **Generic Name**—Available as the primary autocode target.
  - Generic Name (Kana).
  - Generic Synonym Flag.
  - Generic Use Class 1.
  - Generic Use Class 2.

- Generic Common Name.
- Generic Common Name (Kana).
- Generic Dosage Forms.
- Generic Drug Class 1.

- **Trade Name**—Available as the primary autocode target.
  - Trade Name (Kana).
  - Trade Synonym Flag.
  - Trade Use Class 1.
  - Trade Use Class 2.
  - Trade Common Name.
  - Trade Common Name (Kana).
  - Trade Dosage Forms.
  - Trade Drug Class 1.
  - Manufacturer Code.
  - Manufacturer Abbreviation.
- **Case Name**—Default primary autocode target.
  - Case Name (Kana).
  - Case Type.

> **Note:** The primary autocode target can be the Generic Name, Trade Name, or Case Name (default), and is configurable. There are no secondary autocode targets for the JDrug dictionary.

Japanese dictionary support

For new installations only, the Central Coding application supports:

- English and Japanese versions of the supported operating systems.

  This feature does not include localization. The Central Coding user interface is available only in English.

- The MedDRA-J and JDrug (Data File for Ethical Drugs (Coding Table) from Iyaku-Joho-Kenkyujo, Inc.) dictionaries as standard offerings.

  The Central Coding application supports data to be coded in any left to right language supported by MedDRA, WHO-DD, or JDrug.

- Sorting and searching of the Japanese character sets.
- Coding algorithms for the Japanese dictionaries.
  - Synonyms and autocoding for Japanese dictionaries are supported.
  - Stopwords for Japanese dictionaries are not supported because they are not used in the Japanese character sets.
- Coding with both Japanese and English dictionaries in the same database and in the same study.

Dictionary types and language packs

A dictionary type file and a Japanese language pack are provided for each supported coding dictionary. For more information, see *About dictionary types and dictionary schemas* in the *Installation Guide*.

A language pack displays the dictionary level names and additional information labels in the user interface in an alternate language. You install the language pack using the Dictionary Loader tool. For more information, see *Installing the language packs for the Japanese dictionaries* in the *Installation Guide*.

Default date format

The default date format depends on the type of operating system. The date format is set during the installation and can be modified on the System Configuration page.

- For an English operating system, the default date format is DD/MON/YYYY HH24:MI:SS.
- For a Japanese operating system, the default date format is YYYY/MON/DD HH24:MI:SS.

Japanese character support

The Central Coding application supports the following character types:

- Kanji
- Kana types—Katakana and Hiragana
- Alphanumeric

Searches and sorting

Searches, sorting, and compares when using Japanese language and dictionaries are character-width insensitive and Katakana/Hiragana insensitive.

- **Alphanumeric and Special characters**—Are case and width-insensitive.

  Upper and lower case as well as wide and narrow width differences are seen as equal.
- **Kana type**—Are Katakana and Hiragana insensitive.

  The Central Coding application matches Hiragana with the equivalent Katakana and vice versa.
- **Katakana**—Wide and narrow widths are equivalent.
- **Kanji**—No conversion required.

Kana type and character width-insensitive functional areas

The Central Coding application is Katakana/Hiragana and character width-insensitive in the following functional areas:

- Auto-suggestion (autocode algorithm).
- Exact term match (autocode algorithm).
- Exact synonym match (autocode algorithm).
- Search in the coding browser (Start with, Contains, and Auto).
- Code, approve, disapprove, clear and propagate.
- Verbatim search in dictionary.
- Synonym search on Synonym List page.
- Impact Analysis.
- Dictionary type file.

Alphanumeric width-sensitive areas

The Central Coding application is width-sensitive for alphanumeric characters for all login, password, and administrative functions. This includes:

- User names and any associated information.

  The User Name and Password must be entered in narrow alphanumeric characters.

- Coding algorithm names.
- Coding definition names.
- Assignment rule names and text.

Reports and exports

The Central Coding application provides administrative reports and exports for viewing and tracking purposes. The reports are produced in PDF format, and are automatically saved in the Central Coding application. For descriptions of the reports, see ***Report descriptions*** (on page 85).

You can use the reporting user interface to export reports to a comma-separated value (CSV) file for use by an external application, such as the Microsoft Excel spreadsheet software. The exports are not saved in the Central Coding application. For more information, see ***About exporting data*** (on page 91).

Report templates

Each report has two template files: one for use with English data and one for use with Japanese data. The functionality is the same for both templates. The appropriate files are loaded during the Central Coding product installation. For more information, see the *Installation Guide*.

- **English template files**—Contain fonts that are part of the base English operating system. These reports can contain only English data.
- **Japanese template files**—Contain the MS Mincho or MS UI Gothic font so that Japanese text appears correctly in the reports. These reports can contain both Japanese and English data.

  The Japanese templates are loaded into the database if you are using:

  - A Japanese operating system.

    or

  - An English operating system and you select the Global locale on the Determine Database Sort page during the Central Coding installation. If you select the English or European locale, only the reports that support English are loaded into the database.

Data mappings from the source applications

Clintrial data mappings

The Clintrial data mappings are set up using the Clintrial application. For more information, see the Clintrial *Manage, Classify & Lab Loader* guide.

InForm data mappings

The InForm data mappings (coding maps) are set up using the Oracle Central Designer application. For more information, see the Central Designer *User Guide*, *Volume 1: Study Objects*.

> **Note:** **If you create or modify a coding map in the Central Designer application, use a full deployment package to deploy the changes. The Central Coding application does not support changes to coding maps deployed in incremental deployment packages.**

Users, rights, roles, and work teams

- **User**—A person who works with the Central Coding application through the user interface.

  Each user is assigned to one or more roles. During the Central Coding installation, you are prompted to create a single initial user and to create a password for the user. This user logs into the Central Coding application and creates all additional users. For more information, see the *Installation Guide*.

- **Right**—A privilege that identifies a feature to which a user has access.

  Rights control the pages that appear in the user interface and the actions available on each page. Rights are defined by the application; you cannot create new rights.

- **Role**—A named collection of rights. The Central Coding application provides d

- Rights control the pages that appear in the user interface and the actions available on each page. Rights are defined by the application; you cannot create new rights.efault roles and rights.

  A role:

  - Describes the functions that the users can perform (for example, Coder, Approver, Reporter, System Administrator, and so on).

  - Controls access to the Central Coding application through the rights associated with it.

  Rights are assigned to roles, and roles are assigned to users.

- **Work teams**—A set of users that you organize and group by function for the purpose of performing tasks. There are no default work teams.

  The criteria used to organize work teams may be defined by a system administrator to meet the business needs of an organization. Coding requests are assigned to work teams rather than to individual users. Work teams act as a filter for the list of coding requests that are presented to individual users. Users see only those requests that are assigned to the work team(s) to which they belong.

User security

For security, three types of users can be defined in the Central Coding application. In all cases, the user profile is stored in the Central Coding database along with the user ID. The user types differ in where the system stores the passwords and how the system authenticates the user. The user type is set on the User details page in the Central Coding user interface.

- **Native user**—Password maintained by the Central Coding application.

  When the user logs in, the authentication module encrypts the password entered by the user and compares it to the encrypted password stored in the database. The user is granted access to the application only if the passwords match.

- **Windows user**—Does not have a password stored in the database.

  When the user logs in, the authentication module uses the username and password entered on the Login page and uses a Windows API to authenticate the user.

  In this mode, the Central Coding application has no knowledge of what the password is, and it is up to Windows to determine if the user is granted access. This user type requires Central Coding users to be created as part of a Windows domain. The format of the user ID supports just the user ID, such as **joe** if you want to log in to the current domain, or **EAST\joe** if you want to authenticate the user **joe** in the domain **EAST**.

- **Certificate user**—The system checks a digital certificate for a valid user name and password.

System Administrator role and the Central Coding administrator responsibilities

The *System Administrator* role in the Central Coding application is not the same as the person referred to as the *administrator* in this guide. The administrator for whom this guide is written performs many more functions than are defined for the System Administrator role.

The Central Coding *administrator* uses the Central Coding application to:

- Create and maintain user, role, and work team information.
- Manage the assignment of rights to roles.
- Assign users to roles.
- Assign users to work teams.
- Assign roles to users.
- Assign work teams to users.

Getting help

The Central Coding application provides extensive online help to give you easy access to procedural, conceptual, and detailed task-related information.

- **Central Coding Help Center**—Provides access to the Central Coding documentation from the user interface.

  To open the Central Coding Help Center page, click the **Help text** link () in the top right corner of the main application window. The page appears in a second browser window that you can resize and move for easy viewing.

- **Page-level help**—Describes the page function(s) and fields for each page in the user interface.

  To open a help page, click the **Help** link () button in the top right corner of any page or dialog box. The page-level help is part of the *User Guide*. The page-level help opens in a second browser window that you can resize and move for easy side-by-side viewing with other pages.

  > **Note:** The popup blocker in your browser may prevent the help pages from opening. If this occurs, either turn off the popup blocker or press the Ctrl key before you click the Help button.

- **Hover help**—Provides a brief description of what the selected menu item, action, button, or icon does, and what, if any, keyboard shortcuts exist for the item.

  To display hover Help hold your mouse pointer over the item and the hover Help text appears in a popup window. When you move your mouse pointer off the item, the hover Help disappears.

CHAPTER 2

Getting started

In this chapter

About getting started

After you log in to the Central Coding application, you can change your password, familiarize yourself with your account details, and set the list page size to define the number of rows of data that you want to display on the list view pages in the user interface.

Logging in to the Central Coding application

Use this procedure to log in to the Central Coding application. After you log in, the user interface opens and displays all the folders that you are allowed to access based on your user profile, roles, and rights. The first folder is selected and its contents are visible by default. Your Display Name, which is set by an administrator, appears on all pages that are part of the main application window.

If you are locked out of the system due to an authentication failure (that is, you exceed the allowed number of login attempts), your password must be reset. See your administrator for assistance.

1. Launch the Central Coding application.

   The Login page appears. Your administrator determines the method for opening the application. By default, the system is configured to open by typing the following command in your browser:

   ```
   http://[server name]/[Coding virtual directory name]
   ```

   The **Coding virtual directory** name is the unique name for the application server where the Central Coding software is installed. This name is defined during the Central Coding installation.

2. In the **User Name** field, type your system login name.
3. In the **Password** field, type your login password.

   This password is used in conjunction with your user name to authenticate you to the system.

4. Click **Login**.

   The main window of the Central Coding application appears in its own browser window.

   or

   You are prompted to change your password. Proceed to step 5.

   > **Note:** You are always prompted to change your password the first time you log in to the Central Coding application.

5. In the **User Name** field, type your system login name.
6. In the **New Password** field, type your new password.

   Passwords can be from 1 to 32 characters. For security reasons, Oracle recommends using a combination of letters and numbers and a minimum of 6 characters. Passwords are case-sensitive.

7. In the **Confirm Password** field, retype your new password.
8. Click **Login**.

   The main window of the Central Coding application appears in its own browser window.

Logging out of the Central Coding application

1. In the **Main window**, click **Logout**.

   A confirmation dialog box appears.

2. Click **OK**.

Viewing your account profile

Your account profile is defined by an administrator and provides details on your account and personal information.

- In the **Main window**, click **My Profile**.

  The My Profile dialog box appears. For a description of the fields on this page, see ***My Profile dialog box*** (on page 316).

Changing your password

1 In the **Main window**, click **My Profile**.

The My Profile dialog box appears.

2 Click **Change password**.

The Change Password dialog box appears.

> **Note:** This link appears only when an administrator sets the account type to **SuperUser** or **User**. It does not appear if the account type is **Machine**.

3 Complete the following fields:

- **User Name**—Your system log in name. This field is read-only.
- **Old Password**—The log in password you are currently using. REQUIRED.
- **New Password / Confirm Password**—The new log in password you want to use. REQUIRED.

> **Note:** Passwords can be from 1 to 32 characters. For security reasons, Oracle recommends using a combination of letters and numbers and a minimum of 6 characters. Passwords are case-sensitive. Passwords cannot be reused for a configurable amount of time.

4 Click **Save**.

Setting the list page size

Use this procedure to specify the number of rows that you want to display on list view pages. Use this option to specify a page size that works best for the screen resolution you are using to allow the data to fit on one page.

1 In the **Main window**, click **My Profile**.

  The My Profile dialog box appears. For a description of the fields on this page, see ***My Profile dialog box*** (on page 316).

2 In the **List page size** box, type the number of rows that you want to display on a list view page.

  You can enter a value from 1 to 100. The default is 15.

  Note: You must manually refresh the page after changing this setting.

PART 2: END-USER TASKS

CHAPTER 3

Coding and approving requests

In this chapter

Viewing your coding requests

About viewing your coding requests

You can view the list of coding requests assigned to your work teams, and view request and coding details.

Note: A coder typically performs these tasks.

Viewing the list of your coding requests

1 Select **Coding Requests**.

The Coding Requests page appears. For a description of the fields on this page, see Coding Requests page.

2 Optionally, filter the list of requests to identify the items that you want to view, and click **Apply**.

You can do any or all of the following:

- In the **Verbatim** field, type the verbatim text that you want to search for.

  Searches are *case-insensitive*. The search supports the special characters *, %, ?, and _. The search text field can be an arbitrary text string and can contain wildcard characters to facilitate matching when the exact text is not known. The percent sign (%) or asterisk (*) matches any sequence of characters; the question mark (?) or underscore (_) matches any single character.

- In the **Subject ID** field, type the subject ID for the subject that you want to search for.
- In the **Show** filter field, select one of the following:
  - **All**—Displays all requests.
  - **To Do**—Displays all requests for which further action is required to code the verbatim.
  - **Done**—Displays all requests for which no further action is required to code the verbatim.
  - **Pending Delivery**—Displays all requests that are coded, but are not yet delivered to the source application.
  - **Undeliverable**—Displays all requests that could not be delivered to the source application.
- In the **Study** filter field, select a study for which you want to view the associated coding requests.
- In the **View** filter field, select a coding definition for which you want to view the associated coding requests.

Viewing the details of one of your coding requests

Use this procedure to view all the information in the Central Coding application about a coding request. The information includes details about the coding method and status, assignment rule, coding definition, and identification information about the request from the source application.

1 Select **Coding Requests**.

The Coding Requests page appears.

2 Select a request.

3 Select **Actions > Details**.

or

Click the **Details** link.

The Request Details page appears. For a description of the fields on this page, see ***Request Details page*** (on page 333).

Viewing the full coding details

Use this procedure to view the full coding details for a coded item. The details include the dictionary name and version, the coded term and value, and the level of the dictionary hierarchy where the match was found.

1 Select **Coding Requests**.

The Coding Requests page appears.

2 In the **Show** filter field, select **Done**.

3 Click **Apply**.

4 Click the **Code** link for the request for which you want to view the coding details.

The View Full Coding dialog box appears. For a description of the fields on this page, see ***View Full Coding dialog box*** (on page 335).

> **Note:** The **Code** link appears only for coded items.

Coding your coding requests

Depending on the roles and rights assigned in your user profile, you can perform some or all of the following tasks on the coding requests that are assigned to your work teams:

- Interactively code requests using the coding browser.
- Suggest synonyms.
- Clear code values.
- Create queries for requests that need more information in order to be coded.

> **Note:** A coder typically performs these tasks.

Coding an item and propagating the value—Search method

Use this procedure to code a request using the Search method of interactive coding, and to propagate the value. Use the Search method to search selected fields in a dictionary for text that begins with or contains the verbatim text.

The application automatically propagates the selected code value to all other uncoded requests with the same verbatim, coding definition, and context information. The code is propagated only to requests associated with studies that are marked as unlocked in the Central Coding application. For more information, see *Locking a study in the Central Coding application* (on page 211).

> **Note: You can code and propagate to items that have never been coded, or you can code and propagate to items that have been coded and have assigned code values. Before coding and propagating to previously coded items, you must clear and propagate the code values. For more information, see *Clearing and propagating the code value* (on page 65).**

1 Select **Coding Requests**.

The Coding Requests page appears.

or

Select **Approvals**.

The Approvals page appears.

2 Select a request.

3 Select **Actions > Code**.

or

Click the **Code** button.

or

Click the **Verbatim** link.

The Coding Browser dialog box appears. By default, the coding browser opens in Search mode. The dictionary elements that appear are configured for the coding definition in use. For a description of the fields on this page, see *Coding Browser dialog box—Search mode* (on page 324).

4 In the **Search for** field, type the text that you want to code.

> **Note:** All searches are case-insensitive.

5 In the **In field** field, select the hierarchy level of the dictionary that you want to search.

6 Select **Return All Matches** if you want all the matched terms found to display in the coding browser.

By default, the coding browser displays 200 matches. This number, and whether this option is available, is set by your administrator. For more information, see *Changing the number of matched terms that display in the coding browser* in the *Installation Guide*.

7 To start the search, do one of the following:

- To run a search for matches that start with the text entered in the **Search for** field, click the **Starts With** button.
- To run a search for matches that contain the text entered in the **Search for** field, click the **Contains** button.

  Optionally, to display only terms that match the verbatim in its entirety, select the **Contains whole words only** option.
- To run the autocode algorithm associated with the request, click the **Auto** button.

  Optionally, if you want the system to ignore the step in the coding algorithm that looks for an auto-suggested code value, select the **Exclude Auto Suggestion step** option.

If any dictionary entries are found that match the search criteria, they appear in the display area in the coding browser.

- A red superscript letter **P** indicates that the result represents the primary path for the MedDRA dictionaries that support the concept of primary path.
- The blue superscript letters **nc** indicate that the coding is not current for the MedDRA dictionaries that support the concept of currency.
- If no terms are found, a message appears that indicates that no terms were found, and the display area is cleared.

8 Optionally, if you are coding a verbatim at the Trade Name level in the WHO-DD dictionary, select the link in the **Drug Code** or **Trade Name** column to display the Medicinal Product information for the verbatim. The Medicinal Product information can further clarify which code is appropriate for the verbatim.

9 Select the **Use as Auto Suggestion** option if you want the system to use the new code value you accept for all new incoming requests with the same verbatim, dictionary, coding definition, and context information.

10 Click the **Accept** link to the left of the code value that you want to accept.

The Coding Browser dialog box closes.

If the verbatim was previously coded, a dialog box appears.

a In the **Reason** field, specify a reason for recoding the verbatim.

b Optionally, to attach a note that contains the reason for recoding the verbatim to the coding request, select the **Add as notes** checkbox. For more information, see *Adding a note to a coding request* (on page 74).

The application automatically propagates the selected code value to all other uncoded requests with the same verbatim, coding definition, and context information.

Coding an item and propagating the value—Browse method

Use this procedure to code a request using the Browse method of interactive coding, and to propagate the value. Use the Browse method to examine the target coding dictionary, from level to level, selecting relevant terms. When you establish an appropriate term, you can apply the term and code to the verbatim.

The application automatically propagates the selected code value to all other uncoded requests with the same verbatim, coding definition, and context information. The code is propagated only to requests associated with studies that are marked as unlocked in the Central Coding application. For more information, see ***Locking a study in the Central Coding application*** (on page 211).

> **Note:** You can code and propagate to items that have never been coded, or you can code and propagate to items that have been coded and have assigned code values. Before coding and propagating to previously coded items, you must clear and propagate the code values. For more information, see ***Clearing and propagating the code value*** (on page 65).

1 Select **Coding Requests**.

The Coding Requests page appears.

or

Select **Approvals**.

The Approvals page appears.

2 Select a request.

3 Select **Actions > Code**.

or

Click the **Code** button.

or

Click the **Verbatim** link.

The Coding Browser dialog box appears. By default, the coding browser opens in Search mode. The dictionary elements that appear are configured for the coding definition in use.

4 Click the **Browse** icon ().

The page refreshes and the contents of the browser change. A tree hierarchy view appears in the display area. Each level in the hierarchy contains all the dictionary entries relevant to that level.

For a description of the fields on this page, see ***Coding Browser dialog box—Browse mode*** (on page 329).

5 Expand each level as needed until you find an acceptable term and code value.

6 Click the term that you want to use as the code value.

A confirmation dialog box appears.

7 Click **OK**.

The Coding Browser dialog box closes.

If the verbatim was previously coded, a dialog box appears.

a In the **Reason** field, specify a reason for recoding the verbatim.

b Optionally, to attach a note that contains the reason for recoding the verbatim to the coding request, select the **Add as notes** checkbox. For more information, see *Adding a note to a coding request* (on page 74).

The application automatically propagates the selected code value to all other uncoded requests with the same verbatim, coding definition, and context information.

Coding a single item—Search method

Use this procedure to search for a code value for a single item. Use the Search method to search selected fields in a coding dictionary for text that begins with or contains the verbatim text.

1 Select **Coding Requests**.

The Coding Requests page appears.

or

Select **Approvals**.

The Approvals page appears.

2 Select a request.

> **Note:** You can code a request that has never been coded or you can recode a request that has been coded and has an assigned code value.

3 Select **Actions > Code Single**.

or

Click the **Code Single** button.

or

Click the **Verbatim** link.

The Coding Browser dialog box appears. By default, the coding browser opens in Search mode. The dictionary elements that appear are configured for the coding definition in use. For a description of the fields on this page, see *Coding Browser dialog box—Search mode* (on page 324).

4 In the **Search for** field, type the text that you want to code.

> **Note:** All searches are case-insensitive.

5 In the **In field** field, select the hierarchy level of the dictionary that you want to search.

6 Select **Return All Matches** if you want all the matched terms found to display in the coding browser.

By default, the coding browser displays 200 matches. This number, and whether this option is available, is set by your administrator. For more information, see *Changing the number of matched terms that display in the coding browser* in the *Installation Guide*.

7 Start the search.

You can:

- To run a search for matches that start with the text entered in the **Search for** field, click the **Starts With** button.
- To run a search for matches that contain the text entered in the **Search for** field, click the **Contains** button.

  Optionally, to display only terms that match the verbatim in its entirety, select the **Contains whole words only** option.
- To run the autocode algorithm associated with the request, click the **Auto** button.

  Optionally, if you want the system to ignore the step in the coding algorithm that looks for an auto-suggested code value, select the **Exclude Auto Suggestion step** option.

If any dictionary entries are found that match the search criteria, they appear in the display area in the coding browser.

- A red superscript letter **P** indicates that the result represents the primary path for the MedDRA dictionaries that support the concept of primary path.
- The blue superscript letters **nc** indicate that the coding is not current for the MedDRA dictionaries that support the concept of currency.
- If no terms are found, a message appears that indicates that no terms were found, and the display area is cleared.

8 Optionally, if you are coding a verbatim at the Trade Name level in the WHO-DD dictionary, select the link in the **Drug Code** or **Trade Name** column to display the Medicinal Product information for the verbatim. The Medicinal Product information can further clarify which code is appropriate for the verbatim.

9 Select the **Use as Auto Suggestion** option if you want the system to use the new code value you accept for all new incoming requests with the same verbatim, dictionary, coding definition, and context information.

10 Click the **Accept** link to the left of the code value that you want to accept.

If the verbatim was previously coded, a dialog box appears.

a In the **Reason** field, specify a reason for recoding the verbatim.

b Optionally, to attach a note that contains the reason for recoding the verbatim to the coding request, select the **Add as notes** checkbox. For more information, see ***Adding a note to a coding request*** (on page 74).

The system saves the code value for the selected request only, and the Coding Browser dialog box closes.

Coding a single item—Browse method

Use this procedure to browse for a code value for a single item. Use the Browse method to examine the target coding dictionary, from level to level, and select relevant terms. When you find an appropriate term, you can apply the term and code to the verbatim.

1 Select **Coding Requests**.

The Coding Requests page appears.

or

Select **Approvals**.

The Approvals page appears.

2 Select a request.

> **Note:** You can code a request that has never been coded or you can recode a request that has been coded and has an assigned code value.

3 Select **Actions > Code Single**.

or

Click the **Code Single** button.

or

Click the **Verbatim** link.

The Coding Browser dialog box appears. By default, the coding browser opens in Search mode. The dictionary elements that appear are configured for the coding definition in use. For a description of the fields on this page, see *Coding Browser dialog box—Search mode* (on page 324).

4 Click the **Browse** icon ( ).

The page refreshes and the contents of the browser change. A tree hierarchy view appears in the display area. Each level in the hierarchy contains all the dictionary entries relevant to that level. For a description of the fields on this page, see *Coding Browser dialog box—Browse mode* (on page 329).

5 Expand each level as needed until you find an acceptable term and code value.

6 Click the term that you want to use as the code value.

A confirmation dialog box appears.

7 Click **OK**.

The Coding Browser dialog box closes.

If the verbatim was previously coded, a dialog box appears.

a In the **Reason** field, specify a reason for recoding the verbatim.

b Optionally, to attach a note that contains the reason for recoding the verbatim to the coding request, select the **Add as notes** checkbox. For more information, see *Adding a note to a coding request* (on page 74).

The system saves the code value for the selected request only.

Viewing the approved synonyms for a code

Use this procedure to view the list of approved synonyms for a selected code. You can view synonyms only from the coding browser. The coding browser must be in the Search mode.

1 Select **Coding Requests**.

The Coding Requests page appears.

2 Select a request.

3 Open the coding browser.

To do this:

- Select **Actions > Code**.

  or

  Click the **Code** button.

  or

- Select **Actions > Code Single**.

  or

  Click the **Code Single** button.

  or

- Click the **Verbatim** link.

The Coding Browser dialog box appears. By default, the coding browser opens in Search mode. The dictionary elements that appear are configured for the coding definition in use.

4 Make sure that the coding browser is in the **Search** mode and code the item.

For more information, see ***Coding a single item—Search method*** (on page 59) or ***Coding an item and propagating the value—Search method*** (on page 56).

The View Synonyms link appears to the right of the coded term. This link appears only after the term is coded and only if there is an active synonym list specified by the coding definition in use.

5 Click the **View Synonyms** link.

The Synonyms for [Code value] dialog box appears. For a description of the fields on this page, see ***Synonyms for [Code value] dialog box*** (on page 328).

Viewing the Medicinal Product information for a verbatim

Use this procedure to view the Medicinal Product information while searching for codes in the WHO-DD dictionary. You can view Medicinal Product information only from the coding browser in Search mode.

> **Note:** This functionality is available only when coding to the Trade Name level in the WHO-DD dictionary.

1 Select **Coding Requests**.

The Coding Requests page appears.

2 Select a request.

3 Open the coding browser.

To do this:

- Select **Actions > Code**.

  or

  Click the **Code** button.

  or

- Select **Actions > Code Single**.

  or

  Click the **Code Single** button.

  or

- Click the **Verbatim** link.

The Coding Browser dialog box appears. By default, the coding browser opens in Search mode. The dictionary elements that appear are configured for the coding definition in use.

4 Make sure that the coding browser is in the **Search** mode and code the item.

For more information, see ***Coding a single item—Search method*** (on page 59) or ***Coding an item and propagating the value—Search method*** (on page 56).

The letters OF (Old Form) appear next to drug codes for old entries. You can use the hover Help on the drug code to view the name of the country where the entry is old.

5 Click the link in the **Drug Code** or **Trade Name** column.

The View Medicinal Product Information dialog box appears. For a description of the fields on this page, see ***View Medicinal Product Information dialog box*** (on page 332).

Suggesting a synonym

> **Note:** You can suggest synonyms only from the coding browser. The coding browser must be in the Search mode.

1 Select **Coding Requests**.

The Coding Requests page appears.

2 Select a request.

3 Open the coding browser.

To do this:

- Select **Actions > Code**.

  or

  Click the **Code** button.

  or

- Select **Actions > Code Single**.

  or

  Click the **Code Single** button.

  or

- Click the **Verbatim** link.

The Coding Browser dialog box appears. By default, the coding browser opens in Search mode. The dictionary elements that appear are configured for the coding definition in use.

4 Make sure that the coding browser is in the **Search** mode and code the item.

For more information, see ***Coding a single item—Search method*** (on page 59) or ***Coding an item and propagating the value—Search method*** (on page 56).

The Suggest Synonyms link appears to the right of the coded term. This link appears only after the term is coded and only if there is an active synonym list specified by the coding definition in use.

5 Click the **Suggest Synonyms** link.

The Suggest Synonym dialog box appears.

6 In the **Suggested Synonym** field, type the synonym that you want to propose for the term.

7 Click **Accept**.

The proposed synonym is added to the synonym list that is associated with the coding definition for the coding request. After it is approved by an administrator, the synonym is activated.

Clearing and propagating the code value

Use this procedure to remove the code value for the selected verbatim and for all other coded requests (with a delivery status of either delivered or undelivered) with the same verbatim, code value, coding definition, and context information.

The code value is cleared only for requests associated with studies that are marked as unlocked in the Central Coding application. For more information, see ***Locking a study in the Central Coding application*** (on page 211).

> **Note: Clearing the code value(s) in the Central Coding application clears the corresponding code value(s) in the source application.**

1 Select **Coding Requests**.

The Coding Requests page appears.

or

Select **Approvals**.

The Approvals page appears.

2 Select one or more requests.

> **Note: The Central Coding application cannot clear the code value for a request with a Partially coded ( ) request status. Instead, you must manually code the request.**

3 Select **Actions** > **Clear and Propagate**.

A dialog box appears.

4 In the **Reason** field, specify a reason for clearing and propagating the code value.

5 Optionally, to attach a note that contains the reason for clearing and propagating the code value to the coding request, select the **Add as notes checkbox**. For more information, see ***Notes*** (on page 74).

The application removes the code value for the selected verbatim and for all other coded requests (with a delivery status of either delivered or undelivered) with the same verbatim, code value, coding definition, and context information.

The coding statuses of the requests change to **Uncoded** ( ).

Clearing the code value for a single request

> **Note:** Clearing the code value(s) in the Central Coding application clears the corresponding code value(s) in the source application.

1 Select **Coding Requests**.

The Coding Requests page appears.

2 Select one or more requests.

> **Note:** The Central Coding application cannot clear the code value for a request with a **Partially coded** ( ) request status. Instead, you must manually code the request.

3 Select **Actions > Clear Code**.

A dialog box appears.

4 In the **Reason** field, specify a reason for clearing the code value.

5 Optionally, to attach a note that contains the reason for clearing the code value to the coding request, select the **Add as notes checkbox**. For more information, see *Notes* (on page 74).

The application removes the code value for the selected request. The coding status of the request changes to **Uncoded** ( ).

Completing the review of an autocoded request

Use this procedure to complete the review of an autocoded request. This task allows a coder to review all autocoded items when the system is configured to require the review. Autocoded requests that require a review receive a status of **Needs Review** after they have been successfully autocoded.

1 Select **Coding Requests**.

The Coding Requests page appears.

2 Select one or more requests with a status of **Needs Review** ( ).

3 Select **Actions > Review Complete**.

The request status changes to **Coded, awaiting approval** ( ) or **Completed, awaiting delivery** ( ).

Resending an undeliverable request

Use this procedure to change the delivery status of a request with a failed delivery to the InForm application to **Completed, awaiting delivery**. This action allows the request to be picked up by the Central Coding job queue so that it can be resent to the InForm application.

> **Note:** An administrator typically performs this task, which requires the Retry Delivery right. An administrator can also resend all undeliverable requests at one time. For more information, see ***Resending all undeliverable requests*** (on page 271).

1 Select **Coding Requests**.

The Coding Requests page appears.

2 Select one or more requests with a delivery status of **Undeliverable, retry** ( ).

View the hover text over the icon to view the reason the delivery was unsuccessful. For more information, see ***Error messages for undeliverable requests to the InForm application*** (on page 67).

3 Select **Actions > Retry Delivery**.

The delivery status of the request changes to **Completed, awaiting delivery** ( ).

All requests with a coding status of **Completed, awaiting delivery** ( ) are available for delivery to the InForm application. The job queue picks up the requests and delivers them to the InForm application at the next scheduled time.

Error messages for undeliverable requests to the InForm application

Error messages for undeliverable requests to the InForm application		
Error message	**Description**	**Solution**
InForm user not found	The Central Coding application cannot find an InForm system user.	Add a system user in the InForm application.
Verbatim data value does not match or has changed	The verbatim was changed in the InForm application after it was sent to the Central Coding application.	No action is needed. The verbatim will be updated in the Central Coding application in the next scheduled update.
Coding Value not updated: Page Deleted	The page was deleted in the InForm application after the verbatim was sent to the Central Coding application. The item cannot be delivered.	The verbatim will be marked deleted in the next scheduled update.
Value not updated: Itemset row deleted	The itemset has been deleted in the InForm application and the item cannot be delivered.	The verbatim will be marked deleted in the next scheduled update.

Error messages for undeliverable requests to the InForm application		
Error message	**Description**	**Solution**
Trial not found	The communication between the Central Coding and InForm applications was not working at the time of delivery.	Retry the delivery. If it still comes back as undeliverable, see your system administrator.
Code map not found	When the Central Coding mappings are updated in the InForm application using the same refname, the InForm application does not create a new revision for the mappings. Instead, the InForm application creates an entirely new set of mappings with new GUIDs. As a result, when a verbatim is recoded in the Central Coding application after the updated mappings are installed in the InForm application, the request is undeliverable from the Central Coding application.	Contact Oracle CAG.

Working with queries

Queries

A query indicates that more information is required to code a request. You can generate queries on verbatims from the Coding Requests page, the Approvals page, or the coding browser. You can view the queries and modify query statuses in both the Central Coding application and the InForm application. For more information, see ***Creating a query from the Coding Requests or Approvals page*** (on page 70) or ***Creating a query from the coding browser*** (on page 72).

The Central Coding application sends the query information that you create to the InForm application for review by an InForm site user. Queries are delivered to the InForm application in a scheduled job called Exchange Query Updates, which runs after each iteration of the Get Requests job. The Exchange Query Updates job synchronizes query data in the InForm application and the Central Coding application each time it runs.

In the InForm application, the user that creates the query has the same ID for all queries opened in the Central Coding application. This synchronization is done during the dictionary element configuration. For more information, see ***Dictionary element configuration*** (on page 235).

For more information about jobs and job schedules, see ***Jobs and job schedules*** (on page 25).

An InForm query opened in the Central Coding application can be addressed in the InForm application in the following ways:

- An InForm site user modifies the verbatim associated with the query and marks the query as Answered.
- An InForm site user marks a query as Answered and states that the original value is correct.
- An InForm sponsor user closes the query.

> **Note:** This is not the preferred way to close queries. A query opened by a coder should be closed by a coder.

- The verbatim is deleted in the InForm application.

The query can be closed in the Central Coding application in the following ways:

- A Central Coding user closes the query if it is in the Answered state and the query can be coded.
- The query is closed automatically, if the auto close functionality is enabled, when the verbatim is successfully coded and approved.
- A Central Coding user with the Force Close Query right marks the query in any state as Closed.

> **Note:** This is not the preferred way to close queries. Oracle recommends using this option as infrequently as possible.

- The verbatim is deleted in the InForm application.

For more information about the auto close feature, see ***Configuring auto query and auto close settings*** (on page 233).

Viewing queries and their statuses

1 Click **Queries**.

The Queries page appears.

2 Optionally, filter the list of queries to identify the items that you want to view, and click **Apply**.

You can do any or all of the following:

- In the **Study** filter field, select a study for which to view the associated queries.
- In the **Status** filter field, select one of the following:
  - **All**—Displays requests associated with queries that are assigned any status.
  - **Candidate**—Displays requests associated with queries that are assigned a status of **Candidate**.
  - **Opened**—Displays requests associated with queries that are assigned a status of **Open**.
  - **Answered**—Displays requests associated with queries that are assigned a status of **Answered**.
  - **Closed**—Displays requests associated with queries that are assigned a status of **Closed**.
  - **Deleted**—Displays requests associated with queries that are assigned a status of **Deleted**.
  - **Send Failed**—Displays requests associated with queries that are assigned a status of **Undeliverable**, retry or **Undeliverable, cannot retry**.
- In the **Issuer** filter field, select the name of a user to view all queries that the user entered in the Central Coding application.
- In the **Form** filter field, select a form to view all queries that were entered on items on that form.

For more information about the query status icons and their descriptions, see ***Status icons in the user interface*** (on page 10).

Viewing the audit history for a query

- Click the icon for the query.

The Query History page appears. For more information, see ***Query History page*** (on page 346).

Creating a query from the Coding Requests or Approvals page

1 Select **Coding Requests**.

The Coding Requests page appears.

or

Select **Approvals**.

The Approvals page appears.

2 Select a verbatim.

3 Select **Actions > Create Query Single**.

or

Click **Create Query**.

The Create Query dialog box appears.

4 Enter the following information:

a From the **Reason** drop-down list, select a reason for creating the query.

> **Note:** The options that appear in the Reason drop-down list are configured by an administrator.

or

Click **Other**, and specify the reason for creating the query in the Other text box.

b Optionally, click the **Copy** icon () to copy the reason from the **Reason** drop-down list to the **Other** field.

c Optionally, if you have the required rights, click **Add as standard reason** to add the reason to the standard list that appears in the **Reason** drop-down list in the Create Query dialog box.

d In the **Query State** field, click:

- **Open**—Creates the query in the Open state.
- **Candidate** (if you have the required rights)—Creates the query in the Candidate state.

  For a description of each query state, see *Viewing queries and their statuses* (on page 70).

e Optionally, if you have the required rights, deselect **Auto Close Query upon Coding Complete** to indicate that you do not want the Central Coding application to automatically close the query if the verbatim successfully coded, or if it is deleted in the InForm application. If you deselect this option, you must manually close all queries.

f Optionally, if you have the required rights, deselect **Add to auto query list** to indicate that you do not want the Central Coding application to associate the query with every new instance of the associated verbatim that is entered in the Central Coding application.

The query appears for each instance of the verbatim in the study group.

> **Note:** If you create a query on a hidden verbatim, an error may occur, and you must create the query manually in the InForm application.

Creating a query from the coding browser

1 Select **Coding Requests**.

The Coding Requests page appears.

or

Select **Approvals**.

The Approvals page appears.

2 Select a request.

3 Select **Actions > Code**.

or

Click the **Code** button.

or

Click the **Verbatim** link.

The Coding Browser dialog box appears. By default, the coding browser opens in Search mode. The dictionary elements that appear are configured for the coding definition in use. For a description of the fields on this page, see *Coding Browser dialog box—Search mode* (on page 324).

4 Click the **Create Query** link.

The Create Query dialog box appears.

5 Enter the following information:

a From the **Reason** drop-down list, select a reason for creating the query.

> **Note:** The options that appear in the Reason drop-down list are configured by an administrator.

or

Click **Other**, and specify the reason for creating the query in the Other text box.

b Optionally, click the **Copy** icon ( ) to copy the reason from the **Reason** drop-down list to the **Other** field.

c Optionally, if you have the required rights, click **Add as standard reason** to add the reason to the standard list that appears in the **Reason** drop-down list in the Create Query dialog box.

d In the **Query State** field, click:

- **Open**—Creates the query in the Open state.
- **Candidate** (if you have the required rights)—Creates the query in the Candidate state.

  For a description of each query state, see *Viewing queries and their statuses* (on page 70).

e Optionally, if you have the required rights, deselect **Auto Close Query upon Coding Complete** to indicate that you do not want the Central Coding application to automatically close the query if the verbatim successfully coded, or if it is deleted in the InForm application. If you deselect this option, you must manually close all queries.

f Optionally, if you have the required rights, deselect **Add to auto query list** to indicate that you do not want the Central Coding application to associate the query with every new instance of the associated verbatim that is entered in the Central Coding application.

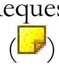
The query appears for each instance of the verbatim in the study group.

> **Note:** **If you create a query on a hidden verbatim, an error may occur, and you must create the query manually in the InForm application.**

Working with notes

Notes

You can attach a note to a coding request from the Coding Requests page or the Approvals page. Each note is associated with one coding request, and contains all note entries for the request. For example, an approver can create a note entry that contains a question for the coder to whom the request is assigned. The coder can then add a note entry that contains the response to the approver's question. Both the question and response are contained in one note associated with the coding request. This allows Central Coding users to exchange information about a coding request from within the Central Coding application, and to track that communication in one location.

To view the information in a note, navigate to the Coding Requests page, the Approvals page, or the All Requests page, and hold your mouse over the Note icon () for a request. Hover Help appears, listing the date, time, and note text for each note entry associated with the coding request. The note entries are sorted from newest to oldest.

> **Note: You cannot modify or delete a note. A note is permanently attached to the coding request with which it is associated. Note information is stored in the audit trail for the associated coding request.**

Adding a note to a coding request

1 Select **Coding Requests**.

The Coding Requests page appears.

or

Select **Approvals**.

The Approvals page appears.

2 Select a coding request.

3 Click **Add Notes**.

The Add Notes dialog box appears.

4 In the **Notes** text box, type the note text for the request.

5 Click **Accept**.

> **Note: You cannot modify or delete a note. A note is permanently attached to the coding request with which it is associated.**

Viewing note details for a coding request

There are two available options for viewing the details for a note, and each note entry within the note.

- Hover Help for each note displays the most recent note entry text.
- The Notes History page contains two sections.
    - The **Verbatim Information** section for the coding request with which the note is associated displays:
        - Verbatim associated with the coding request.
        - Study in which the verbatim exists.
        - Site at which the study in which the verbatim exists is conducted.
        - Visit at which the verbatim was reported.
    - The **Notes History** section for each note entry displays:
        - Date and time when the note entry was created.
        - User name of the user who created the note entry.
        - Note entry text.

To view note details for a coding request:

1. Select **Coding Requests**.

    The Coding Requests page appears.

    or

    Select **Approvals**.

    The Approvals page appears.

2. Do one of the following:
    - Roll your mouse over the Note icon ( ).

        Hover Help appears and displays the note text.

    - Click the Note icon ( ).

        The Notes History page appears. For more information, see ***Notes History page*** (on page 343).

Working with flags

Flags

You can attach a flag to a coding request from the Coding Requests page or the Approvals page to indicate that the request requires attention. The Central Coding application provides a set of flags, identified by color. A Central Coding administrator can configure the meaning of each flag. Flag information is not stored in the audit trail for the associated coding request.

> **Note:** Releases prior to the 3.0 SP0 release included **i** and **c** Needs Resolution markers for coding requests. In the 3.0 SP0 release and greater, the red and green flags replace those markers, and are assigned the same default definitions as the **i** and **c** Needs Resolution markers. The red flag corresponds to the **i** marker (**(I)nForm Query Opened**), and the green flag corresponds to the **c** marker (**(C)oding Query Request**).

Adding a flag to a request

1 Select **Coding Requests**.

The Coding Requests page appears.

or

Select **Approvals**.

The Approvals page appears.

2 Select a request.

3 Click **Actions > Add Flags**.

The Please select flags to add dialog box appears.

4 Select the checkbox for the flag to associate with the request.

5 Click **Accept**.

Removing a flag from a request

1 Select **Coding Requests**.

The Coding Requests page appears.

or

Select **Approvals**.

The Approvals page appears.

2 Click the flag icon to delete.

The Remove Flag confirmation dialog box appears.

3 Click **OK**.

Approving your coding requests

About approving your coding requests

An administrator configures the Central Coding application to apply approvals to coded requests automatically, or to require manual approvals.

To manually approve coding requests, you perform the tasks that are associated with approving the coding requests assigned to your work teams. You can view the requests that are awaiting approval, approve requests, disapprove requests, and view request details. Whether you can perform all or some of these tasks depends on the roles and rights assigned in your user profile.

In the Central Coding application, all approved requests are considered to be complete.

> **Note:** An approver typically performs these tasks.

Viewing the requests to be approved

1 Select **Approvals**.

The Approvals page appears. For a description of the fields on this page, see Approvals page.

2 Optionally, filter the list of requests to identify the items that you want to view, and click **Apply**.

You can do any or all of the following:

- In the **Verbatim** field, type the verbatim text that you want to search for.

  Searches are *case-insensitive*. The search supports the special characters *, %, ?, and _. The search text field can be an arbitrary text string and can contain wildcard characters to facilitate matching when the exact text is not known. The percent sign (%) or asterisk (*) matches any sequence of characters; the question mark (?) or underscore (_) matches any single character.

- In the **Subject ID** field, type the subject ID for the subject that you want to search for.
- In the **Show** filter field, select one of the following:
  - **All**—Displays all options.
  - **Uncoded**—Displays only the requests that are not coded.
  - **Partially coded**—If coding to a primary autocode and secondary target, displays only the requests for which the system has found a single match for the primary autocode target and multiple matches for the secondary target. A user must interactively code the request.
  - **Recode**—Displays only the requests that must be recoded. Requests with this status have been disapproved by an approver.
  - **Needs Review**—Displays only the requests that have been successfully autocoded but must be reviewed.
  - **Coded**—Displays only the requests that have been successfully coded.
  -

Completed—Displays only the requests that have been successfully coded and approved.

- **Delivered**—Displays only the requests that have been successfully returned to the source application.
- **Undeliverable**—Displays only the requests for which the attempt to return the request to the source application was unsuccessful.
- **Autocoded**—Displays only the requests that have been autocoded.

- In the **Study** filter field, select a study for which you want to view the associated coding requests.
- In the **View** filter field, select a coding definition for which you want to view the associated coding requests.

Viewing the details of a coding request awaiting approval

1. Select **Approvals**.

   The Approvals page appears.

2. In the **Show** filter field, select **To Do**, and click **Apply**.
3. Select a request.
4. Select **Actions > Details**.

   or

   Click the **Details** link.

   The Request Details page appears. For a description of the fields on this page, see ***Request Details page*** (on page 355).

Approving a request and propagating its status

Use this procedure to approve the coding for the selected request and for all other coded requests with the same code, verbatim, coding definition, and context information. The approval propagates only to requests associated with studies that are marked as unlocked in the Central Coding application.

1. Select **Approvals**.

   The Approvals page appears. For a description of the fields on this page, see Approvals page.

2. In the **Show** filter field, select **To Do**, and click **Apply**.
3. Select one or more requests.
4. Select **Actions > Approve**.

   or

   Click the **Approve** button.

   The system marks the coding for the affected requests as approved and their status changes to **Completed, awaiting delivery** ( ).

All requests with a coding status of **Completed, awaiting delivery** ( ) are available for delivery to the InForm application. The job queue picks up the requests and delivers them to the InForm application at the next scheduled time.

Approving a single request

1 Select **Approvals**.

The Approvals page appears. For a description of the fields on this page, see Approvals page.

2 In the **Show** filter field, select **To Do**, and click **Apply**.

3 Select one or more requests.

4 Select **Actions > Approve Single**.

or

Click the **Approve Single** button.

The system marks the coding for the affected requests as approved and their status changes to **Completed, awaiting delivery** ( ).

All requests with a coding status of **Completed, awaiting delivery** ( ) are available for delivery to the InForm application. The job queue picks up the requests and delivers them to the InForm application at the next scheduled time.

Disapproving a request and propagating its status

Use this procedure to disapprove the coding for the selected request and for all other coded requests with the same code, verbatim, coding definition, and context information. The disapproval propagates only to requests associated with studies that are marked as unlocked in the Central Coding application.

1 Select **Approvals**.

The Approvals page appears. For a description of the fields on this page, see Approvals page.

2 In the **Show** filter field, select **To Do**, and click **Apply**.

3 Select one or more requests.

4 Select **Actions > Disapprove**.

or

Click the **Disapprove** button.

A dialog box appears.

5 In the **Reason** field, specify a reason for disapproval.

6 Optionally, if you do not want the reason for disapproval to appear in a note attached to the coding request, deselect the **Add as notes checkbox**. For more information, see ***Adding a note to a coding request*** (on page 74).

The coding statuses of the requests change to **Recode** ( ). The disapproved requests are returned to the coder's queue, and the disapproval reason appears in a note attached to the coding request.

Disapproving a single request

1 Select **Approvals**.

The Approvals page appears. For a description of the fields on this page, see Approvals page.

2 In the **Show** filter field, select **To Do**, and click **Apply**.

3 Select one or more requests.

4 Select **Actions > Disapprove Single**.

or

Click the **Disapprove Single** button.

A dialog box appears.

5 In the **Reason** field, specify a reason for disapproval.

6 Optionally, if you do not want the reason for disapproval to appear in a note attached to the coding request, deselect the **Add as notes checkbox**. For more information, see ***Adding a note to a coding request*** (on page 74).

The coding statuses of the requests change to **Recode** ( ). The disapproved requests are returned to the coder's queue, and the disapproval reason appears in a note attached to the coding request.

Deleting delivered coding requests

About deleting requests after delivery

After a verbatim has been coded and returned to the source application, you can delete the coding request information from the Central Coding database. Optionally, you can also delete the audit information for these requests from the database tables. This functionality is useful especially for environments in which a source application other than the InForm or Clintrial application is used in conjunction with the Central Coding application, and the coding request and audit information is no longer useful after the verbatim is coded and delivered to the source application.

Deleting coding requests and audit information

1 On the System Configuration page, select the **Show Delete Request After Delivery Option** checkbox.

   This option is set at the system configuration level, and specifies that you want the **Delete request after delivery** checkbox to be available for each assignment rule. For more information, see *Configuring coding request deletion options* (on page 123).

2 Optionally, on the System Configuration page, to indicate that you want the Central Coding application to delete the audit trail information for all deleted delivered coding requests, select the **Delete Request Audit Information** checkbox.

   This option is set at the system configuration level, and specifies that if a request is deleted based on the **Delete request after delivery** setting, the corresponding audit records are also deleted.

3 On the [Assignment Rule Name] page, select the **Delete request after delivery** checkbox.

   This option is set at the assignment rule level, and specifies that you want to delete, for a specified assignment rule, all coding requests that have been coded in the Central Coding application and delivered to the source application.

CHAPTER 4

Reporting and exporting

In this chapter

Reports

The Central Coding application provides administrative reports for viewing and tracking purposes. For descriptions of the reports, see ***Report descriptions*** (on page 85). You request and produce all the reports using the reporting user interface. Because reports use read-only data, they can be accessed by multiple users at the same time.

Note: A user with the Reporter role typically performs these tasks.

Report descriptions

- **Coded Items Report**—Provides detailed information on the coded items that are associated with all studies or one study within a specified date range and/or based on the approval status of the requests.

  The report provides the verbatim, indication, dictionary, coder, study name, delivery status, route of administration, coding type, date coded, subject ID, level, term, code value, and total request count.

- **Coding Consistency Report—**Provides detailed information on the codings for a specified dictionary type, study, verbatim, and coding mode within a specified date range.

  The report provides the grand total request count, and for each verbatim provides the total request count, the requested dictionary level term(s), the code value(s), and the request count per code value.

- **Workteams, Roles, and Rights by User—**Provides a list of assigned work teams, roles, and rights for each active user in the system.

- **Verify Codes Report**—Provides details of the updates made to the codes for all coded requests after changing a dictionary using the Update and Verify Codes action rather than the impact analysis process.

  The report provides the verbatim; study name (host); subject ID; item type; previous and updated dictionary levels, codes, and terms; and count of the total number of updated requests.

  The Central Coding application automatically generates the data for the Verify Codes Report when it updates the codes for all coded requests against a new dictionary.

Viewing the list and status of report requests

- Select **Reports**.

  The Report Requests page appears. For a description of the fields on this page, see ***Report Requests page*** (on page 369).

  The report statuses are:

  - **Scheduled**—The report request is scheduled to be produced.
  - **Running**—The report request is in the process of generating the report result.
  - **Produced**—The report request ran successfully and the result is available.
  - **Failed**—The report request did not run successfully.

Producing a report

1. Select **Reports**.

   The Report Requests page appears.

2. Select **Actions > New**.

   or

   Click **New**.

   The Produce Report dialog box appears.

3. In the **Report Type** field, select the report that you want to run.

   If parameters are required, the page refreshes and the required fields appear.

   > **Note:** The Central Coding application automatically generates the data for the Verify Codes Report when it updates the codes for all coded requests against a new dictionary. Therefore, the report is not available in the **Report Type** field. For more information, see ***Generating the Verify Codes Report for viewing*** (on page 582) and ***Viewing the Verify Codes Report*** (on page 583).

4. Enter the report parameters.

   > **Note:** Because these reports contain a large amount of data, Oracle recommends that you run the reports for one study at a time (where applicable), and that you use short time periods.
   >
   > **Note:** There are no parameters for the **Workteams, Roles and Rights by User** report and the **Verify Codes Report**.

   - For the **Coded Items Report**, complete the information on the page using the descriptions in *Produce Report dialog box—Coded Items Report* (on page 385).
   - For the **Coding Consistency Report**, complete the information on the page using the descriptions in *Produce Report dialog box—Coding Consistency Report* (on page 387).

5. Click **Accept**.

   The Central Coding application generates the report.

Viewing the parameters for a report

1 Select **Reports**.

The Report Requests page appears.

2 Click the **Report Name** link.

The parameters page for the report appears.

3 View the report parameters.

> **Note:** There are no parameters for the **Workteams, Roles and Rights by User** report and the **Verify Codes Report**.

- For the **Coded Items Report**, see *View Report Request dialog box—Coded Items Report* (on page 386) for a description of the fields on the page.
- For the **Coding Consistency Report**, see *View Report Request—Coding Consistency Report* (on page 389) for a description of the fields on the page.

4 Click **OK**.

Viewing the results of a report

1 Select **Reports**.

The Report Requests page appears.

2 Select a report.

3 Do one of the following:

- Select **Actions > View Results**.
- Click **View Results**.
- Click the **Results Exist** ( ) icon.

The Document Viewer page appears. The report appears in PDF format.

> **Note:** If the **Results Exist** icon ( ) does not appear, click the **Refresh** button ( ).

Deleting a report request

1 Select **Reports**.

The Report Requests page appears.

2 Select a report.

3 Select **Actions** > **Remove**.

> **Note:** A confirmation dialog box does **not** appear.

About exporting data

You can use the reporting user interface to export reports to a comma-separated value (CSV) file for use by an external application, such as the Microsoft Excel spreadsheet software. The exports are not saved in the Central Coding application.

Note: A reporter typically performs these tasks.

Export descriptions

You can perform the following types of exports.

- *AutoCode Export* (on page 91).
- *Auto Suggestion List Export* (on page 92).
- *Coded Items Export* (on page 92).
- *Coder Metrics Export* (on page 93).
- *Coding Consistency Export* (on page 93).
- *Query Export* (on page 94).
- *Study Metrics Export* (on page 94).
- *Synonym List Export* (on page 95).
- *Uncoded Items Export* (on page 95).

AutoCode Export

The AutoCode export provides detailed information on the percentage of autocoded items for a study or all studies within a specified date range to a comma-separated value (CSV) file for use by an external application such as the Microsoft Excel spreadsheet software. The report can be filtered by date, coding definition, or study.

The export provides the following data:

- Study name.
- Coding definition.
- Number of verbatims.
- Percentage of autocoded items.

Auto Suggestion List Export

The Auto Suggestion List Export provides detailed information about the auto-suggestion list for a coding definition to a comma-separated value (CSV) file for use by an external application such as the Microsoft Excel spreadsheet software. The report can be filtered by coding definition.

The export provides the following data:

- Auto suggested verbatim text.
- Indication (WHO-DD only).
- Route of Administration (WHO-DD only).
- Target code.
- Target term.
- Secondary code.
- Secondary term.

Coded Items Export

The Coded Items Export provides detailed information on the coded items that are associated with all studies or one study within a specified date range and/or based on the approval status of the requests to be exported to a comma-separated value (CSV) file for use by an external application such as the Microsoft Excel spreadsheet software.

The export provides the following data:

- Verbatim.
- Dictionary.
- Coder.
- Date coded (in the format you specify on the System Configuration page).
- Term and code value for the appropriate dictionary level(s).
- Coding type (interactive or autocode).
- Match text.
- Algorithm Step.
- Date the coding request was received by the Central Coding application (in the format you specify on the System Configuration page).
- Study name.
- Associated form.
- Associated site.

- Delivery status.
- Route of administration.
- Indication.
- Workteam to which the request is assigned in the Central Coding application (one column per workteam).

Coder Metrics Export

The Coder Metrics Export provides detailed information about the coding work that each coder has done in the specified time frame, including the number of verbatims manually coded, approved, and in the Awaiting Approval state, as well as the number of queries opened and closed.

The export provides the following data:

- (Optional) Coding definition.
- **Coder Name**—User for whom information is presented.
- **Manually coded**—Number of terms that were manually coded during the time frame, including verbatims that were received before the time frame.
- **Manually Approved**—Number of coded terms that were manually approved during the time frame.
- **Waiting for Approval**—Number of terms that were coded by a coder during the time frame and were awaiting approval at the end of the time frame.
- **Queries Opened**—Number of queries opened by coders during the time frame.
- **Queries Closed**—Number of queries closed either automatically or by coders during the time frame.

Coding Consistency Export

The Coding Consistency Export provides detailed information on the codings for a specified dictionary type, study, verbatim, and coding mode within a specified date range to be exported to a comma-separated value (CSV) file for use by an external application such as the Microsoft Excel spreadsheet software.

The export provides the following data for each verbatim:

- Requested dictionary level term(s).
- Code value(s).
- Request count per code value.

The export also includes the option to export data for only those verbatims that are coded inconsistently.

Query Export

The Query Export provides detailed information on the queries opened in the Central Coding application for a study or query status. The query listing is exported to a comma-separated value (CSV) file for use by an external application such as the Microsoft Excel spreadsheet software.

The export provides the following data for each verbatim with an associated query:

- Verbatim text.
- Status of the query.
- Indication of whether the query was an autoquery.
- Date and time when the query was entered.
- User ID of the user who last acted on the query.
- Latest query text.
- Status of the verbatim.
- Study in which the verbatim exists.
- Site at which the verbatim exists.
- Subject with whom the verbatim is associated.
- Visit in which the verbatim exists.
- Form on which the verbatim was entered.
- Time and date when the verbatim was last modified in the Central Coding application.

Study Metrics Export

The Study Metrics Export provides detailed information about the coding work in a study during the specified time frame, including the number of verbatims received, autocoded, manually coded, approved, awaiting approval, and delivered, as well as the number of opened and closed queries.

The export provides the following data:

- **Study**—Study for which coding information is presented.
- (Optional) Coding definition.
- **Received**—Number of verbatims that were received during the time frame.
- **Autocoded**—Number of verbatims that were automatically coded in the study during the time frame, including verbatims that were received before the time frame.
- **Manually Coded**—Number of verbatims that were manually coded in the study during the time frame, including verbatims that were received before the time frame.
- **Manually Approved**—Number of verbatims that were manually approved in the study during the time frame.
- **Waiting for Approval**—Number of verbatims that were coded during the time frame and were awaiting approval at the end of the time frame.
- **Delivered**—Number of coded terms that were returned to the source application from the study

during the time frame.

- **Queries Opened**—Number of queries opened by coders in the study during the time frame.
- **Queries Closed**—Number of queries closed by coders in the study during the time frame.

Synonym List Export

The Synonym List Export provides detailed information about a synonym list to a comma-separated value (CSV) file for use by an external application such as the Microsoft Excel spreadsheet software. The report can be filtered by synonym list.

The export provides the following data:

- Synonym Text.
- Status of the synonym.
- Associated Code.
- Associated Term.
- Dictionary Level of the coded term.
- Whether the synonym text is inherited from a parent synonym list.

Uncoded Items Export

The Uncoded Items Export provides detailed information about the uncoded items for a study or all studies within a specified date range to a comma-separated value (CSV) file for use by an external application such as the Microsoft Excel spreadsheet software. The report can be filtered by study, date, or status.

The export provides the following data:

- Uncoded verbatim text.
- Associated dictionary.
- Date received.
- Study name.
- Subject ID.
- Associated form.
- Site.
- Query status.
- Indication (WHO-DD only).
- Route of administration (WHO-DD only).

Exporting report data to a CSV file

1. Select **Reports**.

   The Report Requests page appears.

2. Select **Actions** > **Export**.

   or

   Click **Export**.

   The Produce Report dialog box appears. The fields on this page vary depending on the type of export you select in the **Export Type** field.

3. In the **Export Type** field, select an export. For more information, see *Export descriptions* (on page 91).

4. Enter the export parameters:

   - *AutoCode Export* (on page 373).
   - *Auto Suggestion List Export* (on page 375).
   - *Coded Items Export* (on page 375).
   - *Coder Metrics Export* (on page 376).
   - *Coding Consistency Export* (on page 377).
   - *Query Export* (on page 379).
   - *Study Metrics Export* (on page 380).
   - *Synonym List Export* (on page 382).
   - *Uncoded Items Export* (on page 382).

5. Click **Accept**.

   The Document Viewer page appears, and then the Windows File Download dialog box appears.

6. To save the file, click **Save**.

   or

   To display the file in the Microsoft Excel spreadsheet software in a separate window, click **Open**.

   The Central Coding application exports the data in utf-8 format.

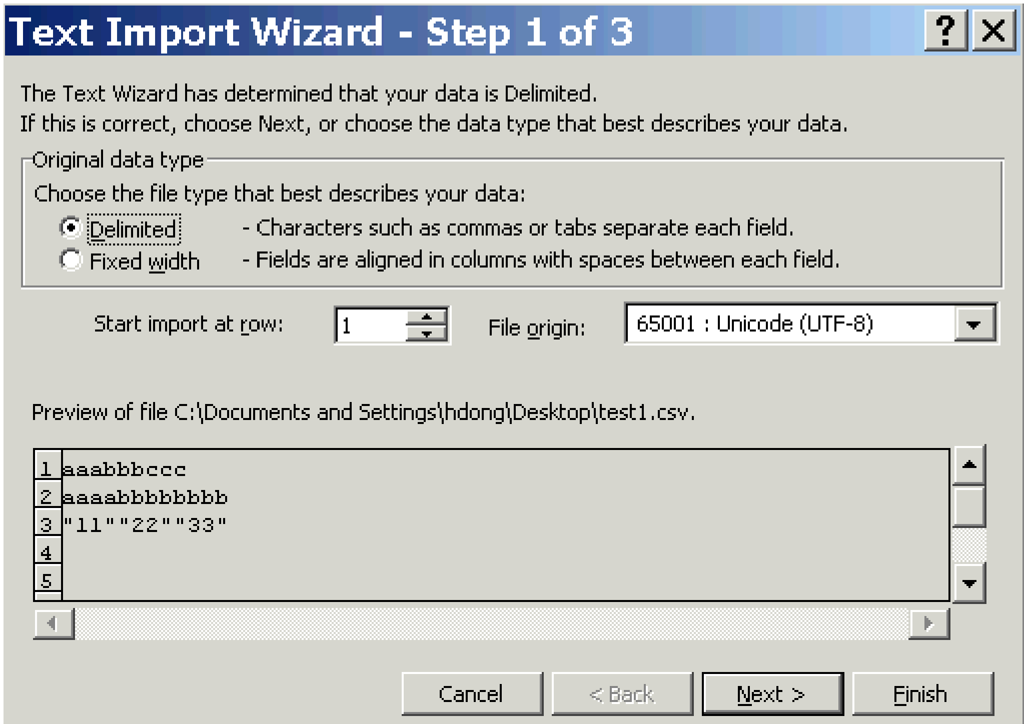
   - If you are using Excel 2007, the export data displays correctly in the spreadsheet.
   - If you are using Excel 2003, all the export data appears in one cell for each row.

     This occurs because this version of Excel uses **Comma** as the default delimiter instead of **Tab**. To change the delimiter to **Tab**, see *Changing the default delimiter* (on page 96).

Changing the default delimiter

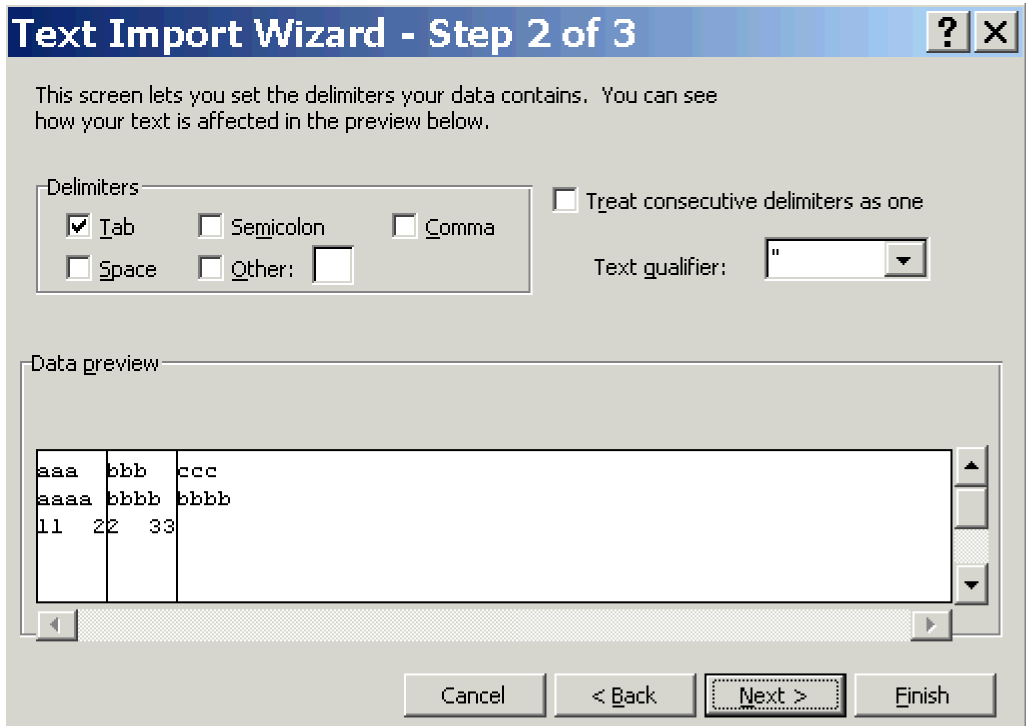
1 Open the Microsoft Excel spreadsheet software and then open the exported CSV file.

The Text Import Wizard - Step 1 of 3 dialog box appears.



2 Click **Next**.

The Text Import Wizard - Step 2 of 3 dialog box appears.



3 In the **Delimiters** group box, select **Tab**.

4 Click **Finish**.

PART 3: ADMINISTRATOR TASKS—Set up and configuration

CHAPTER 5

Users, roles, rights, and work teams

In this chapter

Users

User management

You can add users to the Central Coding application, activate, deactivate, and terminate them, and maintain their information profiles. You cannot delete users. You define access privileges for all users by assigning roles and work teams to the user profiles.

> **Note:** An administrator typically performs these tasks.

User data

User data is divided into two types: system data and profile data.

- **System data**—Includes the user identifier, password, mandatory authentication timeout period, and other information that is actively used by the system to enforce security.
- **Profile data**—Consists of all supplemental data about a user, such as name, title, and contact information.

Before a user can access the Central Coding application

Before a user can access the Central Coding application, the user must be:

- Added to the system.
- Assigned at least one role.
- Assigned at least one work team (coders and approvers only).

  Coders and approvers see only the coding requests that are assigned to the work teams to which they belong. Depending on their responsibilities, administrators may not need to belong to any work teams.
- Activated.

> **Note:** In some installations (including the default), adding and maintaining users, assigning roles, and activating users are handled by two different roles: the User Administrator and the User Manager. Make sure that these roles are assigned to appropriate users.

User account statuses

User account statuses		
User status icon	Hover text	Description
	Active	The user exists in the system and can access the application. New accounts must be activated before they can be used.
	Active Never Used	The user profile is active, but it has not been used.
	Inactive	The user exists in the system but cannot access the application. Inactive accounts can be activated.
	Inactive Never Used	The user profile exists, but it has not been activated or used.
	Terminated	The user can no longer access the application. Terminated accounts cannot be activated.

Viewing the list of users

- Select **Administration > Management > Users**.

  The Users page appears. For a description of the fields on this page, see ***Users page*** (on page 468).

Adding a user

Use this procedure to add a user to the system. New users are created with a unique identifier. The new user has a status of inactive with no access to functionality. This allows you to define the access privileges for the user before allowing the user access to the system.

1 Select **Administration > Management > Users**.

  The Users page appears.

2 Select **Actions > New**.

  or

  Click **New**.

  The New User page appears.

3 Complete the information on the page using the descriptions in ***New User/User Details page*** (on page 470).

4 Select **Actions > Save**.

Viewing or editing the details for a user

1. Select **Administration > Management > Users**.

   The Users page appears.

2. Select a user.

3. Select **Actions > View Details**.

   or

   Click **View Details**.

   or

   Click the **Name** link.

   The User Details page appears.

4. View or edit the information on the page using the descriptions in ***New User/User Details page*** (on page 470).

5. Select **Actions > Save**.

   or

   Click **Save**.

Assigning roles to a user

1. Select **Administration > Management > Users**.

   The Users page appears.

2. Select a user.

3. Select **Actions > View Details**.

   or

   Click **View Details**.

   or

   Click the **Name** link.

   The User Details page appears.

4. Select **Actions > Assign Roles**.

   or

   Click the **Assign Roles** button.

   The Assign Roles to User: [User Name] dialog box appears.

5. Complete the information in the dialog box using the descriptions in ***Assign Roles to User: [User Name] dialog box*** (on page 473).

6. Click **Save**.

Modifying role assignments for a user

1 Select **Administration > Management > Users**.

The Users page appears.

2 Select a user.

3 Select **Actions > View Details**.

or

Click **View Details**.

or

Click the **Name** link.

The User Details page appears.

4 Select **Actions > Assign Roles**.

or

Click the **Assign Roles** button.

The Assign Roles to User: [User Name] dialog box appears.

5 Edit the information in the dialog box using the descriptions in ***Assign Roles to User: [User Name] dialog box*** (on page 473).

6 Click **Save**.

Assigning work teams to a user

1 Select **Administration > Management > Users**.

The Users page appears.

2 Select a user.

3 Select **Actions > View Details**.

or

Click **View Details**.

or

Click the **Name** link.

The User Details page appears.

4 Select **Actions > Assign Work Teams**.

or

Click the **Assign Work Teams** button.

The Assign Work Team to User: [User Name] dialog box appears.

5 Complete the information in the dialog box using the descriptions in ***Assign Work Team to User: [User Name] dialog box*** (on page 474).

6 Click **Save**.

Modifying work team assignments for a user

1. Select **Administration > Management > Users**.

   The Users page appears.

2. Select a user.

3. Select **Actions > View Details**.

   or

   Click **View Details**.

   or

   Click the **Name** link.

   The User Details page appears.

4. Select **Actions > Assign Work Teams**.

   or

   Click the **Assign Work Teams** button.

   The Assign Work Team to User: [User Name] dialog box appears.

5. Edit the information in the dialog box using the descriptions in ***Assign Work Team to User: [User Name] dialog box*** (on page 474).

6. Click **Save**.

Changing a user password

1. Select **Administration > Management > Users**.

   The Users page appears.

2. Select a user.

3. Select **Actions > View Details**.

   or

   Click **View Details**.

   or

   Click the **Name** link.

   The User Details page appears.

4. In the **Password** field, type the new password for the user.

   > **Note:** Passwords can be from 1 to 32 characters. For security reasons, Oracle recommends using a combination of letters and numbers and a minimum of 6 characters. Passwords are case-sensitive.

5. In the **Verify password** field, retype the password.

6. Check the **User must change password** checkbox if you want the user to change this new password the next time he or she logs on to the application.

7 Select **Actions > Save**.

or

Click **Save**.

Activating a user

Use this procedure to activate a user account. Active users exist in the system and can access the application. New accounts must be activated before they can be used.

1 Select **Administration > Management > Users**.

The Users page appears.

2 Select a user.

3 Select **Actions > Activate**.

The status changes to **Active** ( ).

Deactivating a user

Use this procedure to deactivate a user account. Inactive users exist in the system but cannot access the application. Inactive accounts can be activated.

1 Select **Administration > Management > Users**.

The Users page appears.

2 Select a user.

3 Select **Actions > Deactivate**.

The status changes to **Inactive** ( ).

> **Note:** The Central Coding application does not allow you to deactivate the last remaining SuperUser account.

Terminating a user

Use this procedure to terminate a user account. Terminated users can no longer access the application. Terminated accounts cannot be activated.

> **Note:** You cannot *delete* users from the system.

1 Select **Administration > Management > Users**.

The Users page appears.

2 Select a user.

3 Select **Actions > Terminate**.

The status changes to **Terminated** ( ).

Roles and rights

Role and right management

You can add roles to the Central Coding application, specify the rights that are assigned to each role, maintain role information, and delete roles. You can choose to use or modify the default roles, or you can create new roles.

The rights for a given role can be selected or deselected at any time. If a role being modified is assigned to users, those users are affected immediately after the changes to the role are saved. For a complete list of the default roles and their associated rights, see ***Default roles and rights*** (on page 541).

> **Note:** An administrator typically performs these tasks.

Viewing the list of available roles

- Select **Administration > Management > Roles**.

  The Roles page appears. For a description of the fields on this page, see ***Roles page*** (on page 475).

Adding a role and assigning its rights

1 Select **Administration > Management > Roles**.

The Roles page appears.

2 Select **Actions > New**.

or

Click **New**.

The New Role page appears.

3 Complete the information on the page using the descriptions in ***New Role/Role Details page*** (on page 476).

4 Select **Actions > Save**.

or

Click **Save**.

5 Select **Actions > Assign Rights**.

or

Click **Assign Rights**.

The Assign Rights to Roles: [Role Name] dialog box appears. For a complete list of the default roles and their rights, see ***Default roles and rights*** (on page 541).

6 Complete the information in the dialog box using the descriptions in ***Assign Rights to Role: [Role Name] dialog box*** (on page 477).

7 Click **Save**.

Viewing or editing the details of a role

Use this procedure to view or modify the information for a role. The rights for a given role can be selected or deselected at any time. If a role being modified is assigned to users, those users are affected immediately after the changes to the role are saved.

> **Note:** The **Basic Application User** and **Coding Interface Full Access** roles are system roles that you cannot modify or delete.

1 Select **Administration > Management > Roles**.

The Roles page appears.

2 Select a role.

3 Select **Actions > View Details**.

or

Click **View Details**.

The Role Details page appears.

4 View or edit the information on the page using the descriptions in ***New Role/Role Details page*** (on page 476).

5 Select **Actions > Save**.

or

Click **Save**.

Assigning rights to an existing role

> **Note:** The **Basic Application User** and **Coding Interface Full Access** roles are system roles that you cannot modify or delete.

1 Select **Administration > Management > Roles**.

The Roles page appears.

2 Select a role.

3 Select **Actions > View Details**.

or

Click **View Details**.

The Role Details page appears.

4 Select **Actions > Assign Rights**.

or

Click **Assign Rights**.

The Assign Rights to Roles: [Role Name] dialog box appears.

5 Complete the information in the dialog box using the descriptions in ***Assign Rights to Role:***

[Role Name] dialog box (on page 477).

6 Click **Save**.

Modifying the rights that are assigned to a role

Use this procedure to modify the rights that are associated with a role. The rights for a given role can be selected or deselected at any time. If a role being modified is assigned to users, those users are affected immediately after the changes to the role are saved.

For a description of the available rights in the Central Coding application, see ***Default rights*** (on page 546).

> **Note:** The **Basic Application User** and **Coding Interface Full Access** roles are system roles that you cannot modify or delete.

1 Select **Administration > Management > Roles**.

The Roles page appears.

2 Select a role.

3 Select **Actions > View Details**.

or

Click **View Details**.

The Role Details page appears.

4 Select **Actions > Assign Rights**.

or

Click **Assign Rights**.

The Assign Rights to Roles: [Role Name] dialog box appears.

5 Edit the information in the dialog box using the descriptions in ***Assign Rights to Role: [Role Name] dialog box*** (on page 477).

6 Click **Save**.

Deleting a role

> **Note:** If you delete a role that is assigned to a user, the role assignment is also deleted. The **Basic Application User** and **Coding Interface Full Access** roles are system roles that you cannot modify or delete.

1 Select **Administration > Management > Roles**.

The Roles page appears.

2 Select a role.

3 Select **Actions > Delete**.

A confirmation dialog box appears.

4 Click **OK**.

Work teams

Work team management

You can add work teams to the Central Coding application, assign users to the work teams, modify work team information, and delete work teams. There are no default work teams.

> **Note:** An administrator typically performs these tasks.

Viewing the list of work teams

- Select **Administration > Management > Work Teams**.

  The Work Teams page appears. For a description of the fields on this page, see ***Work Teams page*** (on page 478).

Adding a work team and assigning its users

1 Select **Administration > Management > Work Teams**.

The Work Teams page appears.

2 Select **Actions > New**.

or

Click **New**.

The New Work Team page appears.

3 Complete the information on the page using the descriptions in ***New Work Team/Work Team Details page*** (on page 479).

4 Select **Actions > Save**.

or

Click **Save**.

5 Select **Actions > Assign Users**.

or

Click **Assign Users**.

The Assign Users to Work Team: [Work Team Name] dialog box appears.

6 Complete the information on the page using the descriptions in ***Assign Users to Work Team: [Work Team Name] dialog box*** (on page 480).

7 Click **Save**.

Viewing or editing the details for a work team

1. Select **Administration > Management > Work Teams**.

   The Work Teams page appears.

2. Select a work team.
3. Select **Actions > View Details**.

   or

   Click **View Details**.

   The Work Team Details page appears.

4. View or edit the information on the page using the descriptions in ***New Work Team/Work Team Details page*** (on page 479).
5. Select **Actions > Save**.

   or

   Click **Save**.

Assigning a user to an existing work team

1. Select **Administration > Management > Work Teams**.

   The Work Teams page appears.

2. Select a work team.
3. Select **Actions > View Details**.

   or

   Click **View Details**.

   The Work Team Details page appears.

4. Select **Actions > Assign Users**.

   or

   Click **Assign Users**.

   The Assign Users to Work Team: [Work Team Name] dialog box appears.

5. Complete the information in the dialog box using the descriptions in ***Assign Users to Work Team: [Work Team Name] dialog box*** (on page 480).
6. Click **Save**.

Modifying work team assignments

1 Select **Administration > Management > Work Teams**.

The Work Teams page appears.

2 Select a work team.

3 Select **Actions > View Details**.

or

Click **View Details**.

The Work Team Details page appears.

4 Select **Actions > Assign Users**.

or

Click **Assign Users**.

The Assign Users to Work Team: [Work Team Name] dialog box appears.

5 Edit the information in the dialog box using the descriptions in ***Assign Users to Work Team: [Work Team Name] dialog box*** (on page 480).

6 Click **Save**.

Deleting a work team

> **Note:** You cannot delete a work team that has assigned requests.

1 Select **Administration > Management > Work Teams**.

The Work Teams page appears.

2 Select a work team.

3 Select **Actions > Delete**.

A confirmation dialog box appears.

4 Click **OK**.

CHAPTER 6
System configuration options

In this chapter

System configuration options

You can view and set the system settings, which include security related options, impact analysis features, and product version and copyright information.

Note: An administrator typically performs these tasks.

Viewing the system configuration and authentication parameters

- Select **Administration > System > System Configuration**.

  The System Configuration page appears. For a description of the fields on this page, see *System Configuration page—View mode* (on page 520).

Setting the system configuration and authentication parameters

1 Select **Administration > System > System Configuration**.

The System Configuration page appears.

2 Select **Actions > Edit**.

or

Click **Edit**.

3 Complete the information on the page using the descriptions in ***System Configuration page—Edit mode*** (on page 529).

> **Note:** For information on configuring the options for impact analysis, see Configuring your system for impact analysis. For information on configuring the system for queries, see ***Setting system configuration options for queries*** (on page 231).

Displaying context items in the user interface

Use this procedure to display the context items (Indication and Route of Administration) associated with a verbatim in the Verbatim column on the Coding Request and Approvals pages.

> **Note:** Only verbatims coded against the WHO-DD or JDrug dictionary have context items.

1 Select **Administration > System > System Configuration**.

The System Configuration page appears.

2 Select **Actions > Edit**.

or

Click **Edit**.

3 Select **Display Context Items on Coding Requests and Approvals pages**.

> **Note:** By default, this option is **not** selected.

4 Select **Actions > Save**.

or

Click **Save**.

Setting the column width for Japanese characters

By design, the user interface forces long text and characters to wrap to multiple lines to fit into fixed column widths. Use this procedure to increase the width of some columns on the list view pages to prevent a forced break between Japanese characters.

> **Note: This setting affects the list views only when you are using a Japanese operating system or an English operating system with a Global locale (the system accepts both English and Japanese verbatims).**

1 Select **Administration > System > System Configuration**.

The System Configuration page appears.

2 Select **Actions > Edit**.

or

Click **Edit**.

3 In the **Request List View Column Length** field, enter the column width to use on the list view pages.

The default is 100 px. This setting increases the width of the columns that appear to the right of the Code column on the Coding Requests, Approvals, and All Requests pages when viewing the requests for a particular coding definition. That is, when you are using the View filter.

4 Select **Actions > Save**.

or

Click **Save**.

Displaying only current terms in the coding browser

By default, the coding browser is configured to show all terms and codes for a selected dictionary. However, you can configure the coding browser to show current terms only.

1. Select **Administration > System > System Configuration**.

   The System Configuration page appears.

2. Select **Actions > Edit**.

   or

   Click **Edit**.

3. Deselect the **Show Non Current Terms in Browser Search** checkbox.

   By default, this checkbox is selected.

4. Select **Actions > Save**.

   or

   Click **Save**.

Configuring study deletion settings

It is a good practice to limit the studies for which the **Delete Study and All Data** functionality can be used. Use the **Delete Study Mask** field to specify the type of studies that can be completely deleted from the database. For example, you could allow only a UAT study to be completely deleted, while preventing the study itself from being deleted.

> **Note:** Use the **Delete Study and All Data** action to delete all information associated with UAT studies. Use the **Decommission a Study** action to archive as well as delete all information associated with completed production studies.

1 Select **Administration > System > System Configuration**.

The System Configuration page appears.

2 Select **Actions > Edit**.

or

Click **Edit**.

3 In the **Delete Study Mask** field, specify the set of characters that appears in the name of the studies that can be completely deleted. The default is **UAT**. This setting limits the type of study that you can delete using the **Delete Study and All Data** option on the Study Information page.

4 For example, to allow the deletion of all UAT studies and their associated data, type UAT in the Delete Study Mask field and make sure that all UAT studies include UAT in their names. For more information about this configuration option, see *Application settings and lock management options* (on page 529).

5 Select **Actions > Save**.

or

Click **Save**.

Configuring coding request deletion settings

Use this procedure to make the **Delete request after delivery** option available for use on the [Assignment Rule Name] page. The **Delete request after delivery** option allows you to delete, for a specified assignment rule, all coding requests that have been coded in the Central Coding application and delivered to the source application.

1 Select **Administration > System > System Configuration**.

The System Configuration page appears.

2 Select **Actions > Edit**.

or

Click **Edit**.

3 Select the **Show Delete Request After Delivery Option** checkbox.

For more information about this configuration option, see *Application settings and lock management options* (on page 529).

For more information about deleting delivered coding requests, see *Deleting coding requests and audit information* (on page 81).

4 Optionally, to indicate that you want the Central Coding application to delete the audit trail information for all deleted delivered coding requests, select the **Delete Request Audit Information** checkbox.

For more information about this configuration option, see *Application settings and lock management options* (on page 529).

5 Select **Actions > Save**.

or

Click **Save**.

Configuring system configuration settings for jobs

1 Select **Administration > System > System Configuration**.

The System Configuration page appears.

2 Select **Actions > Edit**.

or

Click **Edit**.

3 In the **Get/Put Job Options** section, specify the following:

- **GetRequests Job Chunk Size**—Number of requests to retrieve from the source application in each web service call to the InForm Adapter application. The chunks run sequentially, and each job continues to process until all requests have been retrieved from the source application.
- **ReturnCodes Job Chunk Size**—Number of requests to return to the source application in each web service call to the InForm Adapter application. The chunks run sequentially, and each job continues to process until all requests have been delivered to the source application.
- **Web Service Client Timeout**—The amount of time (in milliseconds) to wait for the web service response before the web service client times out.

Setting the flag definitions

1 Select **Administration > System > Coding Flags**.

The Coding Flags page appears.

2 Click **Edit**.

3 In the **Definition** column, designate a meaning for each flag.

The following definitions are set by default. You can change these definitions at any time.

- **Red flag**—(I)nForm Query
- **Green flag**—(C)oding Query

4 In the **Action** column, select **Enable** or **Disable** to specify whether you want the flags available for use by Central Coding users.

Viewing system information

- Select **Administration > System > System Information**.

  The System Information page appears. For a description of the fields on this page, see ***System Information*** (on page 538).

CHAPTER 7

Synonym lists and synonyms

In this chapter

Synonym list and synonym management

You can create, inherit, copy, modify, activate, deactivate, and delete synonym lists. After creating a synonym list, you can add synonyms to it and then manage the synonyms by activating, deactivating, promoting, masking, and unmasking them. You can also accept or reject the synonyms that have been proposed by a coder or approver.

Note: A dictionary manager or administrator typically performs these tasks.

Setting the system configuration and authentication parameters

1 Select **Administration > System > System Configuration**.

The System Configuration page appears.

2 Select **Actions > Edit**.

or

Click **Edit**.

3 Complete the information on the page using the descriptions in *System Configuration page—Edit mode* (on page 529).

> **Note:** For information on configuring the options for impact analysis, see Configuring your system for impact analysis. For information on configuring the system for queries, see ***Setting system configuration options for queries*** (on page 231).

Synonym list statuses

Synonym list statuses	
Status	**Description**
Active	A synonym list that is available for use by a coding definition. **Note:** A coding algorithm can only use an Active synonym list. An Active synonym list can contain individual synonyms that are Inactive.
Inactive	A synonym list that is not available for use by a coding definition. **Note:** If a coding definition specifies an Inactive synonym list, the synonym list is not used.

Viewing the list of synonym lists

- Select **Coding Setup > Synonym Lists**.

  The Synonym Lists page appears. For a description of the fields on this page, see ***Synonym Lists page*** (on page 409).

Creating a new synonym list and adding synonyms to it

1. Select **Coding Setup > Synonym Lists**.

   The Synonym Lists page appears.

2. Select **Actions > New**.

   or

   Click **New**.

   The New Synonym List page appears. For a description of the fields on this page, see *New Synonym List page* (on page 411).

3. In the **Name** field, type a name for the synonym list.

4. In the **Dictionary** field, select the dictionary and version to which you want to associate the synonym list.

5. Choose whether to create the new synonym list from scratch or by inheriting it from an existing synonym list.

   - To create the new synonym list from scratch, leave the **Parent** field blank.
   - To inherit an existing synonym list, select the synonym list that you want to inherit from the **Parent** field.

   > **Note: When you create a synonym list by inheriting the contents of another list, it always appears to contain the synonyms from both lists. However, the parent synonym list contains only its own synonyms; it does not include the synonyms from the child (inherited) list.**

6. Select **Actions > Save**.

   or

   Click **Save**.

   The page refreshes, the page name changes, and additional options appear. For a description of the fields on this page, see *[Synonym List Name]—Manage synonyms page* (on page 420).

7. Select **Actions > New**.

   or

   Click **New**.

   The New Synonym page appears. For a description of the fields on this page, see *New Synonym page* (on page 423).

8. In the **Synonym** field, type the synonym that you want to add to the synonym list.

9. Click **Code**.

   The Coding Browser dialog box appears. By default, the coding browser opens in Search mode. The dictionary elements that appear are configured for the coding definition in use.

10 Code the synonym.

For more information, see *Coding a single item—Search method* (on page 59) or *Coding a single item—Browse method* (on page 60).

After you close the coding browser, the new synonym, term, and code appear on the New Synonym page.

11 Select **Actions > Save**.

or

Click **Save**.

Copying a synonym list

Use this procedure to create a new synonym list that is a copy of an existing synonym list. A copied synonym list is based on a snapshot of the existing list that you copy at the time you create the new list. Changes you make to the new list are not made to the original copied list.

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select a synonym list.

3 Select **Actions > Copy**.

The New Synonym List—Copied page appears. For a description of the fields on this page, see ***New Synonym List page—Copied*** (on page 412).

4 In the **Name** field, type a name for the synonym list.

> **Note: The Dictionary and Parent fields are read only. The Parent field appears only if the list being copied is an inherited list.**

If the synonym list you want to copy has children and you also want to copy the children synonym lists, check **Include children** at the bottom of the page. The resulting synonym list replicates both the structure and the data of the parent synonym list along with a copy of each child synonym list.

5 Select **Actions > Save**.

or

Click **Save**.

Changing the name of a synonym list

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select a synonym list.

3 Select **Actions > Edit**.

or

Click **Edit**.

The [Synonym List Name] page appears. For a description of the fields on this page, see ***[Synonym List Name] page*** (on page 413).

4 In the **Name** field, edit the text as necessary.

5 Select **Actions > Save**.

or

Click **Save**.

Activating a synonym list

1. Select **Coding Setup > Synonym Lists**.

   The Synonym Lists page appears.

2. Select one or more synonym lists.

3. Select **Actions > Activate**.

   The Reason for Change dialog box appears.

4. In the **Reason** field, type a description for the change.

5. Click **Accept**.

   The status changes to **Active**. The synonym list is available for use by a coding definition.

Deactivating a synonym list

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select one or more synonym lists.

3 Select **Actions > Deactivate**.

The Reason for Change dialog box appears.

4 In the **Reason** field, type a description for the change.

5 Click **Accept**.

The status changes to **Inactive**. The synonym list is not available for use by a coding definition.

Deleting a synonym list

> **Note:** You can only delete a synonym list that is empty (does not contain any synonyms) and is not used in a coding definition.

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select one or more synonym lists.

3 Select **Actions > Delete**.

A confirmation dialog box appears.

4 Click **OK**.

The Reason for Change dialog box appears.

5 In the **Reason** field, type a description for the change.

6 Click **Accept**.

Managing synonyms

Synonym statuses

Synonym statuses	
Status	**Description**
Active	A synonym that was suggested by a coder and approved by a dictionary manager or administrator, or was created by a dictionary manager or administrator in a single step. The synonym is available for use by a synonym list.
Inactive	A synonym that is not available for use in a synonym list. **Note:** An Active synonym list can contain Inactive synonyms.
Promoted	A synonym from an inherited (child) synonym list that was added to its parent synonym list.
Proposed	A synonym suggested by a coder that has not been approved or rejected.
Rejected	A synonym that was proposed by a coder and not approved by a dictionary manager or administrator. The application removes the synonym from the list of synonyms.

Viewing the synonyms in a synonym list

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select a synonym list.

3 Select **Actions > Manage**.

or

Click the **Name** link.

The [Synonym List Name] page appears. For a description of the fields on this page, see ***[Synonym List Name] page*** (on page 420).

Adding a synonym to an existing synonym list

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select a synonym list.

3 Select **Actions > Manage**.

or

Click the **Name** link.

The [Synonym List Name] page appears.

4 Select **Actions > New**.

or

Click **New**.

The New Synonym page appears. For a description of the fields on this page, see ***New Synonym page*** (on page 423).

5 In the **Synonym** field, type the synonym that you want to add to the synonym list.

6 Click **Code**.

The Coding Browser dialog box appears. By default, the coding browser opens in Search mode. The dictionary elements that appear are configured for the coding definition in use.

7 Code the synonym.

You must code a new synonym before you can save it. For more information, see ***Coding a single item—Search method*** (on page 59) or ***Coding a single item—Browse method*** (on page 60).

After you close the coding browser, the new synonym, term, and code appear on the New Synonym page.

8 Select **Actions > Save**.

or

Click **Save**.

The [Synonym List Name] page appears. The synonym is added to the list with a status of Active.

Accepting a proposed synonym

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select a synonym list.

3 Select **Actions > Manage**.

or

Click the **Name** link.

The [Synonym List Name] page appears.

4 Select one or more synonyms.

5 Select **Actions > Accept**.

or

Click the **Accept** button.

The application accepts the proposed synonym, activates it, and adds it to the synonym list.

Rejecting a proposed synonym

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select a synonym list.

3 Select **Actions > Manage**.

or

Click the **Name** link.

The [Synonym List Name] page appears.

4 Select one or more synonyms.

5 Select **Actions > Reject**.

or

Click the **Reject** button.

The Reason for Change dialog box appears.

6 In the **Reason** field, type a description for the change.

7 Click **Accept**.

The application removes the synonym from the list of synonyms.

Activating a synonym

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select a synonym list.

3 Select **Actions > Manage**.

or

Click the **Name** link.

The [Synonym List Name] page appears.

4 Select one or more synonyms.

5 Select **Actions > Activate**.

The Reason for Change dialog box appears.

6 In the **Reason** field, type a description for the change.

7 Click **Accept**.

The status changes to **Active**.

Deactivating a synonym

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select a synonym list.

3 Select **Actions > Manage**.

or

Click the **Name** link.

The [Synonym List Name] page appears.

4 Select one or more synonyms.

5 Select **Actions > Deactivate**.

The Reason for Change dialog box appears.

6 In the **Reason** field, type a description for the change.

7 Click **Accept**.

The status changes to **Inactive**.

Promoting a synonym

You can add synonyms to an inherited synonym list. You can also make these synonyms actual synonyms in the synonym list they were inherited from. This process is known as promoting a synonym.

> **Note:** This option is available only for inherited synonym lists.

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select a synonym list.

3 Select **Actions > Manage**.

or

Click the **Name** link.

The [Synonym List Name] page appears.

4 Select one or more synonyms.

> **Note:** The status of the synonym(s) must be **Active.**

5 Select **Actions > Promote**.

The Reason for Change dialog box appears.

6 In the **Reason** field, type a description for the change.

7 Click **Accept**.

Masking a synonym

You cannot change the status of an inherited synonym. The synonym always has the status that it has in the synonym list that it is inherited from. If you do not want to use a synonym from its parent list, you can "mask" it. A masked inherited synonym is treated by an autocoding algorithm as an inactive synonym.

> **Note:** This option is available only for inherited synonym lists.

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select a synonym list.

3 Select **Actions > Manage**.

or

Click the **Name** link.

The [Synonym List Name] page appears.

4 Select one or more synonyms.

5 Select **Actions > Mask**.

The Reason for Change dialog box appears.

6 In the **Reason** field, type a description for the change.

7 Click **Accept**.

Unmasking a synonym

Use this procedure to show a previously masked synonym to its parent synonym list.

> **Note:** This option is available only for inherited synonym lists.

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select a synonym list.

3 Select **Actions > Manage**.

or

Click the **Name** link.

The [Synonym List Name] page appears.

4 Select one or more synonyms.

5 Select **Actions > Unmask**.

The Reason for Change dialog box appears.

6 In the **Reason** field, type a description for the change.

7 Click **Accept**.

Viewing the details for a synonym

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select a synonym list.

3 Select **Actions > Manage**.

or

Click the **Name** link.

The [Synonym List Name] page appears.

4 Select a synonym.

5 Click **Edit**.

The [Synonym Name] page appears. For a description of the fields on this page, see ***[Synonym Name] page*** (on page 424).

Viewing the full coding details for a synonym

Use this procedure to view the full coding details for a coded item. The details include the dictionary name and version, the coded term and value, and the level of the dictionary hierarchy where the match was found.

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select a synonym list.

3 Select **Actions > Manage**.

or

Click the **Name** link.

The [Synonym List Name] page appears.

4 Click the **Code** link.

The View Full Coding dialog box appears. For a description of the fields on this page, see ***View Full Coding dialog box*** (on page 335).

CHAPTER 8
Stopword lists and stopwords

In this chapter

Stopword list and stopword management

You can create, inherit, copy, modify, activate, deactivate, and delete stopword lists. After creating a stopword list, you can add stopwords to it and manage the stopwords by activating, deactivating, promoting, masking, and unmasking them. You can also accept or reject the stopwords that have been proposed by a coder or approver.

Note: A dictionary manager or administrator typically performs these tasks.

Stopword list statuses

Stopword list statuses	
Status	**Description**
Active	A stopword list that is available for use by a coding definition. **Note:** A coding algorithm can only use an Active stopword list. An Active stopword list can contain individual stopwords that are Inactive.
Inactive	A stopword list that is not available for use by a coding definition. **Note:** If a coding definition specifies an Inactive stopword list, the stopword list is not used.

Viewing the list of stopword lists

- Select **Coding Setup > Stopword Lists**.

  The Stopword Lists page appears. For a description of the fields on this page, see ***Stopword Lists page*** (on page 426).

Creating a new stopword list and adding stopwords to it

1. Select **Coding Setup > Stopword Lists**.

   The Stopword Lists page appears.

2. Select **Actions > New**.

   or

   Click **New**.

   The [New Stopword] page appears. For a description of the fields on this page, see *New Stopword List page* (on page 427).

3. In the **Name** field, type a name for the stopword list.

4. Choose whether to create the new stopword list from scratch or by inheriting it from an existing stopword list.

   - To create the new stopword list from scratch, leave the **Parent** field blank.
   - To inherit an existing stopword list, select the stopword list that you want to inherit from the **Parent** field.

   > **Note:** When you create a stopword list by inheriting the contents of another list, the new list always appears to contain the stopwords from both lists. However, the parent stopword list contains only its stopwords, not the stopwords from the child (inherited) list.

5. Select **Actions > Save**.

   or

   Click **Save**.

   The page refreshes, the page name changes, and additional options appear. For a description of the fields on this page, see *[Stopword List Name] page* (on page 430).

6. Select **Actions > New**.

   or

   Click **New**.

   The New Stopword page appears.

7. In the **Stopword** field, type the stopword that you want to add to the new stopword list.

8. Select **Actions > Save**.

   or

   Click **Save**.

Copying a stopword list

Use this procedure to create a new stopword list that is a copy of an existing stopword list. A copied stopword list is based on a snapshot of the existing list that you copy at the time you create the new list. Changes you make to the new list are not made to the original copied list.

1 Select **Coding Setup > Stopword Lists**.

   The Stopword Lists page appears.

2 Select a stopword list.

3 Select **Actions > Copy**.

   The New Stopword List—Copied page appears. For a description of the fields on this page, see ***New Stopword List Name page—Copied*** (on page 428).

4 In the **Name** field, type a name for the stopword list.

   > **Note: The Parent field is read only. The Parent field appears only if the list being copied is an inherited list.**

5 Select **Actions > Save**.

   or

   Click **Save**.

Changing the name of a stopword list

1. Select **Coding Setup > Stopword Lists**.

   The Stopword Lists page appears.

2. Select a stopword list.
3. Select **Actions > Edit**.

   or

   Click **Edit**.

   The [Stopword List Name] page appears.

4. In the **Name** field, edit the text as necessary.
5. Select **Actions > Save**.

   or

   Click **Save**.

Activating a stopword list

1 Select **Coding Setup > Stopword Lists**.

The Stopword Lists page appears.

2 Select one or more stopword lists.

3 Select **Actions > Activate**.

The Reason for Change dialog box appears.

4 In the **Reason** field, type a description for the change.

5 Click **Accept**.

The status changes to **Active**. The stopword list is available for use by a coding definition.

Deactivating a stopword list

1. Select **Coding Setup > Stopword Lists**.

   The Stopword Lists page appears.
2. Select one or more stopword lists.
3. Select **Actions > Deactivate**.

   The Reason for Change dialog box appears.
4. In the **Reason** field, type a description for the change.
5. Click **Accept**.

   The status changes to **Inactive**. The stopword list is not available for use by a coding definition.

Deleting a stopword list

> **Note:** You can only delete a stopword list that is empty (does not contain any stopwords) and is not used in a coding definition.

1 Select **Coding Setup > Stopword Lists**.

The Stopword Lists page appears.

2 Select one or more stopword lists.

3 Select **Actions > Delete**.

A confirmation dialog box appears.

4 Click **OK**.

The Reason for Change dialog box appears.

5 In the **Reason** field, type a description for the change.

6 Click **Accept**.

Managing stopwords

Stopword statuses

Stopword statuses	
Status	**Description**
Active	A stopword was created by a dictionary manager or administrator in a single step. The stopword is available for use by a stopword list.
Inactive	A stopword that is not available for use in a stopword list. **Note:** An Active stopword list can contain Inactive stopwords.
Promoted	A stopword from an inherited (child) stopword list that was added to its parent stopword list.

Viewing the stopwords in a stopword list

1 Select **Coding Setup > Stopword Lists**.

The Stopword Lists page appears.

2 Select a stopword list.

3 Select **Actions** > **Manage**.

or

Click the **Name** link.

The [Stopword List Name] page appears. For a description of the fields on this page, see *[Stopword List Name] page* (on page 430).

Adding a stopword to an existing stopword list

1 Select **Coding Setup > Stopword Lists**.

The Stopword Lists page appears.

2 Select a stopword list.

3 Select **Actions** > **Manage**.

or

Click the **Name** link.

The [Stopword List Name] page appears.

4 Select **Actions > New**.

or

Click **New**.

The New Stopword page appears. For a description of the fields on this page, see ***New Stopword page*** (on page 432).

5 In the **Stopword** field, type the stopword that you want to add to the stopword list.

6 Select **Actions > Save**.

or

Click **Save**.

The [Stopword List Name] page appears. The stopword is added to the list with a status of **Active**.

Activating a stopword

1 Select **Coding Setup > Stopword Lists**.

The Stopword Lists page appears.

2 Select a stopword list.

3 Select **Actions** > **Manage**.

or

Click the **Name** link.

The [Stopword List Name] page appears.

4 Select one or more stopwords.

5 Select **Actions > Activate**.

The Reason for Change dialog box appears.

6 In the **Reason** field, type a description for the change.

7 Click **Accept**.

The status changes to **Active**.

Deactivating a stopword

1 Select **Coding Setup > Stopword Lists**.

The Stopword Lists page appears.

2 Select a stopword list.

3 Select **Actions** > **Manage**.

or

Click the **Name** link.

The [Stopword List Name] page appears.

4 Select one or more stopwords.

5 Select **Actions > Deactivate**.

The Reason for Change dialog box appears.

6 In the **Reason** field, type a description for the change.

7 Click **Accept**.

The status changes to **Inactive**.

Promoting a stopword

You can add stopwords to an inherited stopword list. Sometimes, you may want to make these stopwords actual stopwords in the stopword list they were inherited from. This process is known as promoting a stopword.

> **Note:** This option is available only for inherited stopword lists.

1 Select **Coding Setup > Stopword Lists**.

The Stopword Lists page appears.

2 Select a stopword list.

3 Select **Actions** > **Manage**.

or

Click the **Name** link.

The [Stopword List Name] page appears.

4 Select one or more stopwords.

> **Note:** The status of the stopword(s) must be **Active**.

5 Select **Actions > Promote**.

The Reason for Change dialog box appears.

6 In the **Reason** field, type a description for the change.

7 Click **Accept**.

Masking a stopword

You cannot change the status of an inherited stopword. The stopword always has the status that it has in the stopword list that it is inherited from. If you do not want to use a stopword from its parent list, you can "mask" it. A masked, inherited stopword is treated by an autocoding algorithm as an inactive stopword.

> **Note:** This option is available only for inherited stopword lists.

1 Select **Coding Setup > Stopword Lists**.

The Stopword Lists page appears.

2 Select a stopword list.

3 Select **Actions** > **Manage**.

or

Click the **Name** link.

The [Stopword List Name] page appears.

4 Select one or more stopwords.

5 Select **Actions > Mask**.

The Reason for Change dialog box appears.

6 In the **Reason** field, type a description for the change.

7 Click **Accept**.

Unmasking a stopword

Use this procedure to show a previously masked stopword to its parent stopword list.

> **Note:** This option is available only for inherited stopword lists.

1 Select **Coding Setup > Stopword Lists**.

The Stopword Lists page appears.

2 Select a stopword list.

3 Select **Actions** > **Manage**.

or

Click the **Name** link.

The [Stopword List Name] page appears.

4 Select one or more stopwords.

5 Select **Actions > Unmask**.

The Reason for Change dialog box appears.

6 In the **Reason** field, type a description for the change.

7 Click **Accept**.

CHAPTER 9
Coding algorithms

In this chapter

Coding algorithm management

You can create new coding algorithms to be used for specific types of autocoding tasks, and modify the default coding algorithm by adding or removing steps or by changing the order in which the steps are performed. All the steps that are available for use in an algorithm are predefined in the application; you cannot create new steps through the Central Coding user interface.

Note: A dictionary manager typically performs these tasks.

Coding algorithm statuses

Coding algorithm statuses	
Status	**Description**
Active	A coding algorithm that is available for use by a coding definition.
Inactive	A coding algorithm that is not available for use by a coding definition.

Available algorithm steps

The steps that are available for use in a coding algorithm are listed in the following table in the order they appear in the user interface. You can use the steps in any order (except where noted), you can use the steps multiple times in an algorithm, or you can choose not to use one or more of the steps.

Available algorithm steps	
Algorithm step	**Description**
Exact Term Match	Attempts to exactly match the supplied text to a term in the dictionary.
Exact Synonym Match	Attempts to exactly match the supplied text to a synonym in the current synonym list.
Term Contains All Words	Attempts to find a term in the dictionary that contains all words that are in the supplied text.
Synonym Contains All Words	Attempts to find a synonym in the current synonym list that contains all words that are in the supplied text.
Eliminate Stopwords	Eliminates words from the supplied text that are in the current stopword list.
Eliminate Punctuation	Eliminates punctuation marks from the supplied text that are in the punctuation string for the current dictionary. The removed punctuation is replaced by spaces. **Note:** An Installer typically defines the punctuation string using the Dictionary Loader tool. **Note:** Oracle recommends that you order the **Eliminate Punctuation** step before the **Eliminate Stopwords** step to help reduce autocoding failures due to a typing error in a verbatim. For example, if a space is missing before a stopword (such as ",@" instead of ", @"), removing the punctuation first allows the algorithm to properly recognize the stopword).
Auto Suggestion	Looks for the auto-suggestion for the coding definition and request data. **Note:** If used, the Auto Suggestion step must be the first step in the algorithm. **Note:** There are two items in the Central Coding application that must be set for the auto-suggestion feature to be enabled. • The **Use as Auto Suggestion** checkbox in the Coding Browser dialog box must be selected. By default, this option is selected. • The Auto Suggestion step must be part of the coding algorithm.
Remove Temperatures	Removes temperature information, if any, from the verbatim (for example, 100.1 F, 99.1 C).
Remove Extra Info	Removes any extra information that is contained within parentheses.

Default coding algorithm

The default coding algorithm is defined in the following table. You can modify this algorithm.

Default coding algorithm		
Step	Name	Description
1	Auto Suggestion	Looks for the auto-suggestion for the coding definition and request data. **Note:** There are two items in the Central Coding application that must be set for the auto-suggestion feature to be enabled. • The **Use as Auto Suggestion** checkbox in the Coding Browser dialog box must be selected. By default, this option is selected. • The Auto Suggestion step must be part of the coding algorithm. If you do not want to use the auto-suggestion feature, you can either: • Deselect the **Use as Auto Suggestion** checkbox in the coding browser. or • Remove the Auto Suggestion step from the coding algorithm. You can deselect Use as Auto Suggestion only when the coding browser is open. If you deselect the checkbox, whatever you code the verbatim to is not saved as an auto-suggestion. The next time you open the coding browser to code a verbatim the checkbox is selected again.
2	Exact Synonym Match	Attempts to exactly match the supplied text to a synonym in the current synonym list.
3	Exact Term Match	Attempts to exactly match the supplied text to a term in the dictionary.
4	Eliminate Punctuation	Eliminates punctuation marks from the supplied text that are in the punctuation string for the current dictionary. The removed punctuation is replaced by spaces. **Note:** An Installer typically defines the punctuation string using the Dictionary Loader tool.
5	Exact Synonym Match	Attempts to exactly match the supplied text to a synonym in the current synonym list.
6	Exact Term Match	Attempts to exactly match the supplied text to a term in the dictionary.

Default coding algorithm		
Step	Name	Description
7	Eliminate Stopwords	Eliminates words from the supplied text that are in the current stopword list.
8	Exact Synonym Match	Attempts to exactly match the supplied text to a synonym in the current synonym list.
9	Exact Term Match	Attempts to exactly match the supplied text to a term in the dictionary.

Viewing the list of coding algorithms

- Select **Coding Setup > Algorithms**.

  The Algorithms page appears. For a description of the fields on this page, see *Algorithms page* (on page 433).

Adding a coding algorithm and assigning its steps

1 Select **Coding Setup > Algorithms**.

The Algorithms page appears.

2 Select **Actions > New**.

or

Click **New**.

The New Algorithm page appears. For a description of the fields on this page, see ***New Algorithm page*** (on page 434).

3 In the **Name** field, type a name for the algorithm.

4 In the **Description** field, type descriptive information about the algorithm.

5 Select **Actions > Save**.

or

Click **Save**.

The page refreshes, the page name changes, and additional options appear. For a description of the fields on this page, see ***[Algorithm Name] page—View mode*** (on page 435).

6 Select **Actions > Add**.

or

Click the **Add** button.

The Add Actions to Algorithm dialog box appears. For a description of the fields on this page, see ***Add Actions to Algorithm dialog box*** (on page 437).

7 Select the step(s) that you want to include in the algorithm.

- The steps that are available for use in a coding algorithm appear one time each in the **Add Actions to Algorithm** dialog box.

  For more information, see ***Available algorithm steps*** (on page 162). You can use the steps in any order (except where noted), you can use the steps multiple times in an algorithm, or you can choose not to use one or more of the steps.

- If used, the Auto Suggestion step must be the first step in the algorithm.

- Oracle recommends that you order the **Eliminate Punctuation** step before the **Eliminate Stopwords** step to help reduce autocoding failures due to a typing error in a verbatim.

  For example, if a space is missing before a stopword (such as ",@" instead of ", @"), removing the punctuation first allows the algorithm to properly recognize the stopword).

8 Click **Accept**.

The [Algorithm Name] page appears.

9 Repeat steps 6 through 8 until you have added all the steps that you want to include in the algorithm.

10 In the **Order** field for one algorithm step, type the number that represents the order in which you want the step to be run.

The page reorders when you exit the field by either selecting the folder tab or clicking anywhere on the page.

11 Repeat step 10 for each algorithm step.

12 Select **Actions > Save**.

or

Click **Save**.

Viewing the details of a coding algorithm

1 Select **Coding Setup > Algorithms**.

The Algorithms page appears.

2 Select an algorithm.

3 Select **Actions > Manage**.

or

Click the **Name** link.

The [Algorithm Name] page appears. For a description of the fields on this page, see *[Algorithm Name] page—View mode* (on page 435).

Adding one or more steps to a coding algorithm

1. Select **Coding Setup > Algorithms**.

   The Algorithms page appears.

2. Select an algorithm.
3. Select **Actions > Manage**.

   The [Algorithm Name] page appears. For a description of the fields on this page, see *[Algorithm Name] page—View mode* (on page 435).

4. Select **Actions > Edit**.

   or

   Click **Edit**.

5. Select **Actions > Add**.

   or

   Click the **Add** button.

   The Add Actions to Algorithm dialog box appears. For a description of the fields on this page, see *Add Actions to Algorithm dialog box* (on page 437).

6. Select the step(s) that you want to include in the algorithm.
   - The steps that are available for use in a coding algorithm appear one time each in the **Add Actions to Algorithm** dialog box. For more information, see *Available algorithm steps* (on page 162). You can use the steps in any order (except where noted), you can use the steps multiple times in an algorithm, or you can choose not to use one or more of the steps.
   - If used, the Auto Suggestion step must be the first step in the algorithm.
   - Oracle recommends that you order the **Eliminate Punctuation** step before the **Eliminate Stopwords** step to help reduce autocoding failures due to a typing error in a verbatim. For example, if a space is missing before a stopword (such as ",@" instead of ", @"), removing the punctuation first allows the algorithm to properly recognize the stopword).
7. Click **Accept**.

   The [Algorithm Name] page appears.

8. Repeat steps 5 through 7 until you have added all the steps that you want to include in the algorithm.
9. In the **Order** field for one algorithm step, type the number that represents the order in which you want the step to be run.

   The page reorders when you exit the field by either selecting the folder tab or clicking anywhere on the page.

10. Repeat step 9 for each algorithm step.
11. Select **Actions > Save**.

    or

    Click **Save**.

Removing a step from a coding algorithm

1. Select **Coding Setup > Algorithms**.

   The Algorithms page appears. For a description of the fields on this page, see ***Algorithms page*** (on page 433).

2. Select an algorithm.

3. Select **Actions > Manage**.

   or

   Click the **Name** link.

   The [Algorithm Name] page appears. For a description of the fields on this page, see ***[Algorithm Name] page—View mode*** (on page 435).

4. Select **Actions > Edit**.

   or

   Click **Edit**.

5. Select one or more algorithm steps.

6. Select **Actions > Remove**.

   or

   Click the **Remove** button.

   The system reorders the remaining steps.

7. Repeat steps 5 and 6 as needed.

8. Select **Actions > Save**.

   or

   Click **Save**.

Changing the order of the steps in a coding algorithm

1 Select **Coding Setup > Algorithms**.

The Algorithms page appears.

2 Select an algorithm.

3 Select **Actions > Manage**.

or

Click the **Name** link.

The [Algorithm Name] page appears.

4 Select **Actions > Edit**.

or

Click **Edit**.

5 In the **Order** field for one algorithm step, type the number that represents the order in which you want the step to be run.

The page reorders when you exit the field by either selecting the folder tab or clicking anywhere on the page.

- If used, the Auto Suggestion step must be the first step in the algorithm.
- Oracle recommends that you order the **Eliminate Punctuation** step before the **Eliminate Stopwords** step to help reduce autocoding failures due to a typing error in a verbatim.

  For example, if a space is missing before a stopword (such as ",@" instead of ", @"), removing the punctuation first allows the algorithm to properly recognize the stopword).

6 Repeat step 5 until the list is in the order you want.

7 Select **Actions > Save**.

or

Click **Save**.

Activating a coding algorithm

1. Select **Coding Setup > Algorithms**.

   The Algorithms page appears.

2. Select one or more algorithms.
3. Select **Actions > Activate**.

   The Reason for Change dialog box appears.

4. In the **Reason** field, type a description for the change.
5. Click **Accept**.

   The status changes to **Active**. The algorithm is available for use by a coding definition.

Deactivating a coding algorithm

1 Select **Coding Setup > Algorithms**.

The Algorithms page appears.

2 Select one or more algorithms.

3 Select **Actions > Deactivate**.

The Reason for Change dialog box appears.

4 In the **Reason** field, type a description for the change.

5 Click **Accept**.

The status changes to **Inactive**. The algorithm is not available for use by a coding definition.

Deleting a coding algorithm

Note: You can only delete an algorithm when it is not used in any coding definition.

1 Select **Coding Setup > Algorithms**.

The Algorithms page appears.

2 Select an algorithm.

3 Select **Actions > Delete**.

A confirmation dialog box appears.

4 Click **OK**.

The Reason for Change dialog box appears.

5 In the **Reason** field, type a description for the change.

6 Click **Accept**.

CHAPTER 10

Coding definitions and auto-suggestions

In this chapter

Coding definition management

You can create, manage, and delete coding definitions. You can also view the auto-suggested codes for terms that are associated with a coding definition and specified verbatim.

> **Note:** An administrator typically performs these tasks.

Auto-suggestions

An auto-suggestion is a manually selected unique coding response for requests with the same verbatim, coding definition, and context information that maps to a dictionary path. Using auto-suggestions increases accuracy and consistency in coding.

If the auto-suggestion feature is enabled, the Central Coding application applies the selected code value to all new incoming requests with the same verbatim, coding definition, and context information. Auto-suggested code values are selected by a coder with the Submit Auto Suggestion right while interactively coding.

> **Note:** The auto-suggestion feature is enabled by default. For more information, see ***Enabling and disabling the auto-suggestion feature*** (on page 179).
>
> **Note:** Auto-suggestions are shared among all verbatims using the same coding definition and context information. Auto-suggestions are not shared across multiple coding definitions.

Enabling and disabling the auto-suggestion feature

To use the auto-suggestion feature:

- The **Use as Auto Suggestion** checkbox in the Coding Browser dialog box must be selected.

  By default, this option is selected.
- The Auto Suggestion step must be part of the coding algorithm.

  If used, the Auto Suggestion step must be the first step in the algorithm.

> **Note:** If you select the Use as Auto Suggestion checkbox in the coding browser but the Auto Suggestion step is not part of the coding algorithm, auto-suggestions are saved to the database but they are not used for coding.

To disable the auto-suggestion feature, do one of the following:

- Deselect the **Use as Auto Suggestion** checkbox in the coding browser.
- Remove the Auto Suggestion step from the coding algorithm.

> **Caution:** You can deselect Use as Auto Suggestion only when the coding browser is open. If you deselect the checkbox, whatever you code the verbatim to is not saved as an auto-suggestion. The next time you open the coding browser to code a verbatim the checkbox is selected again.

Planning considerations—Auto-suggestions and coding definitions

If you want to share auto-suggestions across multiple studies, create one coding definition per dictionary. Auto-suggestions are shared among all verbatims using the same coding definition and context information. Auto-suggestions are not shared across multiple coding definitions.

Viewing the list of coding definitions

- Select **Coding Setup > Coding Definitions**.

  The Coding Definitions page appears. For a description of the fields on this page, see ***Coding Definitions page*** (on page 438).

Adding a coding definition

> **Note:** **If you want to share auto-suggestions across multiple studies, create one coding definition per dictionary. Auto-suggestions are shared among all verbatims using the same coding definition and context information. Auto-suggestions are not shared across multiple coding definitions.**

1. Select **Coding Setup > Coding Definitions**.

   The Coding Definitions page appears.

2. Select **Actions > New**.

   or

   Click **New**.

   The New Coding Definition page appears. For a description of the fields on this page, see ***New Coding Definition page*** (on page 440).

3. In the **Name** field, type a name for the coding definition.
4. In the **Description** field, type descriptive information about the coding definition.
5. In the **Dictionary** field, select the dictionary and version that you want to associate with the coding definition.
6. In the **Synonym List** field, select the synonym list that you want to associate with the coding definition.
7. In the **Stopword List** field, select the stopword list that you want to associate with the coding definition.
8. In the **Coding Algorithm** field, select the algorithm that you want to associate with the coding definition.
9. Select **Actions > Save**.

   or

   Click **Save**.

Viewing or editing the details of a coding definition

1 Select **Coding Setup > Coding Definitions**.

The Coding Definitions page appears.

2 Select a coding definition.

3 Select **Actions > Edit**.

or

Click **Edit**.

or

Click the **Name** link.

The [Coding Definition Name] page appears.

4 View or edit the information on the page using the descriptions in ***[Coding Definition Name] page*** (on page 441).

5 Select **Actions > Save**.

or

Click **Save**.

Deleting a coding definition

Note: You can only delete a coding definition if it is not assigned to any coding requests.

1. Select **Coding Setup > Coding Definitions**.

   The Coding Definitions page appears.

2. Select a coding definition.
3. Select **Actions > Delete**.

   A confirmation dialog box appears.

4. Click **OK**.

   The Reason for Change dialog box appears.

5. In the **Reason** field, type a description for the change.
6. Click **Accept**.

Viewing auto-suggestions

An auto-suggestion is a manually selected unique coding response for requests with the same verbatim, coding definition, and context information that maps to a dictionary path.

Auto-suggestions are shared among all verbatims using the same coding definition and context information. Auto-suggestions are not shared across multiple coding definitions.

1 Select **Coding Setup > Coding Definitions**.

The Coding Definitions page appears.

2 Select a coding definition.

3 Select **Actions > Manage Auto Suggestions**.

The Auto Suggestions page appears. For a description of the fields on this page, see ***Auto Suggestions page*** (on page 444).

4 In the **Verbatim** field, type the text for which you want to find any specific auto-suggested term associated with the selected coding definition.

5 Click the **Search** () icon to start the search.

The auto-suggested codes for the entered verbatim appear on the page.

> **Note:** All available auto-suggested codes appear on the page. If the page is blank there are no auto-suggested codes.

Deleting auto-suggestions

1 Select **Coding Setup > Coding Definitions**.

The Coding Definitions page appears.

2 Select a coding definition.

3 Select **Actions > Manage Auto Suggestions**.

The Auto Suggestions page appears.

> **Note:** All available auto-suggested codes appear on the page. If the page is blank there are no auto-suggested codes.

4 Select an auto-selected code.

5 Select **Actions > Delete**.

CHAPTER 11

Assignment rules

In this chapter

Assignment rules

You can create new assignment rules, modify existing assignment rules, and delete assignment rules. The application maintains the assignment rules as an ordered list so that you can also control the order in which the rules are run.

Note: An administrator typically performs these tasks.

Viewing the list of assignment rules

- Select **Coding Setup > Assignment Rules**.

  The Assignment Rules page appears. For a description of the fields on this page, see *Assignment Rules page* (on page 453).

> **Note:** Before starting long-running get verbatims jobs, Oracle recommends that you review the assignment rules and organize them so that the rule or rules most likely to match the incoming requests are run first. The Central Coding application runs the assignment rules in the order they appear on the Assignment Rules page.

Adding an assignment rule

1. Select **Coding Setup > Assignment Rules**.

   The Assignment Rules page appears.

2. Select **Actions > New**.

   or

   Click **New**.

   The New Assignment Rule page appears.

3. In the **Name** field, type the name of the assignment rule.

   > **Note:** The assignment rule name must be unique.

4. In the **Description** field, type descriptive information about the assignment rule.

5. In the **Coding Definition** field, select the coding definition that you want to use when coding the requests that are processed by this assignment rule.

   > **Note:** Requests are not assigned by any assignment rules associated with coding definitions that use an inactive algorithm, synonym list, or stopword list.

6. Select **Attempt autocode** if you want the system to always attempt to autocode incoming requests.

   By default, this option is selected.

7. Select **Autocoding requires approval** if you want all autocoded values to require an approval.

   By default, this option is **not** selected. If you select this option, the application routes all autocoded requests to the Approvals page so that the approver can approve them.

8. Select **Autocoding requires review** if you want all autocoded values to require a review.

   By default, this option is **not** selected. If you select this option, the application routes all autocoded requests to the Coding Requests page and sets the status to **Needs review** so that the coder can review them.

9. Select **Interactive coding requires approval** if you want all interactively coded values to require an approval.

   By default, this option is **not** selected. After a request is manually coded, the application identifies it as being **Complete, awaiting delivery**, or as requiring an approval. If you select this option, requests that require an approval are routed to the Approvals page so that the approver can review them.

10. Select **Coding result requires delivery** if you want the coded values to be returned to the InForm application.

    By default, this option is selected.

11 Define the rule expression.

a In the **Request property** field, select the property on which to base the assignment rule.

- **ClientName**—The name of the source application for which the Central Coding application is coding the request.
- **Product**—The product type from which the request was sent. The Central Coding application defines this property.
- **ClientHost**—The name of the server for the study.
- **Verbatim–**The original reported text that describes the adverse event, disease, drug, or other item to be coded. This information is defined in the source application.
- **DictType**—The dictionary type.
- **StudyName**—The name of the study.
- **Site**—A mnemonic identifier for the subject site.
- **VisitName**—The name of the visit. This information is defined in the source application.
- **ItemType**—The kind of item to be coded. This information is defined in the source application.
- **FormName**—The form RefName. This information is defined in the source application.

b In the adjacent field, select an operator.

- = (equals)
- != (not equal to)
- <= (less than or equal to)
- >= (greater than or equal to)

c In the **Value** field, type the value for the **Request property**.

d Click the **green plus sign** ( ).

The system adds an expression to the **Rule text** box.

> **Note: Although you can enter an expression directly in the Rule text box manually, Oracle recommends you use the Request property field, operator field, and Value field to avoid invalid syntax.**

12 Repeat step 11 as needed.

The assignment rule that is evaluated by the system appears, in simple syntax language, in the **Rule text** box.

> **Note: The maximum size of an assignment rule is 64K.**

13 Click the **blue check mark** () to the right of the **Rule text** box to check the syntax of the rule text.

> **Caution:** If the system verifies the syntax but the data in the **Value** field is not valid, the system cannot assign incoming requests using this rule.
>
> If a red error message appears below the rule there is a problem and the assignment rule will not run.
>
> The syntax check does not check for line feeds and other non-printable characters.

14 In the **Select work teams** section, select the work teams to which you want to assign the requests that are processed by this rule.

15 Select **Actions > Save**.

or

Click **Save**.

Viewing or editing the details of an assignment rule

1 Select **Coding Setup > Assignment Rules**.

The Assignment Rules page appears.

2 Select a rule.

3 Select **Actions > Edit**.

or

Click **Edit**.

The [Assignment Rule Name] page appears.

4 View or edit the information on the page using the descriptions in ***[Assignment Rule Name] page*** (on page 457).

For step-by-step instructions, see *Adding an assignment rule* (on page 190).

5 Select **Actions > Save**.

or

Click **Save**.

Changing the order in which assignment rules are run

1 Select **Coding Setup > Assignment Rules**.

The Assignment Rules page appears.

2 In the **Order** field for one or more assignment rule(s), type the number that represents the order in which you want the rule to be run.

> **Note:** The Central Coding application runs the assignment rules in the order they appear on the Assignment Rules page.

3 Click Refresh ().

The page refreshes and reorders the assignment rules.

Deleting an assignment rule

1. Select **Coding Setup > Assignment Rules**.

   The Assignment Rules page appears.

2. Select a rule.
3. Select **Actions > Delete**.

   Note: A confirmation dialog box does **not** appear.

CHAPTER 12

Adapters—Required for InForm integration only

In this chapter

Adapter management

You can add and edit adapter information and delete an adapter that is not in use.

> **Note:** An administrator typically performs these tasks.

Viewing the list of adapters

- Select **Administration > System > Adapters**.

  The Adapters page appears. For a description of the fields on this page, see ***Adapters page*** (on page 502).

Adding an adapter

Note: You can add an adapter using the user interface or using the command line. For information about adding an adapter using the command line, see *Adding adapters and studies using the command line* in the *Installation Guide*.

1. Select **Administration > System > Adapters**.

   The Adapters page appears.

2. Select **Actions > Add**.

   or

   Click **Add**.

   The New Adapter page appears.

3. In the **Adapter name** field, type the name of the adapter.
4. In the **Adapter type** field, select the product type from which the request was sent.

   The Central Coding application defines this property.

5. In the **Adapter URL** field, type the URL for the server where the InForm Adapter software is installed.
6. Click **Test** to initiate a test of the connection to the adapter.
   - If the test is successful, the name of the study or studies that are associated with the adapter appear on the page.
   - If the test is not successful, an error message appears on the page.
7. Select **Actions > Save**.

   or

   Click **Save**.

Viewing or editing the details of an adapter

1 Select **Administration > System > Adapters**.

The Adapters page appears.

2 Click the **Name** link for the adapter whose information you want to view.

The [Adapter Name] page appears.

3 View or edit the information on the page using the descriptions in ***[Adapter Name] page*** (on page 504).

Deleting an adapter

Note: You can only delete an adapter if it is not associated with a study.

1 Select **Administration > System > Adapters**.

The Adapters page appears.

2 Select an adapter.

3 Select **Actions > Delete**.

or

Click the **Delete** button.

Note: A confirmation dialog box does **not** appear.

CHAPTER 13

Study information—Required for InForm integration only

In this chapter

Study information management

All studies must be associated with an InForm Adapter. You can manage this association, specify the types of requests to send between the InForm and Central Coding applications, studies to study groups, attach documents to the study information for reference purposes, and lock studies in the Central Coding application.

Note: An administrator typically performs these tasks.

Study groups

Study groups allow administrators to create subsets of studies and configure certain query settings for the studies. This is especially useful for CROs who manage several customers conducting studies. A CRO can create a study group for each customer.

The Central Coding application includes a default study group called System. When you add a study, it is automatically added to the System study group.

> **Note:** All studies in the Central Coding application must belong to a study group.

Users with administration rights can create study groups and assign studies to each group. Each study group contains two configuration settings:

- **Allow Auto Query By Default**—Allows the Central Coding application to duplicate an existing query and apply it to all matching verbatims in the study group that are subsequently entered in the Central Coding application.

  For users with the rights to create queries, selecting this option displays the Add to Auto Query List checkbox in the Create Query dialog box. This option is selected by default. When the checkbox remains selected, the Central Coding application duplicates the query and associates it with each verbatim in the study group that is subsequently created in the Central Coding application. Deselect this checkbox if you do not want the Central Coding application to add the verbatim to the auto query list. An administrator maintains the auto query list from the Auto Query List page.

- **Allow Auto Close Query By Default**—Instructs the Central Coding application to automatically close a query if the verbatim associated with the query is successfully coded and approved.

  For users with the rights to create queries, selecting the Auto Close Query By Default option displays the Auto Close Query Upon Coding Complete checkbox in the Create Query dialog box. This option is selected by default. When the checkbox remains selected, the Central Coding application automatically closes the query when the associated verbatim is successfully coded and approved. Deselect this checkbox for a specific query to prevent the Central Coding application from closing the query after the verbatim is either successfully coded and approved, or deleted.

Creating and modifying a study group

1. Select **Administration > Management > Study Groups**.

   The Study Group List page appears.

2. Do one of the following:
   - To create a study group, click **Add**.
   - To edit a study group, click **Edit**.

3. In the **Name** field, create or modify the name of the study group.

4. By default, the following options are selected:
   - **Allow Auto Query By Default**—Allows the Central Coding application to duplicate an existing query and apply it to all matching verbatims in the study group that are subsequently entered in the Central Coding application. To manually create queries for individual verbatims in the study group, deselect this option.
   - **Allow Auto Close Query By Default**—Allows the Central Coding application to automatically close a query if the verbatim associated with the query is successfully coded and approved. To manually close all queries associated with verbatims in the study group, deselect this option.

Adding a study to a study group

Note: All studies in the Central Coding application must belong to a study group.

1. Select **Administration > Management > Studies**.

   The Study Information page appears.

2. Select the study to add to a study group.

3. Click **Edit**.

4. In the **Study Group** drop-down list, select the study group to which to add the study.

Deleting a study group

1. Select **Administration > Management > Study Groups**.

   The Study Group List page appears.

2. Select the study group to delete.

3. Click **Delete**.

   If the study group is associated with one or more studies, a warning message appears. You cannot delete a study group that is associated with one or more studies. If the study group is not associated with a study, the study group is deleted and a confirmation dialog box does **not** appear.

Viewing the list of study information

Use this procedure to view and manage information about the adapters in the application and their associated studies.

- Select **Administration > Management > Studies**.

  The Study Information page appears. For a description of the fields on this page, see ***Study Information*** (on page 492).

Adding study information

Use this procedure to add a study and its associated information to the Central Coding application. After you add a study to the Central Coding application, you can add it to the job schedules. For more information, see *About managing the job schedules* (on page 218).

1 Select **Administration > Management > Studies**.

The Study Information page appears.

2 Select **Actions > New**.

or

Click **New**.

The New Study Information page appears.

3 In the **Adapter** field, select an adapter.

4 In the **Trial** field, select a study.

Only the studies associated with the selected adapter appear in the list.

The Central Coding application does not support multiple studies with the same study name.

5 In the **URL** field, type the base URL for the study.

6 In the **Study Group** field, select the study group to which to add the study.

Use study groups to apply configuration settings to multiple studies. For more information, see *Study groups* (on page 205).

7 Select whether the study supports query management.

To do this, select the **Support Query** option.

Note: Select this option only when the InForm application is the source application. Deselect this option when another application, such as the Clintrial application, is the source application.

8 Optionally, lock the study.

To do this, select the **Study Locked** option.

Requests associated with studies that are locked in the Central Coding application are visible only to administrators on the All Requests page. The requests are not visible to coders and approvers on the Coding Requests and Approvals pages. You might want to lock a study in the Central Coding application when:

- The study is locked in the InForm application.
- You do not want the requests associated with the study to be visible to coders and approvers on the Coding Requests and Approvals pages.
- You do not want coded values, approvals, disapprovals, and cleared codes to be propagated to the requests associated with the study.
- You do not want the requests that need to be manually recoded after using the verify and update codes feature to be visible to coders and approvers on the Coding Requests and Approvals pages.

9 Select **Actions > Save**.

or

Click **Save**.

Viewing or editing study information

1 Select **Administration > Management > Studies**.

The Study Information page appears.

2 Select a study.

3 Select **Actions > Edit**.

or

Click **Edit**.

The [Study Name] Study Information page appears.

4 View or edit the information on the page using the descriptions in ***[Study Name] Study Information page*** (on page 496).

> **Note: When you move a study from one InForm Adapter to another, the InForm Adapter bookmark for the study is not deleted from the database. As a result, the Central Coding application retrieves only the changed verbatims from the InForm application.**

Locking a study in the Central Coding application

Requests associated with studies that are locked in the Central Coding application are visible only to administrators on the All Requests page. The requests are not visible to coders and approvers on the Coding Requests and Approvals pages. You might want to lock a study in the Central Coding application when:

- The study is locked in the InForm application.
- You do not want the requests associated with the study to be visible to coders and approvers on the Coding Requests and Approvals pages.
- You do not want coded values, approvals, disapprovals, and cleared codes to be propagated to the requests associated with the study.
- You do not want the requests that need to be manually recoded after using the verify and update codes feature to be visible to coders and approvers on the Coding Requests and Approvals pages.

1 Select **Administration > Management > Studies**.

   The Study Information page appears.

2 Select a study.

3 Select **Actions > Edit**.

   or

   Click **Edit**.

   The [Study Name] Study Information page appears.

4 Select **Study Locked**.

   > **Note:** To unlock a study, deselect the **Study Locked** option.

5 Select **Actions > Save**.

   or

   Click **Save**.

Resetting the InForm Adapter bookmark

Use this procedure to reset the bookmark attribute for the InForm Adapter application. Reset the bookmark if you want all the verbatims from the InForm application to be retrieved again. If there are no changes to the verbatims, their statuses change from Received to Coded and they are delivered back to the InForm application.

The bookmark attribute is an index number that identifies the last verbatim stored in the cache. It is set in the GETCODINGDATAREQ element in the GETCODINGDATAREQ web method in the InForm Adapter application. For more information, see the InForm Adapter *Interfaces Guide*.

1 Select **Administration > Management > Studies**.

The Study Information page appears.

2 Select a study.

3 Select **Actions > Reset**.

Note: When you move a study from one InForm Adapter to another, the InForm Adapter bookmark for the study is not deleted from the database. As a result, the Central Coding application retrieves only the changed verbatims from the InForm application.

Deleting study information

About deleting study information

> **Note:** You can only delete a study when there are no jobs running for that study.

There are options for deleting a study in the Central Coding application. You can:

- **Delete only study information**—Use to remove only the study information for the selected study from the system.
- **Delete study information and all associated data**—Use to remove a study and all its associated requests, data, and audit records from the database.

  The following items are **not** deleted:

  - Assignment rules that refer to the study.
  - Coding definitions that were assigned to the study.
  - Reports generated while the study was in the database.
  - The adapter, which might be used by more than one study.

  When a study is decommissioned using the **Decommission a Study** functionality, all study information and its associated data is moved to study specific tables.

  > **Note:** You can use this functionality in conjunction with the **Delete Study Mask** field on the System Configuration page to limit the type of studies that can be deleted. For more information, see ***Configuring study deletion settings*** (on page 122).

Deleting only study information

Use this procedure to remove only the study information for the selected study from the system.

> **Note:** You can only delete a study when there are no jobs running for that study.
>
> **Note:** To remove all the requests, data, and audit records for a study from the database, see ***Deleting study information and all associated data*** (on page 214).

1. Select **Administration > Management > Studies**.

   The Study Information page appears.

2. Select one or more studies.
3. Select **Actions > Delete Study Information**.

   or

   Click the **Delete Study Information** button.

   > **Note:** A confirmation dialog box does **not** appear.

Deleting study information and all associated data

Use this procedure to remove a study and all its associated requests, data, and audit records from the database. When a study is decommissioned using the **Decommission a Study** functionality, all study information and its associated data is moved to study specific tables. The **Delete Study and All Data** action should normally only be used for UAT studies. To decommission live studies, use the **Decommission a Study** functionality.

> **Note:** You can only delete a study when there are no jobs running for that study.
>
> **Note:** To remove study information only, see ***Deleting only study information*** (on page 213).

1 Select **Administration > Management > Studies**.

The Study Information page appears.

2 Select a study.

> **Note:** By default, only studies whose names contain **UAT** appear by default.

3 Select **Actions > Delete Study and All Data**.

A confirmation dialog box appears.

4 Click **OK**.

The following items are **not** deleted:

- Assignment rules that refer to the study.
- Coding definitions that were assigned to the study.
- Reports generated while the study was in the database.
- The adapter, which might be used by more than one study.

> **Note:** The **Delete Study Mask** setting on the System Configuration page is set to **UAT** by default, which limits the **Delete Study and All Data** action to studies with UAT in their names. In most cases, this limits the studies that can be deleted to UAT studies only. To allow deletion of any other type of Central Coding study, either specify another sub-string in the **Delete Study Mask** field, or leave it blank to allow deletion of all studies. For more information, see ***Configuring study deletion settings*** (on page 122).

Decommissioning a study

Use this procedure to archive coding data for a study that is complete. The Central Coding application moves all request-related data from the current database tables to the history database tables.

For Central Coding 3.0 and later, when a study is decommissioned, its data is archived into a set of study specific history tables. For example, if the PFST55 study is decommissioned, study data is moved to tables called PFST55_CCA_REQUEST, PFST55_REQUEST_AUDIT, and so on.

> **Note: The action of decommissioning a study is a final action that cannot be reversed. Select this option only after the Coding Coded Items Report has been run successfully.**

1 Select **Administration > Management > Studies**.

The Study Information page appears.

2 Select a study.

3 Select **Actions > Decommission a Study**.

or

Click the **Decommission a Study** button.

A confirmation dialog box appears.

> **Note: If the job scheduler stops while the study is being decommissioned, an error occurs and the decommissioning process stops. You must restart the job scheduler and then rerun the decommissioning a study process.**

CHAPTER 14

Job schedules—Required for InForm integration only

In this chapter

Managing the job schedules

For each adapter and its associated studies, the Central Coding application uses two job schedules for normal request processing: Get Requests and Return Codes. Optionally, you can choose to run the Get Requests and Return Codes jobs at non-scheduled times. You might want to do this for new adapters for existing studies that have a large amount of uncoded data.

> **Note:** An administrator typically performs these tasks.

Job schedules

After you complete the installation, set up the adapters, add the study information, and complete all other configuration tasks required for your organization, the Central Coding application is ready to get requests from, and return codes to, the InForm application.

The first time you install the Central Coding software, you must define the Get Requests and Return Codes jobs schedules for each adapter, and then add studies to them. There are no default timetables for the job schedules.

You can:

- Create a basic job schedule based on days of the week and time of day.
- Create an advanced job schedule based on months, days of the week, and time of day.

The Central Coding application automatically gets data from, or returns data to, the InForm application only when the job schedules are defined (and the job scheduler is running). The Central Coding application only runs the jobs associated with a study when it is included in the job schedule(s) for its associated adapter.

Planning considerations—Working with studies

There are no special planning considerations when you are working with a new study or with an existing study that does not have a large amount of uncoded data.

However, if you are working with new adapters for existing studies that have a large amount of uncoded data, you might want to run the Get Requests and Return Codes jobs at non-scheduled times. For more information, see *About running statistics on the Central Coding application* in the *Installation Guide*.

Manually running the jobs at an off-peak time allows the data to be transferred without having an impact on performance. After the coding is up to date, you can add the adapter to the job schedules for normal request processing.

> **Note:** Before starting long-running Get Requests jobs, Oracle recommends that you review the assignment rules and organize them so that the rule or rules most likely to match the incoming requests are run first. The Central Coding application runs the assignment rules in the order they appear on the Assignment Rules page. For more information, see ***Assignment Rules page*** (on page 453) and ***Changing the order in which assignment rules are run*** (on page 194).

The Get Requests job schedule

The Get Requests job schedule for an adapter determines when data is retrieved from the InForm application for its associated study or studies. There is one Get Requests job schedule for each adapter. The schedule you define applies to all studies associated with the adapter.

The Get Requests job schedule has its own job queue that runs synchronously with the Return Codes and ASAP (non-scheduled) job queues for each adapter.

The Return Codes job schedule

The Return Codes job schedule for an adapter determines when data is sent to the InForm application for its associated study or studies. There is one Return Codes job schedule for each adapter. The schedule you define applies to all studies associated with the adapter.

The Return Codes job schedule has its own job queue that runs synchronously with the Get Requests and ASAP (non-scheduled) job queues.

Working with the Get Requests job schedules

Creating the Get Requests job schedule for an adapter

Use this procedure to create the Get Requests job schedule for an adapter, which determines when data is retrieved from the InForm application for its associated study or studies. There is one Get Requests job schedule for each adapter. The schedule you define applies to all studies associated with the adapter.

You can:

- Create a basic job schedule based on days of the week and time of day.
- Create an advanced job schedule based on months, days of the week, and time of day.

The Get Requests job schedule has its own job queue that runs synchronously with the Return Codes and ASAP (non-scheduled) job queues for each adapter.

Note: Before starting long-running Get Requests jobs, Oracle recommends that you review the assignment rules and organize them so that the rule or rules most likely to match the incoming requests are run first. The Central Coding application runs the assignment rules in the order they appear on the Assignment Rules page. For more information, see *Assignment Rules page* (on page 453) and *Changing the order in which assignment rules are run* (on page 194).

1 Select **Administration > System > Adapters**.

The Adapters page appears.

2 Select an adapter.

3 In the **Get Requests Schedule** column, click the Schedule icon ( ).

The Schedule [Adapter Name]—Basic page appears.

Note: The icon is blue when a schedule exists ( ).

4 To create a basic schedule, complete the information on the page using the descriptions in *Schedule [Adapter Name]—Basic* (on page 506), and proceed to step 7.

5 To create an advanced schedule, click the **Advanced** button.

The Schedule [Adapter Name]—Advanced page appears.

6 Complete the information on the page using the descriptions in *Schedule [Adapter Name]—Advanced* (on page 507).

7 Select **Actions > Save**.

or

Click **Save**.

Clearing the Get Requests job schedule for an adapter

Use this procedure to clear the Get Requests job schedule for the selected adapter. The Central Coding application gets data automatically from the InForm application when the Get Requests job schedule exists (and the job scheduler is running). If you clear the schedule and want jobs to run automatically, be sure to create the job schedule again.

1 Select **Administration > System > Adapters**.

The Adapters page appears.

2 Select an adapter.

3 Select **Actions > Clear Get Verbatims**.

> **Note:** A confirmation dialog box does **not** appear.

Adding a study to a Get Requests job schedule for an adapter

> **Note:** You must add each study to the schedule individually. The job schedule must exist before you can add a study to it. For more information, see ***Creating the Get Requests job schedule for an adapter*** (on page 220).
>
> **Note:** You can add studies to adapters and job schedules using the user interface or using the command line. For information about adding studies using the command line, see *Adding adapters and studies using the command line* in the *Installation Guide*.

1 Select **Administration > Management > Studies**.

The Study Information page appears.

2 Select the checkbox in the Get Requests column for each study that you want to add to the schedule for the associated adapter.

Removing a study from a Get Requests job schedule for an adapter

> **Note:** The Central Coding application only runs the jobs associated with a study when it is included in the job schedule(s) for its associated adapter.

1 Select **Administration > Management > Studies**.

The Study Information page appears.

2 Deselect the checkbox in the **Get Requests** column for each study that you want to remove from a Get Requests job schedule.

The Get Requests job schedule will no longer include the jobs for the associated study.

Working with the Return Codes job schedules

Creating the Return Codes job schedule for an adapter

Use this procedure to create the Return Codes job schedule for an adapter, which determines when data is sent to the InForm application for its associated study or studies. There is one Return Codes job schedule for each adapter. The schedule you define applies to all studies associated with the adapter.

You can:

- Create a basic job schedule based on days of the week and time of day.
- Create an advanced job schedule based on months, days of the week, and time of day.

The Return Codes job schedule has its own job queue that runs synchronously with the Get Requests and ASAP (non-scheduled) job queues.

1 Select **Administration > System > Adapters**.

The Adapters page appears.

2 Select an adapter.

3 In the **Return Codes** column, click the **Schedule** icon ( ).

The Schedule [Adapter Name]—Basic page appears.

> **Note: The icon is blue when a schedule exists ( ).**

4 To create a basic schedule, complete the information on the page using the descriptions in ***Schedule [Adapter Name]—Basic page*** (on page 506), and proceed to step 6.

5 To create an advanced schedule, click the **Advanced** button.

The Schedule [Adapter Name]—Advanced page appears.

6 Complete the information on the page using the descriptions in ***Schedule [Adapter Name]—Advanced page*** (on page 507).

7 Select **Actions > Save**.

or

Click **Save**.

Clearing the Return Codes job schedule for an adapter

Use this procedure to clear the Return Codes job schedule for the selected adapter. The Central Coding application returns data automatically to the InForm application when the Return Codes job schedule exists (and the job scheduler is running). If you clear the schedule and want jobs to run automatically, be sure to create the job schedule again.

> **Note:** Clearing the return codes clears codes in the Central Coding application. It does **not** clear the codes in the InForm application.

1 Select **Administration > System > Adapters**.

The Adapters page appears.

2 Select an adapter.

3 Select **Actions > Clear Return Codes**.

> **Note:** A confirmation dialog box does **not** appear.

Adding a study to a Return Codes job schedule for an adapter

> **Note:** You must add each study to the schedule individually. The job schedule must exist before you can add a study to it. For more information, see ***Creating the Return Codes job schedule for an adapter*** (on page 222).
>
> **Note:** You can add studies to adapters and job schedules using the user interface or using the command line. For information about adding studies using the command line, see *Adding adapters and studies using the command line* in the *Installation Guide*.

1 Select **Administration > Management > Studies**.

The Study Information page appears.

2 Select the checkbox in the **Return Codes** column for each study that you want to add to the schedule for the associated adapter.

Removing a study from a Return Codes job schedule for an adapter

> **Note:** The Central Coding application only runs the jobs associated with a study when it is included in the job schedule(s) for its associated adapter.

1 Select **Administration > Management > Studies**.

The Study Information page appears.

2 Deselect the checkbox in the **Return Codes** column for each study that you want to remove from a Return Codes job schedule.

The Return Codes job schedule(s) will no longer include the jobs for the associated study.

Working with non-scheduled jobs

About working with non-scheduled jobs

You can run the Get Requests and Return Codes jobs at non-scheduled times. Manually running the jobs at an off-peak time allows the data to be transferred without having an impact on performance.

However, when you manually run a Get Requests or Return Codes job, the Central Coding application creates a separate job queue to transfer the data for each job. These queues, called ASAP queues, run synchronously with the normally scheduled Get Requests and Return Codes job queues for each adapter. Therefore, running multiple, non-scheduled jobs in a short period of time can affect system performance. For more information, see ***Job queues*** (on page 26).

After the coding is up to date, you can add the adapter to the job schedules for normal request processing.

> **Note: The Central Coding application does not allow you to run multiple non-scheduled jobs for the same study at the same time. If you try to run more than one instance of a non-scheduled job, the system displays an error message and does not allow the job to run.**

Running non-scheduled Get Requests jobs

Use this procedure to manually get coding requests from the InForm application. You might want to do this for new adapters for existing studies that have a large amount of uncoded data.

Manually running the jobs at an off-peak time allows the data to be transferred without having an impact on performance. After the coding is up to date, you can add the adapter to the job schedules for normal request processing.

> **Note: You do not need to run non-scheduled jobs when you are working with a new study or with an existing study that does not have a large amount of uncoded data.**

1. Select **Administration > Management > Studies**.

   The Study Information page appears.

2. For the study you want to run the job for, click the **Run** icon ( ) in the **Get Requests** column.

   The Central Coding application creates a separate job queue and immediately begins getting verbatims for the selected study from the InForm application.

3. When the job completes, the **Results Exist** icon ( ) appears in the **Get Requests** column.

4. Click the **Results Exist** icon ( ) to open the View Job Log page, from which you can view details about the job.

Running non-scheduled Return Codes jobs

Use this procedure to manually return codes to the InForm application. You might want to do this for new adapters for existing studies that have a large amount of uncoded data.

Manually running the jobs at an off-peak time allows the data to be transferred without having an impact on performance. After the coding is up to date, you can add the adapter to the job schedules for normal request processing.

> **Note: You do not need to run non-scheduled jobs when you are working with a new study or with an existing study that does not have a large amount of uncoded data.**

1 Select **Administration > Management > Studies**.

The Study Information page appears.

2 For the study you want to run the job for, click the **Run** icon ( ) in the **Return Codes** column.

The Central Coding application creates a separate job queue and immediately begins returning the codes for the selected study to the InForm application.

3 When the job completes, the **Results Exist** icon ( ) appears in the **Return Codes** column.

4 Click the **Results Exist** icon ( ) to open the View Job Log page, from which you can view details about the job.

CHAPTER 15

Queries—InForm integration only

In this chapter

About queries

A query indicates that more information is required to code a request. You can generate queries on verbatims from the Coding Requests page, the Approvals page, or the coding browser. You can view the queries and modify query statuses in both the Central Coding application and the InForm application. For more information, see ***Creating a query from the Coding Requests or Approvals page*** (on page 70) or ***Creating a query from the coding browser*** (on page 72).

The Central Coding application sends the query information that you create to the InForm application for review by an InForm site user. Queries are delivered to the InForm application in a scheduled job called Exchange Query Updates, which runs after each iteration of the Get Requests job. The Exchange Query Updates job synchronizes query data in the InForm application and the Central Coding application each time it runs.

In the InForm application, the user that creates the query have the same ID for all queries opened in the Central Coding application. The user ID is set up on the System Configuration page in the Query Management Options section. The name entered in the Query Create User in Client field must also be added as a user with query rights for each InForm study that uses the Central Coding application.

For more information about jobs and job schedules, see ***Jobs and job schedules*** (on page 25).

An InForm query opened in the Central Coding application can be addressed in the InForm application in the following ways:

- An InForm site user modifies the verbatim associated with the query and marks the query as Answered.
- An InForm site user marks a query as Answered and states that the original value is correct.
- An InForm sponsor user closes the query.

> **Note: This is not the preferred way to close queries. A query opened by a coder should be closed by a coder.**

- The verbatim is deleted in the InForm application.

The query can be closed in the Central Coding application in the following ways:

- A Central Coding user closes the query if it is in the Answered state and the query can be coded.
- The query is closed automatically, if the auto close functionality is enabled, when the verbatim is successfully coded and approved.
- A Central Coding user with the Force Close Query right marks the query in any state as Closed.

> **Note: This is not the preferred way to close queries. Oracle recommends using this option as infrequently as possible.**

- The verbatim is deleted in the InForm application.

For more information about the auto close feature, see ***Configuring auto query and auto close settings*** (on page 233).

Checklist: Configuring your system for working with queries

Checklist: Configuring your system for working with queries			
☑		Task	For more information, see
❑	1	Assign roles and rights to users who work with queries.	***Default roles and rights*** (on page 541). ***Default rights*** (on page 546). ***Required rights for working with queries*** (on page 230).
❑	2	Schedule jobs for each study. **Note:** Query data in the InForm application and the Central Coding application is synchronized depending on the Get Requests job schedule.	***Working with the Get Requests job schedules*** (on page 220). ***Working with the Return Codes job schedules*** (on page 222).
❑	3	Assign studies to study groups. **Note:** Study group settings determine auto close and auto query settings for queries.	***Study groups*** (on page 205). ***Configuring auto query and auto close settings*** (on page 233).
❑	4	Set system configuration options for queries.	***Setting system configuration options for query management*** (on page 231).
❑	5	Create a list of standard query reasons.	***Setting the standard reasons for queries*** (on page 232).
❑	6	Configure auto query and auto close settings for studies.	***Study groups*** (on page 205). ***Creating and modifying a study group*** (on page 205). ***Adding a study to a study group*** (on page 206). ***Auto query and auto close settings*** (on page 233). ***Configuring auto query and auto close settings*** (on page 233).

Required rights for working with queries

Right	Category	Description
Force Close Query	Approval	Allows you to close a query in any state. **Note:** Oracle recommends that you only use this option as infrequently as possible.
Manage Auto Queries	Approval	Allows you to view, edit, and delete auto queries.
Manage Query Standard Reasons	Approval	Allows you to add and edit the reasons that appear in the Reason drop-down list when a user creates, closes, or deletes a query.
Reissue Query	Approval	Allows you to reissue an answered query in the Open or Candidate state.
Issue Candidate Query	Coding	Allows you to create a query in the Candidate state. **Note:** A limited group of coders and approvers generally have this right.
Issue Open Query	Coding	Allows you to create a query in the Open state.
Review Query Listing	Coding	Allows you to navigate to the Queries page.

Setting system configuration options for queries

1. Select **Administration > System > System Configuration**.

   The System Configuration page appears.

2. Select **Actions > Edit**.

   or

   Click **Edit**.

3. In the **Query Management Options** section, specify the following.

   - **Maximum Query Reason Length**—The maximum number of characters a user can enter in the **Reason** field in the Create Query dialog box. By default, this option is set to 255 characters.

     Oracle recommends configuring this setting to match the maximum number of characters allowed in the version of the InForm application with which you are integrating the Central Coding application.

     > **Note:** This setting also applies to the standard query reasons an administrator sets on the Query Default Reason List page.

   - **Query Create User in Client**—The account name for a user in the InForm application that has rights to create queries and indicates to sites and sponsors that the query was opened by a coder. The account name is case-sensitive.

     - For single sign-on InForm studies, the account name has two parts: Trial Company/Short Org ID.user ID.
     - For all other studies, the account name is the user ID only.

     Specify the InForm account name to use during the ExchangeQueryUpdate job. This account name is used to create and update queries in the InForm application, and the user name appears in the InForm application as the user who created each Central Coding query. You do not need to specify a password for the user.

     > **Note:** Create User in Client is blank by default. You must enter an account name that matches an InForm user with query rights in the InForm application in order to transfer query data between the InForm and Central Coding applications.

Standard query reasons

When you create a query in the Central Coding application, you must specify a reason for creating, closing, reissuing, or deleting the query. This reason appears in the Central Coding application and in the InForm application, and is used to communicate to an InForm user the problem with a verbatim as entered. To facilitate more efficient query entry, administrators can create a list of commonly used query reasons to appear in the Reason drop-down list in the Create Query, Close Query, Reissue Query, and Cancel Query dialog boxes, and specify which of the default reasons should appear first in the list.

The Central Coding application includes the following reasons by default. For more information about modifying the existing reasons, or adding a new reason, see ***Setting the standard reasons for queries*** (on page 232).

Action type	Reasons
Create	• Make verbatim more specific • Missing context item (s) • Verbatim misspelled
Close	• Response satisfies query
Reissue	• Response does not satisfy query
Delete	• Query is not valid anymore

Setting the standard reasons for queries

1 **Administration > System > Query Standard Reasons**.

The Query Standard Reason List page appears.

2 Optionally, to view the existing standard reasons for a specific query action, in the **Action Type** drop-down list, select the action type (Open, Close, Reissue, or Delete).

3 Click **Add**.

The Add [Action Type] Standard Reason page appears.

4 In the **Standard Reason** text box, type the text for the reason.

5 In the **Action Type** field, select the action type with which to associate the reason.

6 Click **Save**.

Auto query and auto close settings

You can configure the Central Coding application to create or close queries automatically, under certain conditions, for a specified group of studies, using the Allow Auto Query by Default and Auto Close Query by Default study group configuration settings.

> **Note:** This is especially useful for CROs who manage several customers conducting studies. A CRO can create a study group for each customer.

When a query is marked Answered, and its associated verbatim is either coded and approved, or deleted, you can choose to automatically close the query. You can also instruct the Central Coding application to automatically associate a particular query with a specified verbatim every time the verbatim is entered in the Central Coding application, for a specific study group.

To use this functionality, you must:

1 Create a study group or modify the default System study group.

   For more information, see *Creating and modifying a study group* (on page 205).

2 Add studies to the study group.

   Use the study group to associate studies for which you intend to assign the same auto query and auto close settings. For more information, see *Adding a study to a study group* (on page 206).

3 Use the Allow Auto Query by Default and Allow Auto Close Query by Default settings to configure the auto query and auto close settings for the study group.

   The auto query and auto close settings apply to each study in the study group. For more information, see *Configuring auto query and auto close settings* (on page 233).

When you enable the Allow Auto Query by Default option on the Study Group Detail page for a specific study group, the **Add to auto query list** checkbox appears in the Create Query dialog box when you associate a query with a verbatim in a study that belongs to the study group. This option is selected by default. When the checkbox remains selected, the Central Coding application duplicates the query and associates it with each verbatim in the study group that is subsequently created in the Central Coding application. Deselect this checkbox if you do not want the Central Coding application to add the verbatim to the auto query list. An administrator maintains the auto query list from the Auto Query List page.

When you enable the Allow Auto Close Query by Default option for a study group, the **Auto-close query upon coding complete** checkbox appears in the Create Query dialog box when you create a query associated with a verbatim in a study that belongs to the study group. When the checkbox remains selected, the Central Coding application automatically closes the query when the associated verbatim is successfully coded and approved. Deselect this checkbox for a specific query to prevent the Central Coding application from closing the query after the verbatim is either successfully coded and approved, or deleted.

Configuring auto query and auto close settings

1 Create a study group and add studies to the group.

   For more information, see *Creating and modifying a study group* (on page 205).

2 Select **Administration > Management > Study Groups**.

The Study Group List page appears.

3 Select the study group to configure its auto query and auto close settings.

4 Click **Edit**.

5 By default, the following options are selected:

- **Allow Auto Query By Default**—Allows the Central Coding application to duplicate an existing query and apply it to all matching verbatims in the study group that are subsequently entered in the Central Coding application. To manually create queries for individual verbatims in the study group, deselect this option.
- **Allow Auto Close Query By Default**—Allows the Central Coding application to automatically close a query if the verbatim associated with the query is successfully coded and approved. To manually close all queries associated with verbatims in the study group, deselect this option.

Managing auto queries

An administrator can view and manage queries that were created using the Allow Auto Query by Default setting on the Auto Query List page. The Auto Query List page displays verbatims for which a query is automatically generated for each instance of the verbatim in a specific study group. An administrator can use the auto query list to view and delete verbatim query entries that were created automatically in the Central Coding application.

Viewing the auto query list

1 Select **Queries**.

The Queries page appears.

2 Select **Actions > Manage Auto Query**.

The Auto Query List page appears.

Removing a verbatim query entry from the auto query list

1 Select **Queries**.

The Queries page appears.

2 Select **Actions > Manage Auto Query**.

The Auto Query List page appears.

3 Optionally, in the **Study Group** drop-down list, filter the page to display only verbatim query entries associated with a specific study group.

4 Select the verbatim for which you no longer want the Central Coding application to automatically generate a query.

5 Click **Delete Auto Query**.

CHAPTER 16

Dictionary element configuration

In this chapter

About configuring the dictionary element options

You can perform the element configuration at the dictionary level or at the coding definition level.

- **Dictionary level**—The Central Coding application uses the defined settings to initially configure the settings when creating a new coding definition, and when using the dictionary when no coding definition is in effect (for example, when browsing the dictionary from the Dictionaries page).
- **Coding definition level**—The Central Coding application uses the defined settings whenever the coding definition is in use.

Note: The initial settings for a coding definition are derived from the settings defined for the associated dictionary.

Note: You can configure the element configuration settings in any order. However, Oracle recommends that you set the autocode target(s) first because the elements that are available to include in the request list view pages, in the coding browser displays, as the returned elements, and for reconciliation in impact analysis are determined by the autocode target(s).

Element configuration at the dictionary level

Configuring the autocode targets—Dictionary level

select the autocode target(s) that you want the system to use when autocoding a request against a particular dictionary.

Each dictionary has a default primary autocode target. You can select a different primary target and, optionally, you can select a secondary target. Only the elements that the dictionary allows as targets are available for selection. Use a secondary target if you want to autocode to something other than the primary autocode target (a non-primary path for MedDRA or MedDRA-J, or to include the ATC codes 1-4 for WHO-DD). There are no secondary autocode targets for the JDrug dictionary.

1. Select **Coding Setup > Dictionaries**.

   The Dictionaries page appears.

2. Select a dictionary.
3. Select **Actions > Element Configuration**.

   The Element Configuration page appears. The elements that appear in the **Elements** section of the page depend on the dictionary type.

4. In the **Autocode Target** column in the **Elements** section at the bottom of the page, select the element that you want to use as the primary autocode target.

   > **Note:** Selecting certain dictionary levels may cause additional options to appear in the **Elements** section of the page. The type and number of options depend on the dictionary type.

5. Optionally, in the **Secondary Target** column in the **Elements** section at the bottom of the page, select the element that you want to use as the secondary autocode target.

   > **Note:** To clear the selection of a **Secondary Target** option, select **Actions > Clear Phase 2 Target.**

6. Select **Actions > Save**.

   or

   Click **Save**.

   The application uses the selected dictionary level(s) as the initial primary and secondary targets when creating coding definitions for the selected dictionary.

Configuring the coding request list views—Dictionary level

Use this procedure to configure which fields appear on the coding request list view pages for requests associated with a particular dictionary. The coding request list views appear on the Coding Requests, Approvals, and All Requests pages. You can add, reorder, and remove elements to customize the information that appears on the request list view pages.

1 Select **Coding Setup > Dictionaries**.

The Dictionaries page appears.

2 Select a dictionary.

3 Select **Actions > Element Configuration**.

The Element Configuration page appears. The elements that appear in the **Elements** section of the page depend on the dictionary type.

4 Select the elements that you want to include in the request list views.

a In the **Request List** column in the **Elements** section at the bottom of the page, click the **green plus sign (**) to add the corresponding element to the request list views.

> **Note:** A plus sign appears only for the level term elements that have been configured to be returned with a coding.

The plus sign turns grey ( ) and the element appears in the **Request List Page Display** section at the top left of the page.

b Repeat step 4a for each element to include in the request list views.

5 Reorder the elements so that they will appear in the proper order in the request list views.

a In the **Request List Page Display** section at the top left of the page, click an **up arrow (**) to move its corresponding element up one level.

This action moves the element to the **left** in the request list views.

b In the **Request List Page Display** section at the top left of the page, click the **down arrow (**) to move the corresponding element down one level.

This action moves the element to the **right** in the request list views.

6 Remove any elements that you do not want to include in the request list views.

a In the **Request List Page Display** section at the top left of the page, click the **red "X" (**) to remove the corresponding element.

This action removes the element from the request list views.

b Repeat step 6a for each element to remove from the request list view.

7 Select **Actions > Save**.

or

Click **Save**.

The application uses the configured elements as the initial configuration when creating coding definitions for the selected dictionary.

Configuring the coding browser Search mode display—Dictionary level

Use this procedure to configure the fields that appear in the coding browser Search mode display for a particular dictionary type. You can add, reorder, and remove elements to customize the information that appears in the coding browser display.

1 Select **Coding Setup > Dictionaries**.

The Dictionaries page appears.

2 Select a dictionary.

3 Select **Actions > Element Configuration**.

The Element Configuration page appears. The elements that appear in the **Elements** section of the page depend on the dictionary type.

4 Select the elements to include in the Search mode display.

a In the **Search Term** column in the **Elements** section at the bottom of the page, click the **green plus sign (**) for each element that corresponds to the term for a level, or to a piece of additional information that you want to include in the Search mode display.

> **Note: A plus sign appears only for the level term elements that have been configured to be returned with a coding.**

The plus sign turns grey ( ) and the element appears in the **Search Page Display** section at the top center of the page.

b In the **Search Code** column in the **Elements** section at the bottom of the page, click the **green plus sign (**) for each element that corresponds to the code for a level to include in the Search mode display.

The plus sign turns grey ( ) and the element appears in the **Search Page Display** section at the top center of the page.

5 Reorder the elements so that they will appear in the proper order in the Search mode display.

a In the **Search Page Display** section at the top center of the page, click the **up arrow ( )** to move the corresponding element up one level.

This action moves the element to the **left** in the Search mode display.

b In the **Search Page Display** section at the top center of the page, click the **down arrow (**) to move the corresponding element down one level.

This action moves the element to the **right** in the Search mode display.

6 Remove any elements that you do not want to include in the Search mode display.

a In the **Search Page Display** section at the top center of the page, click the **red "X" (**) to remove the corresponding element.

This action removes the element from the Search mode display.

b Repeat step 6a for each element that you want to remove from the Search mode display.

7 In the **Search Page Display** section at the top center of the page, select the **In Field** checkbox for each element to include in the **In field** drop-down list in the coding browser.

Selecting an element allows for searching in that field.

8 Select **Actions > Save**.

or

Click **Save**.

The application uses the configured elements as the initial configuration when creating coding definitions for the selected dictionary.

Configuring the coding browser Browse mode display—Dictionary level

Use this procedure to configure the fields that appear in the coding browser Browse mode display for a particular dictionary. You can add, reorder, and remove elements to customize the information that appears in the coding browser display.

1 Select **Coding Setup > Dictionaries**.

The Dictionaries page appears.

2 Select a dictionary.

3 Select **Actions > Element Configuration**.

The Element Configuration page appears. The elements that appear in the **Elements** section of the page depend on the dictionary type.

4 Select the elements that you want to include in the Browse mode display.

a In the **Browse** column in the **Elements** section at the bottom of the page, click the **green plus sign (**) for each element to include in the Browse mode display.

The plus sign turns grey ( ) and the element appears in the **Browse Page Display** section at the top right of the page.

b Repeat step 4a for each element to include in the Browse mode display.

5 Reorder the elements so that they will appear in the proper order in the Browse mode display.

> **Note:** Only additional information elements may be re-ordered.

a In the **Browse Page Display** section at the top right of the page, click the **up arrow ( )** to move the corresponding element up one level.

This action moves the element to the **left** in the Browse mode display.

b In the **Browse Page Display** section at the top right of the page, click the **down arrow (**) to move the corresponding element down one level.

This action moves the element to the **right** in the Browse mode display.

6 Remove any elements that you do not want to include in the Browse mode display.

a In the **Browse Page Display** section at the top right of the page, click the **red "X" (**) to remove the corresponding element.

This action removes the element from the Browse mode display.

b Repeat step 6a for each element that you want to remove from the Browse mode display.

7 In the **Browse Page Display** section at the top right of the page, select the **Include Code** checkbox for each element for which you want to display the code with the term in the coding browser display.

This option appears only for elements that represent the terms for levels in the dictionary.

8 In the **Browse Page Display** section at the top right of the page, select the **Include Label** checkbox for each element for which you want to include the label in the coding browser display.

This option appears only for elements that represent additional information on a level.

9 Select **Actions > Save**.

or

Click **Save**.

The application uses the configured elements as the initial configuration when creating coding definitions for the selected dictionary.

Configuring the dictionary elements returned with a coding—Dictionary level

Use this procedure to set the dictionary elements returned with a coding for a particular dictionary. These settings determine what elements are returned and saved in the Central Coding database with a selected coding in the coding browser or by autocoding to the Central Coding application, and which of those elements are exported to the Microsoft Excel spreadsheet software with the request.

For each element, you can choose whether to send it back to the Central Coding application and whether to allow the element to be exported. An element can only be returned to the source application if it is configured to be returned with a coding.

1 Select **Coding Setup > Dictionaries**.

The Dictionaries page appears.

2 Select a dictionary.

3 Select **Actions > Element Configuration**.

The Element Configuration page appears. The elements that appear in the **Elements** section of the page depend on the dictionary type.

4 In the **Return** column in the **Elements** section at the bottom of the page, select the elements to be returned to the Central Coding application and saved in the Central Coding database from the coding browser or by autocoding.

> **Note:** Only returned data is available to be retrieved by, or sent to, the source application.

5 In the **Exportable** column in the **Elements** section at the bottom of the page, select the elements that you want to be exportable.

> **Note:** This option is available for selection if you also select the element in the **Return** column.

6 Select **Actions > Save**.

or

Click **Save**.

The application uses the configured elements as the initial configuration when creating coding definitions for the selected dictionary.

Selecting elements for autoreconciliation during impact analysis—Dictionary level

> **Note:** For more information, see ***Central Coding system configuration settings for impact analysis*** (on page 291).

1 Select **Coding Setup > Dictionaries**.

The Dictionaries page appears.

2 Select a dictionary.

3 Select **Actions > Element Configuration**.

The Element Configuration page appears. The elements that appear in the **Elements** section of the page depend on the dictionary type.

4 In the **Requires Reconciliation** column in the **Elements** section at the bottom of the page, select the elements that you want to be reconciled during impact analysis.

> **Note:** By default, the items that are selected in the Return column are also selected in this column. You can edit the selections as needed.

5 Select **Actions > Save**.

or

Click **Save**.

The application uses the configured elements as the initial configuration when creating coding definitions for the selected dictionary.

Element configuration at the coding definition level

Configuring the autocode targets—Coding definition level

Use this procedure to select the autocode target(s) that you want the system to use when autocoding a request against a particular coding definition.

Each dictionary has a default primary autocode target. You can select a different primary target and, optionally, you can select a secondary target. Only the elements that the dictionary allows as targets are available for selection. Use a secondary target if you want to autocode to something other than the primary autocode target (a non-primary path for MedDRA or MedDRA-J, or to include the ATC codes 1-4 for WHO-DD). There are no secondary autocode targets for the JDrug dictionary.

1 Select **Coding Setup > Coding Definitions**.

   The Coding Definitions page appears.

2 Select a coding definition.

3 Select **Actions > Element Configuration**.

   The Element Configuration page appears. The elements that appear in the **Elements** section of the page depend on the dictionary type. For a description of the fields on this page, see *Element Configuration page* (on page 397).

4 In the **Autocode Target** column in the **Elements** section at the bottom of the page, select the element that you want to use as the primary autocode target.

   > **Note:** Selecting certain dictionary levels may cause additional options to appear in the **Elements** section of the page. The type and number of options depend on the dictionary type.

5 Optionally, in the **Secondary Target** column in the **Elements** section at the bottom of the page, select the element that you want to use as the secondary autocode target.

   > **Note:** To clear the selection of a **Secondary Target** option, select **Actions > Clear Phase 2 Target.**

6 Select **Actions > Save**.

   or

   Click **Save**.

   The application uses the selected dictionary level(s) as the primary and secondary targets when autocoding against the selected coding definition.

Configuring the coding request list views—Coding definition level

Use this procedure to configure which fields appear on the coding request list view pages for requests associated with a particular coding definition. The coding request list views appear on the Coding Requests, Approvals, and All Requests pages. You can add, reorder, and remove elements to customize the information that appears on the request list view pages. Any changes you make using this procedure will appear in the user interface for all requests that are associated with the selected coding definition.

1 Select **Coding Setup > Coding Definitions**.

The Coding Definitions page appears.

2 Select a coding definition.

3 Select **Actions > Element Configuration**.

The Element Configuration page appears. The elements that appear in the **Elements** section of the page depend on the dictionary type.

4 Select the elements that you want to include in the request list views.

a In the **Request List** column in the **Elements** section at the bottom of the page, click the **green plus sign (**) to add the corresponding element to the request list views.

> **Note:** A plus sign appears only for the level term elements that have been configured to be returned with a coding.

The plus sign turns grey ( ) and the element appears in the **Request List Page Display** section at the top left of the page.

b Repeat step 4a for each element to include in the request list views.

5 Reorder the elements so that they will appear in the proper order in the request list views.

a In the **Request List Page Display** section at the top left of the page, click an **up arrow (**) to move its corresponding element up one level.

This action moves the element to the **left** in the request list views.

b In the **Request List Page Display** section at the top left of the page, click the **down arrow (**) to move the corresponding element down one level.

This action moves the element to the **right** in the request list views.

6 Remove any elements that you do not want to include in the request list views.

a In the **Request List Page Display** section at the top left of the page, click the **red "X" (**) to remove the corresponding element.

This action removes the element from the request list views.

b Repeat step 6a for each element to remove from the request list view.

7 Select **Actions > Save**.

or

Click **Save**.

Configuring the coding browser Search mode display—Coding definition level

Use this procedure to configure the fields that appear in the coding browser Search mode display for a particular coding definition. You can add, reorder, and remove elements to customize the information that appears in the coding browser display. Any changes you make using this procedure will appear in the coding browser search mode display for all requests that are associated with the selected coding definition.

1 Select **Coding Setup > Coding Definitions**.

The Coding Definitions page appears.

2 Select a coding definition.

3 Select **Actions > Element Configuration**.

The Element Configuration page appears. The elements that appear in the **Elements** section of the page depend on the dictionary type.

4 Select the elements to include in the Search mode display.

a In the **Search Term** column in the **Elements** section at the bottom of the page, click the **green plus sign (**) for each element that corresponds to the term for a level, or to a piece of additional information that you want to include in the Search mode display.

> **Note:** A plus sign appears only for the level term elements that have been configured to be returned with a coding.

The plus sign turns grey ( ) and the element appears in the **Search Page Display** section at the top center of the page.

b In the **Search Code** column in the **Elements** section at the bottom of the page, click the **green plus sign (**) for each element that corresponds to the code for a level to include in the Search mode display.

The plus sign turns grey ( ) and the element appears in the **Search Page Display** section at the top center of the page.

5 Reorder the elements so that they will appear in the proper order in the Search mode display.

a In the **Search Page Display** section at the top center of the page, click the **up arrow (** **)** to move the corresponding element up one level.

This action moves the element to the **left** in the Search mode display.

b In the **Search Page Display** section at the top center of the page, click the **down arrow (**) to move the corresponding element down one level.

This action moves the element to the **right** in the Search mode display.

6 Remove any elements that you do not want to include in the Search mode display.

a In the **Search Page Display** section at the top center of the page, click the **red "X" (**) to remove the corresponding element.

This action removes the element from the Search mode display.

b Repeat step 6a for each element that you want to remove from the Search mode display.

7 In the **Search Page Display** section at the top center of the page, select the **In Field** checkbox for each element to include in the **In field** drop-down list in the coding browser.

Selecting an element allows for searching in that field.

8 Select **Actions > Save**.

or

Click **Save**.

Configuring the coding browser Browse mode display—Coding definition level

Use this procedure to configure the fields that appear in the coding browser Browse mode display for a particular coding definition. You can add, reorder, and remove elements to customize the information that appears in the coding browser display. Any changes you make using this procedure will appear in the coding browser Browse mode display for all requests that are associated with the selected coding definition.

1 Select **Coding Setup > Coding Definitions**.

The Coding Definitions page appears.

2 Select a coding definition.

3 Select **Actions > Element Configuration**.

The Element Configuration page appears. The elements that appear in the **Elements** section of the page depend on the dictionary type.

4 Select the elements that you want to include in the Browse mode display.

a In the **Browse** column in the **Elements** section at the bottom of the page, click the **green plus sign (**) for each element to include in the Browse mode display.

The plus sign turns grey ( ) and the element appears in the **Browse Page Display** section at the top right of the page.

b Repeat step 4a for each element to include in the Browse mode display.

5 Reorder the elements so that they will appear in the proper order in the Browse mode display.

Note: Only additional information elements may be re-ordered.

a In the **Browse Page Display** section at the top right of the page, click the **up arrow ( )** to move the corresponding element up one level.

This action moves the element to the **left** in the Browse mode display.

b In the **Browse Page Display** section at the top right of the page, click the **down arrow (**) to move the corresponding element down one level.

This action moves the element to the **right** in the Browse mode display.

6 Remove any elements that you do not want to include in the Browse mode display.

a In the **Browse Page Display** section at the top right of the page, click the **red "X" (**) to remove the corresponding element.

This action removes the element from the Browse mode display.

b Repeat step 6a for each element that you want to remove from the Browse mode display.

7 In the **Browse Page Display** section at the top right of the page, select the **Include Code** checkbox for each element for which you want to display the code with the term in the coding browser display.

This option appears only for elements that represent the terms for levels in the dictionary.

8 In the **Browse Page Display** section at the top right of the page, select the **Include Label** checkbox for each element for which you want to include the label in the coding browser display.

This option appears only for elements that represent additional information on a level.

9 Select **Actions > Save**.

or

Click **Save**.

Configuring the dictionary elements returned with a coding—Coding definition level

Use this procedure to set the dictionary elements returned with a coding for a particular coding definition. These settings determine what elements are returned and saved in the Central Coding database with a selected coding in the coding browser or by autocoding to the Central Coding application, and which of those elements are exported to the Microsoft Excel spreadsheet software with the request.

For each element, you can choose whether to send it back to the Central Coding application and whether to allow the element to be exported. An element can only be returned to the source application if it is configured to be returned with a coding.

Note: Any changes you make using this procedure will affect all coding requests associated with the selected dictionary type.

1 Select **Coding Setup > Coding Definitions**.

The Coding Definitions page appears.

2 Select a coding definition.

3 Select **Actions > Element Configuration**.

The Element Configuration page appears. The elements that appear in the **Elements** section of the page depend on the dictionary type.

4 In the **Return** column in the **Elements** section at the bottom of the page, select the elements to be returned to the Central Coding application and saved in the Central Coding database from the coding browser or by autocoding.

Note: Only returned data is available to be retrieved by, or sent to, the source application.

5 In the **Exportable** column in the **Elements** section at the bottom of the page, select the elements that you want to be exportable.

> **Note:** This option is available for selection if you also select the element in the **Return** column.

6 Select **Actions > Save**.

or

Click **Save**.

Configuring elements for autoreconciliation during impact analysis—Coding definition level

> **Note:** For more information, see ***Central Coding system configuration settings for impact analysis*** (on page 291).

1 Select **Coding Setup > Coding Definitions**.

The Coding Definitions page appears.

2 Select a coding definition.

3 Select **Actions > Element Configuration**.

The Element Configuration page appears. The elements that appear in the **Elements** section of the page depend on the dictionary type.

4 In the **Requires Reconciliation** column in the **Elements** section at the bottom of the page, select the elements that you want to be reconciled during impact analysis.

> **Note:** By default, the items that are selected in the Return column are also selected in this column. You can edit the selections as needed.

5 Select **Actions > Save**.

or

Click **Save**.

Manually resetting the element configuration for a coding definition

Use this procedure to reset the element configuration settings for a coding definition to the element configuration settings defined for its associated dictionary. You might want to do this if:

- You changed the element configuration settings for a coding definition and you want to reset them to their default settings.
- An administrator updated the dictionary type information for the dictionary associated with a coding definition.

  An administrator can update dictionary type information for installed dictionaries, which can affect the element configuration settings for the dictionary. The dictionary type can only be updated using the Dictionary Loader tool. For more information, see *Updating a dictionary type and applying the changes to installed dictionaries* in the *Installation Guide*.

  > **Note:** Changes to the dictionary element configuration settings that result from a dictionary type update apply only to coding definitions created *after* the dictionary update. If you want the updated element configuration settings to be applied to existing coding definitions, you must use this procedure to manually reset the element configuration settings for each coding definition.

1 Select **Coding Setup > Coding Definitions**.

The Coding Definitions page appears.

2 Select one or more coding definitions.

3 Select **Actions > Reset Element Configuration**.

A confirmation dialog box appears.

4 Click **OK**.

PART 4: ADMINISTRATOR TASKS—Ongoing management

CHAPTER 17

Using the job log

In this chapter

About using the job log

Use the job log to view detailed information about the Get Requests or Return Codes jobs, and to stop a running job.

Viewing the job log for all adapters in the system

- Select **Administration > System > Jobs**.

  The View Job Log page appears. The details for all jobs run by the Central Coding application appear. For a description of the fields on this page, see ***View Job Log page*** (on page 499).

Viewing the job log for a specific adapter

1 Select **Administration > Management > Studies**.

The Study Information page appears.

2 Click the **Results Exists** icon ( ) in the **Get Requests** or **Return Codes** column for the adapter whose job log you want to view.

The View Job Log page appears. For a description of the fields on this page, see ***View Job Log page*** (on page 499).

Stopping a running job

1 Select **Administration > System > Jobs**.

The View Job Log page appears. The details for all jobs run by the Central Coding application appear. For a description of the fields on this page, see *View Job Log page* (on page 499).

You can also view the job lob for a specific adapter. For more information, see *Viewing the job log for a specific adapter* (on page 256).

2 Select **Actions > Stop Job**.

CHAPTER 18

Managing unassigned coding requests

In this chapter

About checking for unassigned coding requests

You can check that all coding requests that enter the Central Coding application from the source application are being correctly routed by the existing assignment rules.

When the requests and assignment rules are set up correctly, no requests appear on the Unassigned Requests page. Requests that appear on the Unassigned Requests page are not assigned to a work team, or are not being routed by the existing assignment rules.

> **Note:** An administrator typically performs these tasks.

Viewing the list of unassigned requests

Use this procedure to view the requests that are not being distributed by the assignment rules. When the requests and assignment rules are set up correctly, no requests appear on the Unassigned Requests page. Requests that appear on the Unassigned Requests page are not assigned to a work team, or are not being routed by the existing assignment rules.

If there are any unassigned requests, make sure that the status of the synonym list, stopword list, and algorithm used by the coding definition associated with the assignment rules is Active.

- Select **Coding Setup > Unassigned Requests**.

  The Unassigned Requests page appears. For a description of the fields on this page, see *Unassigned Requests page* (on page 460).

Viewing the details of an unassigned coding request

1. Select **Coding Setup > Unassigned Requests**.

   The Unassigned Requests page appears.

2. Select a request.

3. Select **Actions > Details**.

   or

   Click the **Details** button.

   or

   Click the **Details** link.

   The Request Details page appears. For a description of the fields on this page, see ***Request Details page*** (on page 462).

Running the assignment rules

Use this procedure to run the assignment rules to check whether a change to an assignment rule correctly routes a request. You can only run assignment rules on unassigned requests.

- When there are unassigned requests in the Central Coding application, you can update the assignment rules and then manually run them to check whether they correctly route the requests.
- If you change an option in an assignment rule you cannot manually run that rule on requests that are already assigned to check whether it continues to correctly route the requests. You can only run the rule on unassigned requests.

1 Select **Coding Setup > Unassigned Requests**.

The Unassigned Requests page appears. All requests that are not correctly routed by the assignment rules appear on the Unassigned Requests page.

2 Select the requests on which to run the assignment rules.

> **Note: If you do not select a request or requests, the Central Coding application runs the assignment rules on all the unassigned requests that appear on the Unassigned Requests page.**

3 Select **Actions > Run Assignment Rules**.

or

Click **Run Assignment Rules**.

CHAPTER 19

Managing all coding requests

In this chapter

About managing all coding requests

You can view and manage information for all coding requests that are in the Central Coding application. These include the coding requests that are assigned to all work teams and are in studies marked as both locked and unlocked in the Central Coding application. For more information, see ***Locking a study in the Central Coding application*** (on page 211).

The coding requests that appear to coders and approvers on the Coding Requests and Approvals pages include only those requests that are assigned to their work teams, and that are from studies marked as unlocked in the Central Coding application.

Note: An administrator typically performs these tasks.

Viewing all coding requests and their statuses

Use this procedure to view the complete list of coding requests in the Central Coding application, view the work teams assigned to requests, and run an audit history report for a request. This list includes the requests assigned to all work teams, and requests in studies marked as either locked or unlocked in the Central Coding application.

1 Select **Administration > Management > Requests**.
The All Requests page appears. For a description of the fields on this page, see ***All Requests page*** (on page 481).

2 Optionally, filter the list of requests to identify the items that you want to view, and click **Apply**.

You can do any or all of the following:

- In the **Verbatim** field, type the verbatim text that you want to search for.

  Searches are *case-insensitive*. The search supports the special characters *, %, ?, and _. The search text field can be an arbitrary text string and can contain wildcard characters to facilitate matching when the exact text is not known. The percent sign (%) or asterisk (*) matches any sequence of characters; the question mark (?) or underscore (_) matches any single character.

- In the **Subject ID** field, type the subject ID for the subject that you want to search for.
- In the **Show** filter field, select the coding requests that you want to view, based on the coding request status, delivery status, or autocode status.
  - **All**—Displays all options.
  - **Uncoded**—Displays only the requests that are not coded.
  - **Partially coded**—If coding to a primary and secondary target, displays only the requests for which the system has found a single match for the primary autocode target and multiple matches for the secondary target. A user must interactively code the request.
  - **Recode**—Displays only the requests that must be recoded. Requests with this status have been disapproved by an approver.
  - **Needs Review**—Displays only the requests that have been successfully autocoded but must be reviewed.
  - **Coded**—Displays only the requests that have been successfully coded.
  - **Completed**—Displays only the requests that have been successfully coded and approved.
  - **Delivered**—Displays only the requests that have been successfully returned to the source application.
  - **Undeliverable**—Displays only the requests for which the attempt to return the request to the source application was unsuccessful.
  - **Autocoded**—Displays only the requests that have been autocoded.
- In the **Study** filter field, select a study for which you want to view the associated coding requests. The page displays only those requests that are associated with the selected study.
- In the **View** filter field, select a coding definition for which you want to view the associated coding requests. The page displays only those requests that are associated with the selected coding definition.

Viewing the details of any coding request

1. Select **Administration > Management > Requests**.

   The All Requests page appears.

2. Select a request.

3. Select **Actions > Details**.

   or

   Click the **Details** button.

   or

   Click the **Details** link.

   The Request Details page appears. For a description of the fields on this page, see ***Request Details page*** (on page 488).

Viewing work team assignments

1 Select **Administration > Management > Requests**.

The All Requests page appears.

2 Select a request.

3 Select **Actions > View Work Team Assignments**.

or

Click the **View Work Team Assignments** button.

The Workteam Assignment page appears. For a description of the fields on this page, see *Workteam Assignment page—View mode* (on page 486).

Editing work team assignments

1. Select **Administration > Management > Requests**.

   The All Requests page appears.

2. Select a request.

3. Select **Actions > View Work Team Assignments**.

   or

   Click the **View Work Team Assignments** button.

   The Workteam Assignment page appears.

4. Select **Actions > Edit**.

   or

   Click **Edit**.

5. Edit the information on the page using the descriptions in *Workteam Assignment page—Edit mode* (on page 487).

Resending all undeliverable requests

Use this procedure to change the delivery status of all requests with a failed delivery to the source application to **Needs delivery**. This allows the request(s) to be resent to the source application.

> **Note:** An administrator typically performs this task, which requires the Retry Delivery right. An administrator can also resend one undeliverable request at one time. For more information, see ***Resending an undeliverable request*** (on page 67).

1 Select **Administration > Management > Requests**.

The All Requests page appears.

2 Optionally, view the hover text over the icon for a request with a delivery status of **Undeliverable ( )** to view the reason the delivery was unsuccessful.

For more information, see ***Error messages for undeliverable requests to the InForm application*** (on page 67).

3 Select **Actions > Retry Delivery for All**.

The delivery status for each request changes to **Coded, awaiting delivery** ( ).

All requests with a coding status of **Completed, awaiting delivery** ( ) are available for delivery to the InForm application. The job queue picks up the requests and delivers them to the InForm application at the next scheduled time.

CHAPTER 20

Managing system locks

In this chapter

About managing system locks

You can view all locked objects in the system, and can revoke the locks so that other users can access the objects. Items are considered to be locked when they are being edited by a logged on user. The application unlocks objects when a user is done editing. However, if there is a system failure before the lock is removed, or a user does not remove the lock, you might have to manually remove the lock.

Note: An administrator typically performs these tasks.

Viewing the list of locked objects

- Select **Administration > System > Locks**.

  The Locks page appears. For a description of the fields on this page, see ***Locks page*** (on page 501).

Revoking a lock

Use this procedure to revoke the lock on a system object. Items are considered to be locked when they are being edited by a logged on user. The application unlocks objects when a user is done editing. However, if there is a system failure before the lock is removed, or a user does not remove the lock, you might have to manually remove the lock.

1 Select **Administration > System > Locks**.

   The Locks page appears.

2 Select one or more objects.

3 Select **Actions > Revoke**.

   or

   Click the **Revoke** button.

   The system clears the lock on each selected object. Any unsaved changes made to the object are lost.

CHAPTER 21

Viewing coding dictionary information

In this chapter

About viewing coding dictionary information

You can view the list of loaded dictionaries, the details for each dictionary, and the coding browser for each dictionary to become familiar with the terms in the dictionary hierarchy.

The coding dictionaries are loaded using the Dictionary Loader tool. Dictionaries cannot be added or removed using the Central Coding user interface.

> **Note:** A dictionary manager typically performs these tasks.

Viewing the list of installed dictionaries

- Select **Coding Setup > Dictionaries**.

  The Dictionaries page appears. For a description of the fields on this page, see ***Dictionaries page*** (on page 394).

Viewing the details of a dictionary

1 Select **Coding Setup > Dictionaries**.

The Dictionaries page appears.

2 Select a dictionary.

3 Select **Actions > View Details**.

or

Click **View Details**.

The [Dictionary Name] page appears. For a description of the fields on this page, see *[Dictionary Name] page* (on page 395).

Browsing the dictionary hierarchy

Use this procedure to open the coding browser so that you can view the terms associated with the dictionary hierarchy.

Note: **You can use this version of the coding browser for review purposes only. It cannot be used to code requests.**

1 Select **Coding Setup > Dictionaries**.

The Dictionaries page appears.

2 Select a dictionary.

3 Select **Actions > Browse Dictionary**.

The Coding Browser dialog box appears. By default, the coding browser opens in Search mode. For a description of the fields on this page, see *Coding Browser dialog box—Search mode* (on page 324).

4 Click the **Browse** icon ( ).

The page refreshes and the contents of the browser change. For a description of the fields on this page, see *Coding Browser dialog box—Browse mode* (on page 329).

The hierarchy of terms for the selected dictionary appears in a tree format in the display area at the bottom of the dialog box.

5 Expand and collapse the tree as needed until you become familiar with the terms in the dictionary hierarchy.

or

Click the **Search** icon ( ) and use the **Search** actions.

The **Auto** button runs an abbreviated algorithm with the following steps:

- Exact Term Match.
- Eliminate Punctuation.
- Exact Term Match.
- Term Contains All Words.

CHAPTER 22

Auditing

In this chapter

About auditing

For any coding request, you can run an audit history report that tracks many system activities.

Note: An administrator typically performs this task.

The Central Coding application audits changes to:

- Users, roles, rights, and work teams.
- Coding request information.

  Includes changes to codes, terms, dictionary version, and the reason for change.
- Coding request statuses.

  Includes approvals.
- Dictionaries.

  Includes changes to synonym lists associated with the dictionary and changes from impact analysis.
- Synonym lists.
- Stopword lists.
- Algorithms.

The application records which user makes the change, and the date and time of the change. Changes do not overwrite previously recorded information. The audit trail is an incremental, chronological trail of each change and the reason for the change.

The InForm application audits changes to coded values.

Viewing the audit history for a request

1. Select **Administration > Management > Requests**.

   The All Requests page appears.

2. Select a request.

3. Select **Actions > View Audit History**.

   or

   Click the **View Audit History** button.

   The Audit History Report page appears, from which you can view the audit history for a request in PDF format.

   > **Note:** All dates in the report appear with the date format set on the System Configuration page.

PART 5: ADMINISTRATOR TASKS—Impact analysis

CHAPTER 23

Impact analysis

In this chapter

About impact analysis

Impact analysis is the process of evaluating both coded and uncoded verbatim terms against a new dictionary version to determine which verbatim terms will be impacted by the upgrade.

> **Note: The Central Coding application supports impact analysis for the MedDRA, MedDRA-J, WHO-DD, and JDrug dictionaries. The application does not support impact analysis for custom dictionaries.**

Reasons to use impact analysis

During the life of many clinical studies, it is sometimes necessary to change the version of the dictionary that the study is coded against. When a new version of a dictionary becomes available, you may choose to use the new version, and in some cases it may be mandatory to use the new version for regulatory reports.

You can use impact analysis to:

- Upgrade to a new dictionary version.
- Reassign verbatims to different work teams for the same version of the dictionary.
- Change a coding definition for a set of verbatims for the same version of the dictionary.

The impact analysis feature in the Central Coding application provides flexibility so that you can report only the information about coding changes that matters to you. For example, if you code to the LLT, you might want to know if the LLT changes, but you might not care about path changes. Or, you might just want to know if any paths change.

Dictionary path change details are tracked in the Central Coding Configuration Settings document, which is available from Oracle Global Support. These changes are reviewed by customers and Oracle before the upgrade begins.

Pre-requisites for running impact analysis

1. Obtain and verify the dictionary license.
2. Load the dictionary.
3. Load the synonym lists (if applicable).
4. Confirm that you have access to all studies to be upgraded.
5. Verify that all users have the correct coding roles and assigned rights.

   The following rights are required to perform the impact analysis functions.

   - Reconcile Synonyms
   - Reconcile Verbatims
   - Edit CodingDefs
   - Edit SynonymLists
   - Run Impact Analysis
6. In the Central Coding application, stop the **Get Request** job for each study that has a dictionary to be upgraded.

   This step prevents new verbatim terms from coming into the Central Coding application while the upgrade is in process.
7. In the Central Coding application, verify the impact analysis configuration settings.

   For more information, see ***Central Coding system configuration settings for impact analysis*** (on page 291).
8. If necessary, modify the impact analysis configuration settings.

   For more information, see ***Modify the Central Coding system configuration settings*** (on page 296).

Central Coding system configuration settings for impact analysis

The following impact analysis actions can be configured to occur automatically, or to require a user action in the user interface.

- ***Reassociate Synonym*** (on page 292)
- ***Set Delete Synonym As Default*** (on page 293)
- ***Allow Uncode*** (on page 294)
- ***Skip Auto Suggestion Step*** (on page 294)
- ***Requires Reconciliation*** (on page 295)
- ***Auto Reconcile Terms*** (on page 295)

Note: These options are documented in the Central Coding Configuration Settings document, which is available from Oracle Global Support.

Reassociate Synonym

Purpose

Indicates whether you want synonyms to be automatically or manually reassociated with current terms in the new dictionary. The choice affects which synonyms are available to manually reconcile (reassociate) on the Reconcile Synonyms page. This setting is only valid for MedDRA LLT terms.

Location in the user interface

Administration folder > System Configuration page

Options

- **Selected**—If you select this option, all synonyms associated with LLTs that have become non-current in the new version of the dictionary are automatically reassociated to a current LLT in the new dictionary version where possible.
    - The Central Coding application reassociates the synonyms according to MSSO policy:
    - Every LLT is associated with a PT.
    - Every PT has an associated LLT that has the same code and term as the PT.

  The synonyms that are automatically reassociated do not appear on the Reconcile Synonyms page. However, they are included in the Synonym Reconciliation Report.

- **Not selected**—If you do not select this option (default), you must manually reconcile (reassociate) the synonyms with current terms in the new dictionary, or delete the synonyms.

  The synonyms that require reconciliation appear on the Reconcile Synonyms page and are included in the Synonym Reconciliation Report.

Set Delete Synonym As Default

Purpose

Indicates whether you want unused synonyms to be automatically marked for deletion. The choice may save a step during the reconciling synonyms step on the Reconcile Synonyms page.

Location in user interface

Administration folder > System Configuration page

Options

- **Selected**—If you select this option, the Delete option in the Action column on the Reconcile Synonyms page is selected by default for all deleted terms.

  Users can edit the selections as needed. The synonyms are deleted when the changes are approved.

- **Not selected**—If you do not select this option (default), the Delete option in the Action column on the Reconcile Synonyms page is not selected by default.

  The deleted terms on the Reconcile Synonyms page are not automatically marked for deletion. Users can interactively code the synonym to find a new term.

> **Note: When a user performs the Approve All action, a message appears to remind the user that one or more synonyms will be deleted. You must perform an action on each synonym to continue.**

Allow Uncode

Purpose

Allow users to have the option to not accept the code and term value from either the original or the new coding dictionary, and to return the verbatim to the coder's queue. The choice affects whether an option is available during the reconciling verbatims step on the Reconcile Verbatims page.

Location

Administration folder > System Configuration page.

Options

- **Selected**—If you select this option, the Accept Uncode column appears on the Reconcile Verbatims page.

  During the verbatim reconciliation process users can select the original code and term, select the new code and term, manually recode the verbatim, or choose the Uncode option. If they choose the Uncode option the verbatim is returned to the coder's queue.

- **Not selected**—If you do not select this option (default), the Accept Uncode column does not appear on the Reconcile Verbatims page.

  During the verbatim reconciliation process users can select the original code and term, select the new code and term, or manually recode the verbatim.

  > **Note:** When a user performs the Approve All action, a message appears if any verbatims are not coded, and the approval does not proceed.

Skip Auto Suggestion Step

Purpose

Indicates whether you want impact analysis to skip the Auto Suggestion step in the coding algorithm during impact analysis, which allows it to search for a possible better choice even if there is an auto-suggestion for a verbatim.

Location in user interface

Administration folder > System Configuration page

Options

- **Selected**—If you select this option (default), impact analysis skips the Auto Suggestion step in the coding algorithm. As a result, impact analysis can continue to look for a possible better choice regardless of whether there is an auto-suggestion for the verbatim.
- **Not selected**—If you do not select this option, the Central Coding application uses the auto-suggestion for a verbatim (if any) as the coding and impact analysis cannot continue to search for a possible better choice.

Requires Reconciliation

Purpose

Indicates the dictionary levels for which you want the code and term to be autoreconciled.

Location in user interface

Coding Definitions folder > Element Configuration page

Options

- **Selected**—If you select this option for a dictionary level, any difference in the term or the code of the level, or the text of an Additional Information element, will require reconciliation.

  By default, the items that are selected in the Return column are also selected in this column. You can edit the selections as needed.

  New codings that differ from the original codings only in elements that do not have this checkbox selected do not appear on the Reconcile Verbatims page. However, they are included in the Impact Analysis Report.

  > **Note:** If the Auto Reconcile Terms checkbox on the Source And Target Coding Definitions dialog box is selected, only the code will require autoreconciliation.

- **Not selected**—If you do not select this option for a dictionary level, any difference in the term or the code of the level, or the text of an Additional Information element, will not require reconciliation.

  Although a level may not be selected, if an Additional Information element from that level is selected, it is considered in the second comparison.

  This setting is coding definition specific. An impact analysis run uses the setting of the target coding definition.

Auto Reconcile Terms

Purpose

Indicates whether you do not want to consider any changes in the terms on any level. You select this option when choosing the coding definitions during impact analysis. You can set this option for each new (target) coding definition.

Location in user interface

Coding Definitions folder > Choose Source And Target Coding Definitions dialog box

Options

- **Selected**—If you select this option, any changes in the terms on any level are not considered. The Central Coding application autoreconciles only the terms and requires manual reconciliation only of the codes.

> **Note: The application autoreconciles the term, even if the Requires Reconciliation option is selected for an element on the Element Configuration page.**

- **Not selected**—If you do not select this option during impact analysis, any changes in the terms on any level are considered.

Modify the Central Coding system configuration settings

Use this procedure to modify the default reconciliation options that appear on the Reconcile Verbatims page. These options are installed with the Central Coding application. For more information, see *Reconcile Verbatims page* (on page 449).

You can modify the default selections using this procedure or change individual selections as needed when you reconcile the verbatims. For more information, see *Reconciling verbatims* (on page 310).

1 Select **Administration > System > Reconciliation Options**.

   The Reconciliation Options page—View mode appears. For a description of the fields on this page, see *Reconciliation Options page—View mode* (on page 510).

2 From the **Actions** menu, select **Edit**.

   or

   Click the **Edit** button.

   The Reconciliation Options page—Edit mode appears. For a description of the fields on this page, see *Reconciliation Options page—Edit mode* (on page 512).

3 In the **Default Actions** column, select the options that you want to be automatically selected on the **Reconcile Verbatims** page.

   Users can edit the selections as needed.

   When the **Allow Uncode** option on the System Configuration page is selected, the options in the Default Actions column are:

   - **Accept New**—The new autocode result (code, term, and path represented by the code and term) displays in the **New Code and Term** column and is selected by default.

- **Keep Original**—The coding (code, term, and path represented by the code and term) in the **Original Code and Term** column is selected by default.
- **Uncoded**—The **Uncode** option in the **Accept Uncode** column is selected by default.

> **Note:** This option allows the Central Coding application to clear the code value and return the verbatim to the coder's queue to be recoded in the standard workflow, so that you can complete the impact analysis process. Before you can approve the verbatims you reconcile, you must either recode the verbatims or mark them as uncoded. For more information, see *Reconciling verbatims* (on page 310).

When the **Allow Uncode** option on the System Configuration page is **not** selected, the options in the Default Action column are:

- **Accept New**—The new autocode result (code, term, and path represented by the code and term) displays in the **New Code and Term** column and is selected by default.
- **Keep Original**—The coding (code, term, and path represented by the code and term) in the **Original Code and Term** column is selected by default.

4 Select **Actions > Save**.

or

Click **Save**.

Steps to perform impact analysis

Step 1: Upgrade synonym lists

Upgrading a synonym list for impact analysis

Use this procedure to create a new synonym list that is a copy of an existing synonym list for use in impact analysis. You can upgrade (copy) an existing synonym list or you can create a new synonym list from scratch.

> **Note:** After you upgrade a synonym list to a particular dictionary version, you cannot upgrade it to the same dictionary version again.

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select a synonym list.

> **Note:** The synonym list you select must belong to a dictionary type for which there is a new dictionary.

3 Select **Actions > Upgrade**.

The Upgrade Synonym List dialog box appears. For a description of the fields on this page, see *Upgrade Synonym List dialog box* (on page 414).

4 In the new **Synonym List** field, type a name for the new synonym list.

> **Note:** The name of the synonym list must be unique.

5 If the synonym list you are upgrading is inherited and the parent synonym list has not yet been upgraded, in the new **Parent Synonym List** field, type a name for the upgraded parent synonym list.

> **Note:** If the synonym list you are upgrading is inherited and the parent synonym list has already been upgraded, the new **Parent Synonym List** field is populated with the name for the upgraded parent synonym list.

6 In the new **Dictionary Version** field, select the dictionary version for the new synonym list.

7 Click **OK**.

The Upgrade Synonym List In Process page appears. For a description of the fields on this page, see *Upgrade Synonym List In Process page* (on page 416).

If there are no synonym differences between the source and target dictionaries:

- The **Step** column displays **Update**.
- The **Status** column displays **Not Started**.
- You can run the Synonym Reconciliation Report (optional).

  For more information, see *Running the Synonym Reconciliation Report* (on page 299).
- You can update the synonyms to save all approved changes to the database.

For more information, see ***Updating a synonym list*** (on page 303).

If there are synonym differences between the source and target dictionaries:

- The **Step** column displays **Reconcile**.
- The **Status** column displays **Not Started**.
- You can reconcile the synonyms, approve all changes, and update the changes to the database.

  For more information, see ***Reconciling synonyms*** (on page 301) and ***Updating a synonym list*** (on page 303).

> **Note: Depending on the timing and size of the synonym list, you might see a step and status of Prepare—Not Started or Prepare—Running before the Update and/or Reconcile steps appear.**

Running the Synonym Reconciliation Report

The Synonym Reconciliation Report displays a snapshot of the synonym upgrade and reconciliation process at the time you run the report.

You can run the report at any time before you update the synonym list; that is, after the synonym upgrade and/or during or after the synonym reconciliation process. When you update the synonym list to save the changes to the database, the Central Coding application automatically runs the final version of the report.

The Central Coding application saves only the current version of the report. However, you can keep a history of all versions of the report that you run by saving them from the Document Viewer page.

> **Note: This differs from the way the Central Coding application manages the standard reports. You can run and save multiple versions of the standard reports.**

1. Select **Coding Setup > Synonym Lists**.

   The Synonym Lists page appears.

2. Select **Actions > View Upgrade Process**.

   The Upgrade Synonym List In Process page appears.

3. Select a synonym list.

   > **Note: The synonym list must have a step and status of Reconcile—Not Started, Reconcile—In Process, or Update—Not Started.**

4. Click the **Generate Report** button.

   When the report is complete, the Results Exist ( ) icon appears in the Report column.

5. Click the **Results Exist** ( ) icon.

   The Document Viewer page appears and displays the report in PDF format.

Viewing the status of synonym list upgrades

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select **Actions > View Upgrade Process**.

The Upgrade Synonym List In Process page appears. For a description of the fields on this page, see *Upgrade Synonym List In Process page* (on page 416).

Canceling a synonym list upgrade

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select **Actions > View Upgrade Process**.

The Upgrade Synonym List In Process page appears.

3 Select a synonym list.

4 Select **Actions > Cancel**.

Rerunning a synonym list upgrade

> **Note:** You can only rerun a synonym list upgrade if the Status on the Upgrade Synonym List In Process page is Failed.

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select **Actions > View Upgrade Process**.

The Upgrade Synonym List In Process page appears.

3 Select **Actions > Rerun**.

Step 2 : Reconcile synonyms

Reconciling synonyms

Use this procedure to reconcile the synonym differences between dictionary versions. If the code and term pair associated with any synonym no longer exists in the new dictionary, you must reassign or delete the synonyms. You can choose to reconcile all or some of the synonyms at one time.

> **Note: It is the combination of the code and term that must exist in the new dictionary. If the code still exists but the term associated with that code has changed in the new version of the dictionary, the synonym must be reconciled.**

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select **Actions > View Upgrade Process**.

The Upgrade Synonym List In Process page appears.

3 Select a synonym list.

The list must have a step and status of **Reconcile— NotStarted** or **Reconcile—InProcess**.

4 Select **Actions > Reconcile**.

or

Click the **Reconcile** button.

The Reconcile Synonyms page appears. For a description of the fields on this page, see *Reconcile Synonyms page* (on page 418).

5 Reconcile each synonym by selecting a new term and code to associate it with or by deleting it.

> **Note: An administrator determines whether the Central Coding application automatically reassociates synonyms with current terms in the new dictionary (MedDRA only). The synonyms that are automatically reassociated do not appear on the Reconcile Synonyms page. However, they do appear in the Synonym Reconciliation Report.**

For each synonym you can:

- Interactively code the synonym(s) by clicking the **Code** link in the **New Term** column to open the **Coding Browser** dialog box.

  Interactive coding can be required for one synonym or for several synonyms associated with the term. After you code the synonym, it appears in the **New Term** column.

  or

- Remove the associated synonym from the synonym list by selecting **Delete** in the **Action** column.

  > **Note: An administrator determines whether the Delete option is selected by default for all synonyms associated to a code and term that do not exist in the new dictionary. For more information, see *Central Coding system configuration settings for impact analysis* (on page 291).**

6 If you do not want to finish reconciling the synonyms or are not ready to approve your changes, click **Previous** to return to the previous page.

You can continue reconciling the synonyms at a later time.

7 To save all your reconciliation selections, do one of the following:

- Select **Actions > Approve All**.

  or

- Click the **Approve All** button.

A confirmation dialog box appears. You can select or click **Approve All** at any point during the reconciliation process.

8 To continue with the approval, click **OK**.

The application deletes any synonyms that have not been recoded. The Central Coding application makes permanent the synonym list with all the existing and new synonym terms and codes.

9 To cancel the approval, click **Cancel**.

Running the Synonym Reconciliation Report

The Synonym Reconciliation Report displays a snapshot of the synonym upgrade and reconciliation process at the time you run the report.

You can run the report at any time before you update the synonym list; that is, after the synonym upgrade and/or during or after the synonym reconciliation process. When you update the synonym list to save the changes to the database, the Central Coding application automatically runs the final version of the report.

The Central Coding application saves only the current version of the report. However, you can keep a history of all versions of the report that you run by saving them from the Document Viewer page.

> **Note:** This differs from the way the Central Coding application manages the standard reports. You can run and save multiple versions of the standard reports.

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select **Actions > View Upgrade Process**.

The Upgrade Synonym List In Process page appears.

3 Select a synonym list.

> **Note:** The synonym list must have a step and status of Reconcile—Not Started, Reconcile—In Process, or Update—Not Started.

4 Click the **Generate Report** button.

When the report is complete, the Results Exist ( ) icon appears in the Report column.

5 Click the **Results Exist** ( ) icon.

The Document Viewer page appears and displays the report in PDF format.

Saving the synonym changes to the database

Use this procedure to save all approved synonym changes made during the reconciliation process to the system database. The Central Coding application moves the changes from the temporary work area portion of the database to the system database. This action makes the synonym list permanent in the system database.

Caution: You cannot undo this action.

1 Select **Coding Setup > Synonym Lists**.

The Synonym Lists page appears.

2 Select **Actions > View Upgrade Process**.

The Upgrade Synonym List In Process page appears. For a description of the fields on this page, see ***Upgrade Synonym List In Process page*** (on page 416).

3 Select a synonym list.

4 Select **Actions > Update**.

or

Click the **Update** button.

A confirmation dialog box appears.

5 Click **OK**.

The Central Coding application automatically generates the final version of the Synonym Reconciliation Report and saves the new synonym list to the database.

Step 3: Upgrade a coding definition and assignment rules

Upgrading a coding definition and assignment rules

Use this procedure to create a new coding definition. You can use a coding definition for an earlier version of a dictionary as the basis for the new coding definition that uses a new dictionary version. This includes selecting a synonym list for the new dictionary version and deciding how to handle the assignment rules for the new coding definition.

Before performing the upgrade, you must decide how to manage the assignment rules. For more information, see ***Upgrade Coding Definition dialog box*** (on page 442). You can choose to:

- Update all the existing assignment rules associated with the source coding definition to use the new coding definition.
- Copy all existing assignment rules associated with the source coding definition, and make the

copied rules use the new coding definition.

- Create all assignment rules from scratch.

> **Note:** If you choose to create a new coding definition from scratch, you must create and assign new assignment rules as needed. For more information, see *Adding a coding definition* (on page 182) and *Adding an assignment rule* (on page 190).

1 Select **Coding Setup > Coding Definitions**.

The Coding Definitions page appears.

2 Select a coding definition.

3 From the **Actions** menu, select **Upgrade**.

The Upgrade Coding Definition dialog box appears. For a description of the fields on this page, see *Upgrade Coding Definition dialog box* (on page 442).

4 In the new **Coding Definition Name** field, type a name for the new coding definition.

5 In the new **Dictionary Version** field, select the dictionary version that you want to associate with the new coding definition.

6 In the new **Synonym List** field, select the synonym list that you want to associate with the new coding definition.

7 Decide how you want to manage the assignment rules.

- Select the **Update assignment rules with new coding definition** option to replace the source coding definition with the target coding definition for all existing assignment rules.
  - Use this option to assign any future requests that would have been assigned to the source coding definition to the new coding definition.
  - During the upgrade process, all assignment rules that were assigned to the source coding definition will be assigned to the new upgraded coding definition.

  > **Note:** All new requests that meet the rules will be assigned to the new coding definition during the next run of assignment rules.

- Select the **Copy assignment rules and use new coding definition** option if you want to make a copy of the assignment rules associated with the source coding definition for the new (target) coding definition, so that you can edit them based on the set of verbatims you want coded with the new dictionary version.
  - The original assignment rules will continue to assign future requests to the old coding definition.
  - During the upgrade process, all assignment rules that were assigned to the source coding definition will be copied to another rule and the new rule will be assigned to the upgraded coding definition.

  > **Note:** The Central Coding application runs the assignment rules in the order they appear on the Assignment Rules page. Because the copy of the assignment rule(s) appears after the "original" assignment rules on the Assignment Rule page, selecting this option has no immediate effect on new coding requests.

- Select the **No Changes to Assignment Rules** option if you want to create a new set of assignment rules from scratch.

  The assignment rules are not touched during the upgrade process. You must create assignment rules for the new coding definition after the upgrade. For more information, see *Adding an assignment rule* (on page 190).

  > **Note:** The original assignment rules will continue to assign future requests to the old coding definition.

> **Note:** Make sure that, if desired, you change the priority of the new assignment rules so that they run as needed. For more information, see ***Changing the order in which assignment rules are run*** (on page 194).
>
> **Note:** While you are editing assignment rules, you might want to remove any affected studies from the job scheduler. For more information, see ***Removing a study from a Get Requests job schedule for an adapter*** (on page 221) and ***Removing a study from a Return Codes job schedule for an adapter*** (on page 223).

8 Click **OK**.

The Central Coding application validates all auto-suggestions belonging to the source coding definition; it copies all valid auto-suggestions to the new coding definition and deletes invalid ones.

Step 4: Run impact analysis

Running impact analysis

Use this procedure to run impact analysis, which compares the values of your coded data between the selected dictionary versions.

> **Note:** The impact analysis process copies all the data into a temporary work area portion of the database. It does not update the actual request tables. This allows you to work on reconciling the verbatims at your own pace. Then, when you are ready, you can approve and update the data. Updating the data saves the approved changes to the request tables and applies the changes to your clinical (production) data. For more information, see ***Reconciling verbatims*** (on page 310) and ***Saving the verbatim changes to the database*** (on page 312).

1 Select **Coding Setup > Coding Definitions**.

The Coding Definitions page appears.

2 Optionally, select a coding definition.

- If you select a coding definition, the one you select appears in the **Source Coding Definition Name** field in the Choose Source And Target Coding Definitions dialog box. See steps 3 and 4.
- If you do not select a coding definition, you can select one in the **Source Coding Definition Name** field in the Choose Source And Target Coding Definitions dialog box. See steps 3 and 4.

3 Select **Actions > Run Impact Analysis**.

The Choose Source And Target Coding Definitions dialog box appears. For a description of the fields on this page, see ***Choose Source And Target Coding Definitions dialog box*** (on page 446).

4 In the **Source Coding Definition Name** field, select a coding definition.

If you selected a coding definition in step 2, it appears in the field.

5 In the **Target Coding Definition Name** field, select the coding definition that you want to compare the data against.

6 Select the **Auto Reconcile Terms** checkbox if you do not want to consider any changes in terms on any level.

> **Note:** The application autoreconciles the term, even if the **Requires Reconciliation** option is selected for an element on the Element Configuration page. For more information, see ***Central Coding system configuration settings for impact analysis*** (on page 291).

7 Click **OK**.

The In Process page appears. For a description of the fields on this page, see ***In Process page*** (on page 447).

If there are no code differences between the dictionary versions:

- The **Step** column displays **Update**.
- The **Status** column displays **Not Started**.
- You can run the Impact Analysis Report (optional).

  For more information, see ***Running the Impact Analysis Report*** (on page 309).
- You can update the verbatims.

  For more information, see ***Saving the verbatim changes to the database*** (on page 312).

If there are code differences between the dictionary versions:

- The **Step** column displays **Reconcile**.
- The **Status** column displays **Not Started**.
- You can reconcile the verbatims, approve all changes, and update the changes to the database.

  For more information, see ***Reconciling verbatims*** (on page 310) and ***Saving the verbatim changes to the database*** (on page 312).

> **Note:** Depending on the timing and the number of requests to be processed, you might see a step and status of Prepare—Not Started or Prepare—Running before the Update and/or Reconcile steps appear.

Exporting impact analysis data

Use this procedure to export all reconciled data to a commas separated value (CSV) file so that you can view it automatically as a Microsoft Excel spreadsheet software file within the browser, or so that you can save it.

1 Navigate to the In Process page.

You can access this page from the **Impact Analysis** folder:

- Select **Coding Setup > Impact Analysis**.

  The In Process page appears.

or

You can access this page from the **Coding Definition** folder:

a Select **Coding Setup > Coding Definitions**.

The Coding Definitions page appears.

b Select **Actions > View Impact Analysis Process**.

The In Process page appears.

2 Select a coding definition set.

3 Click **Export**.

The Export Result Viewer page appears with a Windows File Download dialog box.

4 Click **Open**.

The Microsoft Excel spreadsheet software opens and displays the reconciled data; the file is in CSV format.

The information that is exported is the same information that is in the Impact Analysis Report.

or

Click **Save**.

The Windows Save As dialog box appears, from which you can save the file in CSV format.

Canceling the impact analysis process

1 Navigate to the In Process page.

You can access this page from the **Impact Analysis** folder:

- Select **Coding Setup > Impact Analysis**.

  The In Process page appears.

or

You can access this page from the **Coding Definition** folder:

a Select **Coding Setup > Coding Definitions**.

The Coding Definitions page appears.

b Select **Actions > View Impact Analysis Process**.

The In Process page appears.

2 Select a coding definition set.

You can only perform this action when the step and status are:

- Reconciliation—Not Started
- Reconciliation—In Process
- Update—Not Started

You cannot perform this action if the step and status are:

- Update—Not Started
- Update—Complete

3 Select **Actions > Cancel**.

A confirmation dialog box appears.

Rerunning impact analysis

> **Note:** You can only rerun impact analysis if the Status on the In Process page is Failed.

1 Navigate to the In Process page.

You can access this page from the **Impact Analysis** folder:

- Select **Coding Setup > Impact Analysis**.

  The In Process page appears.

or

You can access this page from the **Coding Definition** folder:

a Select **Coding Setup > Coding Definitions**.

The Coding Definitions page appears.

b Select **Actions > View Impact Analysis Process**.

The In Process page appears.

2 Select a coding definition set.

3 Select **Actions > Rerun**.

Running the Impact Analysis Report

The Impact Analysis Report provides a snapshot of the impact analysis and verbatim reconciliation process at the time you run the report.

You can run the report at any time before you update the clinical data; that is, after running impact analysis and/or during or after the verbatim reconciliation process. When you update your clinical data to save the changes to the database, the system automatically runs the final version of the report.

The Central Coding application saves only the current version of the report. However, you can keep a history of all versions of the report that you run by saving them from the Document Viewer page.

> **Note: This differs from the way the Central Coding application manages the standard reports. You can run and save multiple versions of the standard reports.**

1 Navigate to the In Process page.

You can access this page from the **Impact Analysis** folder:

- Select **Coding Setup > Impact Analysis**.

  The In Process page appears.

or

You can access this page from the **Coding Definition** folder:

a Select **Coding Setup > Coding Definitions**.

The Coding Definitions page appears.

b Select **Actions > View Upgrade Process**.

The In Process page appears.

2 Select a coding definition set.

> **Note: The coding definition set must have a step and status of Reconcile—Not Started, Reconcile—In Process, or Update—Not Started.**

3 Click the **Generate Report** button.

When the report is complete, the Results Exist ( ) icon appears in the Report column.

4 Click the **Results Exist** ( ) icon.

The Document Viewer page appears and displays the report in PDF format.

Step 5: Reconcile verbatims

Reconciling verbatims

Use this procedure to reconcile the verbatims after running impact analysis. For each verbatim you can choose to accept the original code and term, the new code and term, search for a new code and term using interactive coding, or if allowed, return the verbatim to the coder's queue. You can choose to reconcile all or some of the verbatims at one time.

1 Navigate to the In Process page.

You can access this page from the **Impact Analysis** folder:

- Select **Coding Setup > Impact Analysis**.

  The In Process page appears.

or

You can access this page from the **Coding Definition** folder:

a Select **Coding Setup > Coding Definitions**.

The Coding Definitions page appears.

b Select **Actions > View Impact Analysis Process**.

The In Process page appears.

2 Select a coding definition set.

The coding definition set must have a status of Reconcile—Not Started or Reconcile—In Process.

3 Select **Actions > Reconcile**.

or

Click the **Reconcile** button.

The Reconcile Verbatims page appears. For a description of the fields on this page, see *Reconcile Verbatims page* (on page 449).

4 Review the results of the impact analysis for each verbatim.

- Optionally, in the **Reason** filter field, select the verbatims that you want to view, based on the type of change found during impact analysis.
  - **No selection**—No filter; displays all options.
  - Deleted Terms
  - Path Change
  - Path Change Same Primary SOC (MedDRA only)
  - Path Change New Primary SOC (MedDRA only)
  - **Possible Better Choice**—The autocoding algorithm has found a new match even though the original choice is still available in the new dictionary.
- In the **Reason** column, view the type of change found during impact analysis.
- In the **Original Code and Term** column, view the original code and term from the source

dictionary.

- In the **New Code and Term** column, view the autocoded code and term from the new target dictionary, if one was found. A verbatim target might appear on this page because it did not autocode with the new coding definition.

> **Note:** Click the code and term link in the Original Code and Term column or the New Code and Term column to open the Compare Coding Results dialog box, from which you can view the differences in the coding results between the source and target dictionary versions. For more information, see ***Compare Coding Results dialog box*** (on page 452).

5 Reconcile each verbatim, as needed.

- To accept the original coding represented by the code and term that appear in the **Original Code and Term** column, click the radio button in the column.

  The radio button is disabled if the original term or path no longer exists in the new dictionary.

- To accept the new coding represented by the code and term that appear in the **New Code and Term** column, click the radio button in the column.

  A code and term appear if the impact analysis process was able to autocode the verbatim using the new coding definition.

- To interactively code the verbatim (and its context items, if it has them), click the **Code** link in the **New Code and Term** column.

  The Coding Browser dialog box appears.

- To clear the existing coding result and return the verbatim to the coder's queue to be recoded, click the **Uncode** radio button in the **Accept Uncode** column.

> **Note:** The Accept Uncode column appears only if an administrator selects the Allow Uncode option on the System Configuration page. For more information, see ***Central Coding system configuration settings for impact analysis*** (on page 291).

6 Optionally, select the **Done** checkbox for each verbatim to indicate that all decisions for the verbatim are complete.

This feature is designed to help you keep track of the work to be done on the verbatim. It has no effect on the Approve All action.

7 If you do not want to finish reconciling the verbatims or are not ready to approve your changes, click **Previous** to return to the previous page.

You can continue reconciling the verbatims at a later time.

8 To save all your reconciliation selections, do one of the following:

- Select **Actions > Approve All**.

  or

- Click the **Approve All** button.

A confirmation dialog box appears. You can select or click **Approve All** at any point during the reconciliation process.

9 To continue with the approval, click **OK**.

The application applies the default reconciliation option to any verbatims that you do not explicitly reconcile. The In Process page reappears.

10 To cancel the approval, click **Cancel**.

Step 6: Save changes

Saving the verbatim changes to the database

Use this procedure to save all approved verbatim changes made during the reconciliation process to the system database. The Central Coding application moves the changes from the temporary work area portion of the database to the system database, applies the changes to your clinical data, and displays the updated verbatims in the user interface.

> **Caution:** You cannot undo this action.

1 Navigate to the In Process page.

You can access this page from the **Impact Analysis** folder:

- Select **Coding Setup > Impact Analysis**.

  The In Process page appears.

or

You can access this page from the **Coding Definition** folder:

a Select **Coding Setup > Coding Definitions**.

The Coding Definitions page appears.

b Select **Actions > View Impact Analysis Process**.

The In Process page appears.

2 Select a coding definition set.

The coding definition set must have a step and state of **Update—Not Started**.

3 Select **Actions > Update**.

or

Click the **Update** button.

A confirmation dialog box appears.

4 Click **OK**.

The Central Coding application automatically generates the final version of the Impact Analysis Report and saves all approved verbatim changes to the database.

Post impact analysis tasks

1 Run the **Return Code** job for each study that has been updated.

This step sends the code values back to the InForm application.

2 Enable the **Get Requests** job for each study that has been updated.

3 Verify that all terms now appear under the correct coding definition and dictionary.

This information appears on the Coding Requests page (in the Coding Requests folder) and on the All Requests page (in the Administration > Management folder).

APPENDIX A

Page-level help reference

In this appendix

Main window

My Profile dialog box

Use the My Profile dialog box to view the details of your user profile, initiate a change to your log in password, and set the number of rows you want to display on a list view page.

Fields

My Profile dialog box	
Field	**Description**
User Information	
Display name	Your screen name. The display name appears in the upper-left corner of the user interface.
Account name	Your system log in name (user name).
Change password link	Opens the **Change Password** dialog box, from which you can change your log in password. **Note:** This link appears only when an administrator sets the account type to **SuperUser** or **User**. It does not appear if the account type is **Machine**.
User Settings	
List page size	The number of rows that you want to display on list view pages. You can enter a value from 1 to 100. The default is 15. Use this option to specify a page size that works best for the screen resolution you are using to allow the data to fit on one page. **Note:** You must manually refresh the page after changing this setting.
Personal Information	
First name	Your first name.
Last name	Your last name.
Title	Your title, such as Dr., Mr., or Mrs.
Culture	A combination of attributes including, but not limited to, language, date formats, and currency.
Address	Your street address.
City	Your city.
State / Province	Your state or province.
Postal code	Your postal code.
Country	Your country.
Company	The name of the company where you work.

My Profile dialog box	
Field	**Description**
Department	The department where you work.
Position	Your job or company position.
Home page	The address of your Web page.
Email	Your email address.
Fax	Your fax number.
Telephone	Your telephone number.
Mobile	Your cellular/mobile telephone number.
Pager	Your pager number.
Description	Descriptive information about you or your user profile.

Buttons

My Profile dialog box	
Button	**Description**
Save	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Change Password dialog box

Use the Change Password dialog box to change your log in password.

Fields

Change Password dialog box	
Field	**Description**
User Name	Your system log in name. This field is read-only.
Old Password	The log in password you are currently using. REQUIRED.
New Password / Confirm Password	The new log in password you want to use. REQUIRED. **Note:** Passwords can be from 1 to 32 characters. For security reasons, Oracle recommends using a combination of letters and numbers and a minimum of 6 characters. Passwords are case-sensitive.

Buttons

Change Password dialog box	
Button	Description
Save	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Coding Requests folder

Coding Requests page

Use the Coding Requests page to view the list of coding requests assigned to your work teams.

> **Note:** Some of the information that appears on this page is configurable by an administrator through the element configuration options. The descriptions in the following table represent the default configuration.

Fields

Coding Requests page	
Field	Description
Verbatim	The verbatim for which you want to search. Searches are *case-insensitive*. The search supports the special characters *, %, ?, and _. The search text field can be an arbitrary text string and can contain wildcard characters to facilitate matching when the exact text is not known. The percent sign (%) or asterisk (*) matches any sequence of characters; the question mark (?) or underscore (_) matches any single character.
Subject ID	The client identifier for the subject whose coding requests you want to view.
Show filter	A filter that identifies the items you want to view, based on whether the coding is complete. • **All**—Displays all requests. • **To Do**—Displays all requests for which further action is required to code the verbatim. • **Done**—Displays all requests for which no further action is required to code the verbatim. • **Pending Delivery**—Displays all requests that are coded, but are not yet delivered to the source application. • **Undeliverable**—Displays all requests that could not be delivered to the source application.
Study filter	A filter that identifies the items you want to view, based on the name of a study.
View filter	A filter that identifies the items you want to view, based on a coding definition. **Note:** The information that appears in this page changes depending on which coding definition you select from the filter.
Apply button	Initiates the search for the text in the Verbatim field and applies the filters.

Coding Requests page	
Field	**Description**
Page controls **Note:** The page controls appear only when there are multiple pages of data.	
Current page	The number of the page that currently appears in the list view.
Page count button	Click to display the total number of pages of data as of the current date and time.
✓	Selects the item(s) on which you can perform a task.
A	The autocode status. • **Autocoded ( )**—The request was successfully autocoded. • **Blank**—The request was not autocoded.
Status	The coding status. • **Uncoded ( )**—The item is not coded. • **Partially coded ( )**—If coding to a primary autocode target and a secondary autocode target, the application found a single match for the primary target and multiple matches for the secondary target. You must manually select the code you want to use. • **Needs review ( )**—The request is successfully autocoded but must be reviewed. • **Recode ( )**—The request must be recoded. Requests with this status have been disapproved by an approver. By default, the disapproval reason appears in a note associated with the request. • **Coded, awaiting approval ( )**—The request is successfully coded but needs an approval. • **Completed, awaiting delivery ( )**—The request is successfully coded and approved, but is not yet delivered to the source application. • **Completed, delivered ( )**—The request is successfully coded, approved, and delivered to the source application. • **Undeliverable, retry ( )**—The request may be successfully coded and approved, but the Central Coding application cannot deliver the request to the source application because of a communication issue.

Coding Requests page	
Field	**Description**
Query	The query status. • **Open** ()—Entered in the Central Coding application by a Central Coding user to be addressed by an InForm user. • **Candidate** ()—Entered by a Central Coding user. A Central Coding user with the Issue Candidate Query right can create a Candidate query. • **Answered** ()—Open query that was addressed by an InForm user. • **Closed** ()—Query on a verbatim that was successfully coded and approved. A query can enter the Closed state if it is manually closed by a Central Coding user or automatically closed by the Central Coding application. • **Deleted** ()—Candidate query that was deleted by a Central Coding user with the Issue Candidate Query right. Only queries in the Candidate state can be deleted. • **Undeliverable, retry** ( )—The Central Coding application cannot deliver the query data to the source application because of a communication issue. The Central Coding application will retry delivery when the next Get Requests job runs. • **Undeliverable, cannot retry** ( )—The Central Coding application cannot deliver the query data to the InForm application because the form is unable to accept queries. This could happen if a form is locked or deleted in the InForm application. As a result, the query is closed in the Central Coding application.
Notes	Indicates that there is a note associated with the coding request.
Flag	Indicates that the coding request requires attention. A Central Coding administrator can configure the meaning of each coding flag.
Verbatim	The original reported text that describes the adverse event, disease, drug, or other item to be coded. Click the link to open the coding browser. **Note:** This information comes from the source application. **Note:** Verbatims that are updated in the source application are highlighted in yellow for easy identification. The highlight is removed when the request status changes to **Completed, delivered**. **Note:** The first 25 characters of the context items (Indication and Route of Administration) associated with the verbatim appear below the verbatim if the **Display Context Items on Coding Requests and Approvals pages** option on the System Configuration page is selected. You can view the full Route of Administration or Indication text on the Requests Details page.
Dictionary	The dictionary and version associated with the coding definition.

Coding Requests page	
Field	**Description**
Code	The classification level code value. Click this link to open the View Full Coding dialog box, from which you can view the full coding details for a coded item. The details include the dictionary name and version, the coded term and value, and the level of the dictionary hierarchy where the match was found. **Note:** The sort on this column is case-insensitive.
Dictionary-specific hierarchical levels	The terms associated with the levels of the dictionary that are displayed on the page based on your selections on the Element Configuration page.
Site	A mnemonic identifier for the subject site. You can hover over the abbreviated name to view the full name of the site. **Note:** This information comes from the source application and appears in the SiteName field on the request detail pages.
Study	The name of the study. **Note:** The name is an active link if you are integrated with the InForm application. Click the link to open the InForm application login page.
Form Name	RefName of the form with which the request is associated. This information comes from the source application.
Subject ID	The client identifier for the subject.
Coder	The user who coded the request.
Date Coded	The date the request was initially coded.
Last Updated	The date the coding for the request was last updated.
Details	A link to the Request Details page, from which you can view all the information in the Central Coding application about a coding request. Click the link to open the page.

Actions

Coding Requests page		
Action	**Shortcut**	**Description**
Code Single	Ctrl+Shift+S	Opens the Coding Browser dialog box, from which you can interactively code the selected verbatim. The system codes only the selected item.
Review Complete	Ctrl+Shift+R	Completes the review of an autocoded request.

Coding Requests page		
Action	**Shortcut**	**Description**
Clear and Propagate		Removes the code value for the selected verbatim and for all other coded requests (with a delivery status of either delivered or undelivered) with the same verbatim, code value, coding definition, and context information. A confirmation dialog box does **not** appear. The code value is cleared only for requests associated with studies that are marked as unlocked in the Central Coding application.
Clear Code		Removes the code value for the selected verbatim only. A confirmation dialog box does **not** appear.
Add Notes	Ctrl+Shift+O	Opens the Add Notes dialog box, from which you can add a note to the selected coding request.
Add Flags	Ctrl+Shift+F	Opens the Please select flags to add dialog box, from which you can add a flag to the selected coding request.
Create Query Single	Ctrl+Shift+Q	Opens the Create Query dialog box, from which you can create a query associated with the selected coding request.
Approve Candidate		Opens the Approve Query dialog box, from which you can approve a query in the Candidate state, and assign it to the Open state.
Reissue Query		Opens the Reissue Query dialog box, from which you can reissue a candidate or closed query by assigning it to the Open state.
Close Query		Opens the Close Query dialog box, from which you can close an open or answered query.
Delete Query		Opens the Cancel Query dialog box, from which you can delete a candidate query.
Retry Query Delivery		Changes the delivery status for a query that failed delivery to the source application back to the previous pending state, so that the query can be resent to the source application.
Retry Delivery		Changes the delivery status for a request that failed delivery to the source application to **Completed, awaiting delivery** (). This allows the request to be resent to the source application.
Details	Ctrl+Shift+V	Opens the Request Details page, from which you can view all the information in the Central Coding application about a coding request.

Buttons

Coding Requests page		
Button	**Shortcut**	**Description**
Code	Ctrl+Shift+C	Code and propagate. Opens the Coding Browser dialog box, from which you can interactively code and propagate the value for the selected verbatim. The application automatically propagates the selected code value to all other uncoded requests with the same verbatim, coding definition, and context information. The code is propagated only to requests associated with studies that are marked as unlocked in the Central Coding application.
Code Single	Ctrl+Shift+S	Opens the Coding Browser dialog box, from which you can interactively code the selected verbatim. The system codes only the selected item.
Create Query	Ctrl+Shift+Q	Opens the Create Query dialog box, from which you can create a query associated with the selected coding request.
Add Notes	Ctrl+Shift+O	Opens the Add Notes dialog box, from which you can add a note to the selected coding request.
Add Flags	Ctrl+Shift+F	Opens the Please select flags to add dialog box, from which you can add a flag to the selected coding request.
Refresh ()		Updates the information on the page.
Help ()		Opens online page-level help that describes the page function(s) and fields.

Coding Browser dialog box—Search mode

Use the Coding Browser in the Search mode to search selected fields in a dictionary for text that begins with or contains the verbatim text.

Fields

Coding Browser dialog box—Search mode	
Field	**Description**
Dictionary	The coding dictionary type associated with the term. This field is read-only.

Coding Browser dialog box—Search mode	
Field	Description
Version	The version of the coding dictionary. This field is read-only.
Culture	A combination of attributes including, but not limited to, language, date formats, and currency.
Verbatim	The original reported text that describes the adverse event, disease, drug, or other item to be coded. This field is read-only. **Note:** This information comes from the source application.
Indication	The disease or disorder for which the drug was taken. **Note:** This field appears only for items associated with the WHO-DD or JDrug dictionary. If other dictionaries are defined to have context information, that information appears in this location.
Route of Administration	The route by which the drug was administered. **Note:** This field appears only for items associated with the WHO-DD or JDrug dictionary. If other dictionaries are defined to have context information, that information appears in this location.
Create Query link	Create a query in the Central Coding application to be answered by an InForm user. **Note:** This option is only available if the Central Coding application is integrated with the InForm application.
Search for	The text you want to code.
In field	The hierarchy level of the dictionary that you want to search.
Exclude Auto Suggestion step	Indicates whether to use the Auto Suggested code value for the item. This feature applies only when autocoding an item. • If you select this option, the step in the coding algorithm that looks for the auto-suggested code value is not run. • If you do not select this option, the step in the coding algorithm that looks for the auto-suggested code value is run, and the browser returns the auto-suggested code value for the verbatim and for the context information, if any.
Return All Matches	Indicates whether you want all the matched terms found to display in the browser. **Note:** By default, the coding browser displays 200 matches. This number, and whether this option is available, is set by your administrator. For more information, see *Changing the number of matched terms that display in the coding browser* in the *Installation Guide*.
Search icon ()	A link that changes the coding mode to the Search mode. **Note:** This link is active only when the browser is in the Browse mode.

Coding Browser dialog box—Search mode	
Field	**Description**
Browse icon ( )	A link that changes the coding mode to the hierarchical Browse mode. Click the icon to change the mode. **Note:** This link is active only when the browser is in the Search mode.
Reset tree icon ( )	An icon that resets the hierarchy tree to the top. **Note:** This link is active only when the browser is in the Browse mode.
Contains whole words only	Indicates that you want to search for terms that contain the verbatim text in its entirety, rather than view results that contain only part of the verbatim text. This feature only applies if you click the Contains button to perform a search.
Use as Auto Suggestion	Indicates whether you want the system to use the code value you accept for all new incoming requests with the same verbatim, dictionary, coding definition, and context information. By default, this option is selected. **Note:** If you want to use the auto-suggestion feature, this checkbox must be selected and the Auto Suggestion step must be part of the coding algorithm. **Note:** You can deselect Use as Auto Suggestion only when the coding browser is open. If you deselect the checkbox, whatever you code the verbatim to is not saved as an auto-suggestion. The next time you open the coding browser to code a verbatim the checkbox is selected again.
Accept link	Saves the associated code. Click the link to save the code and close the browser dialog box. This link appears next to each code value that the browser returns. **Note:** A red superscript letter **P** indicates that the result represents the primary path for the MedDRA dictionaries that support the concept of primary path. The blue superscript letters **nc** indicate that the coding is not current for the MedDRA dictionaries that support the concept of currency.
Results/matches returned	The configured dictionary elements that the browser returned for the verbatim being coded. An administrator can configure the browser display using the Element Configuration page in the Central Coding user interface. For more information, see ***Element Configuration page*** (on page 397). **Note:** To help you choose a new coding when interactively coding from the Verbatim Reconciliation page (during impact analysis), the original result now appears as a read-only first row in the Search results display of the Coding Browser. This row has a different background color than the selectable results and is labeled **Original Coding** in the column where the **Accept** link normally appears.

Coding Browser dialog box—Search mode	
Field	Description
View Synonyms link	A link to the View Synonyms dialog box, from which you can view the list of approved synonyms for a selected code. Click the link to open the dialog box. **Note:** This link appears only after the term is coded and only if there is an active synonym list specified by the coding definition in use.
Suggest Synonyms link	A link to the Suggest Synonym dialog box, from which you can propose a synonym for the selected coded term. Click the link to open the dialog box. **Note:** This link appears only after the term is coded and only if there is an active synonym list specified by the coding definition in use.
Medicinal Product link	A link to the Medicinal Product dialog box, from which you can view the Medicinal Product information for the drug. Click the **Drug Code** or **Trade Name** link to open the dialog box.

Buttons

Coding Browser dialog box—Search mode	
Button	Description
Starts With	Runs a search for matches that start with the text entered in the **Search for** field. **Note:** This button is active only when the browser is in the Search mode.
Contains	Runs a search for matches that contain the text entered in the **Search for** field. **Note:** This button is active only when the browser is in the Search mode.
Auto	Runs the autocode algorithm on the text entered in the **Search for** field. **Note:** This button is active only when the browser is in the Search mode.
Cancel	Closes the dialog box without returning any coding.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Suggest Synonym dialog box

Use the Suggest Synonym dialog box to propose a synonym for the selected coded term.

Fields

Suggest Synonym dialog box	
Field	**Description**
Suggested synonym	The synonym you want to propose for the term. REQUIRED.
Term	The coded term.
Code	The classification level code value.

Buttons

Suggest Synonym dialog box	
Button	**Description**
Accept	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Synonyms for [Code value] dialog box

Use the Synonyms for [Code value] dialog box to view the list of approved synonyms for a selected code.

Fields

Synonyms for [Code value] dialog box	
Field	**Description**
Synonym	The approved synonyms for the code value.

Buttons

Synonyms for [Code value] dialog box	
Button	**Description**
Previous	Navigates back to the previous view.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Coding Browser dialog box—Browse mode

Use the Coding Browser in the Browse mode to examine the target coding dictionary, from level to level, and select relevant terms. When you find an appropriate term, you can apply the term and code to the verbatim.

Fields

Coding Browser dialog box—Browse mode	
Field	**Description**
Dictionary	The coding dictionary type associated with the term. This field is read-only.
Version	The version of the coding dictionary. This field is read-only.
Culture	A combination of attributes including, but not limited to, language, date formats, and currency.
Verbatim	The original reported text that describes the adverse event, disease, drug, or other item to be coded. This field is read-only. **Note:** This information comes from the source application.
Indication	The disease or disorder for which the drug was taken. This field is read-only. **Note:** This field appears only for items associated with the WHO-DD or JDrug dictionary. If other dictionaries are defined to have context information, that information appears in this location.
Route of Administration	The route by which the drug was administered. This field is read-only. **Note:** This field appears only for items associated with the WHO-DD or JDrug dictionary. If other dictionaries are defined to have context information, that information appears in this location.
Create Query link	Create a query in the Central Coding application to be answered by an InForm user. **Note:** This option is only available if the Central Coding application is integrated with the InForm application.
Search for	The text you want to code. **Note:** This field is active only when the browser is in the Search mode.
In field	The hierarchy level of the dictionary that you want to search. **Note:** This field is active only when the browser is in the Search mode.
Exclude Auto Suggestion step	Indicates whether to use the Auto Suggested code value for the item. This feature applies only when autocoding an item. **Note:** This field is active only when the browser is in the Search mode.

Coding Browser dialog box—Browse mode	
Field	**Description**
Return All Matches	Indicates whether you want all the matched terms found to display in the browser. **Note:** This field is active only when the browser is in the Search mode.
Search icon ( )	A link that changes the coding mode to the Search mode. Click the icon to change the mode. **Note:** This link is active only when the browser is in the Browse mode.
Browse icon ( )	A link that changes the coding mode to the hierarchical Browse mode. **Note:** This link is active only when the browser is in the Search mode.
Reset tree icon ( )	An icon that resets the hierarchy tree to the top. Click the icon to reset the tree. **Note:** This link is active only when the browser is in the Browse mode.
Contains whole words only	Indicates that you want to search for terms that contain the verbatim text in its entirety, rather than view results that contain only part of the verbatim text. This feature only applies if you click the Contains button to perform a search.
Use as Auto Suggestion	Indicates whether you want the system to use the code value you accept for all new incoming requests with the same verbatim, dictionary, coding definition, and context information. By default, this option is selected. **Note:** If you want to use the auto-suggestion feature, this checkbox must be selected and the Auto Suggestion step must be part of the coding algorithm. However, if you select the **Use as Auto Suggestion** checkbox but the Auto Suggestion step is not part of the coding algorithm, auto-suggestions are saved to the database but they are not used for coding. **Note:** You can deselect Use as Auto Suggestion only when the coding browser is open. If you deselect the checkbox, whatever you code the verbatim to is not saved as an auto-suggestion. The next time you open the coding browser to code a verbatim the checkbox is selected again.
Results/matches returned	The configured dictionary elements that the browser returned for the verbatim being coded. An administrator can configure the browser display using the Element Configuration page in the Central Coding user interface. For more information, see ***Element Configuration page*** (on page 397). **Note:** Double-click a term on the classification level to accept its code value and to close the browser dialog box.

Buttons

Coding Browser dialog box—Browse mode	
Button	**Description**
Starts With	Runs a search for matches that start with the text entered in the **Search for** field. **Note:** This button is active only when the browser is in the Search mode.
Contains	Runs a search for matches that contain the text entered in the **Search for** field. **Note:** This button is active only when the browser is in the Search mode.
Auto	Runs the autocode algorithm on the text entered in the **Search for** field. **Note:** This button is active only when the browser is in the Search mode.
Cancel	Closes the dialog box without returning any coding.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Recode Reason dialog box

Use the Recode Reason dialog box to specify a reason for assigning a new code to a coded request.

Fields

Recode Reason dialog box	
Field	**Description**
Reason	The reason for assigning a new code to the selected coded request.
Add as Notes	Indicates that you want to allow users to view the reason for assigning a new code to the selected coding request in a note associated with the request.

Buttons

Recode Reason dialog box	
Button	**Description**
Accept	Saves the changes and closes the dialog box.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

View Medicinal Product Information dialog box

Use the Medicinal Product dialog box to view the Medicinal Product information for the drug.

> **Note:** This functionality is available only when coding to the Trade Name level in the WHO-DD dictionary.

Fields

View Medicinal Product Information dialog box	
Field	**Description**
Drug Code	Code associated with the medicinal product.
Trade Name	Trade name for the medicinal product.
Medicinal Product	Medicinal product name.
Name Specifier	Additional information used to distinguish medicinal products with the same Medicinal Product Name.
Country of Sale	Country in which the medicinal product is marketed.
MA Holder	Company with the license or marketing authorization for the medicinal product, within a given country.
MA Holder Country	Country in which the MA Holder for the medicinal product exists.
Company	Name of the company that owns the medicinal product.
Company Country	Country in which the company that owns the medicinal product exists.
ICH Med Prod ID	Unique identifier in the WHO-DD dictionary for the medicinal product.
Sequence Number 3	Numeric identifier for the medicinal product base substance.
Sequence Number 4	Numeric identifier for the medicinal product Preferred Name or Trade Name.
MA Number	Unique identifier for the marketing authorization for the medicinal product.
MA Date	Date when the marketing authorization was issued.
MA Withdrawal Date	Date when the marketing authorization for the medicinal product was withdrawn.
Product Type	Type of medicinal product. For example, Medicinal Product, Herbal Remedy, or Vaccine.
Product Group	Set of medicinal products to which the medicinal product belongs. For example, a product group could include all medicinal products that include the same base substance, but are marketed under different names worldwide.

View Medicinal Product Information dialog box	
Field	Description
Pharmaceutical Product	Additional information for a product that is packaged with the medicinal product. For example, if the medicinal product is a topical cream that is packaged with an oral supplement, the information about the oral supplement is also supplied.

Buttons

View Medicinal Product Information dialog box	
Button	Description
OK	Closes the dialog box.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Request Details page—Coding Requests

Use the Requests Details page to view all the information in the Central Coding application about a coding request. The information includes details about the coding method and status, assignment rule, coding definition, and identification information about the request from the source application.

Fields

Request Details page	
Field	Description
Request Information	
Verbatim	The original reported text that describes the adverse event, disease, drug, or other item to be coded.
Dictionary	The dictionary and version associated with the coding definition.
Status	The coding status.
Reason	Descriptive text about the reason for the change. 1000 characters maximum.
Date Coded	The date the request was initially coded.
Date Completed	The date the request was completed.

Request Details page	
Field	Description
Request Information	
Item Type	The kind of item to be coded. This information is defined in either the Central Designer or Clintrial application. Examples of item types are: • **AE**—Adverse event • **MEDPROD**—Medical product • **DISEASE**—Disease • **LABDATA**—Lab data • **Drug**
Coding Mode	The method used to code the request.
Algorithm Step	The step in the coding algorithm where the match was found. This information appears only if the request was autocoded.
Autocode Match Level	The level in the dictionary hierarchy where the coding algorithm searches for a match when performing autocoding. This information appears only if the request was autocoded.
Coder	The user who coded the request.
Auto Approve (A)	Indicates whether an autocoded request was automatically approved by the system.
Auto Approve (I)	Indicates whether a manually coded request was automatically approved by the system.
Single Coded	Indicates whether the code value was found for this request only or if the value was propagated.
Autocode Requires Review	Indicates whether the autocoded request requires a review.
Needs Delivery	Indicates whether the request has been delivered to the source application.
Query status icon	Indicates that the selected coding request has an associated query, and specifies the query state. Hold your mouse over the icon to see the query text. Click the icon to open the Query History page for the query.
Note icon ( )	Indicates that the selected coding request has an associated note. Hold your mouse over the icon to see the most recent note text associated with the request. Click the icon to open the Notes History page for the note.

Request Details page	
Field	**Description**
Request Information	
Number of Matches	The number of coding values found. This information appears only if the request was autocoded.
Match Text	The text to which the code value was matched. This information appears only if the request was autocoded
View Codes link	Click this link to open the View Full Coding dialog box, from which you can view the full coding details for a coded item. The details include the dictionary name and version, the coded term and value, and the level of the dictionary hierarchy where the match was found. **Note:** This link appears only if the request has been coded.
Request Identification	
Client Name	The name of the source application for which the Central Coding application is coding the request.
Client Item Identifier	A unique identifier on the client for the item to be coded. This identifier is passed back with the response so that the client can update the correct records with the result. This information is provided by the source application.
Product	The product type from which the request was sent. The Central Coding application defines this property.
Host	The name of the server for the study.
Visit Name	The name of the visit. This information is provided by the source application.
URL	The URL to the page in the source application on which the request is based.
Subject ID	The client identifier for the subject. This information is provided by the source application.
Subject Initials	The subject initials of the subject. This information is provided by the source application.
Site	A unique identifier for the subject site that the Central Coding application uses internally. This information is provided by the source application.
SiteMnemonic	A mnemonic identifier for the subject site. **Note:** This information comes from the source application and appears in the Site column on the request list view pages.
SiteName	SiteMnemonic, enclosed in brackets, followed by the name of the site.

Request Details page	
Field	**Description**
Request Identification	
Study	The name of the study.
Visit	A data structure that describes a subject visit or a collection of monitoring forms. This information is provided by the source application.
Form Name	The form with which the request is associated. This information comes from the source application.
Mapping	The data code mapping name defined in the source application. This identifier defines the items to be returned to the source application and the location where the items are to be returned.
Route of Administration	The route by which the drug was administered. This information is provided by the source application. **Note:** This field appears only for items associated with the WHO-DD or JDrug dictionary. If other dictionaries are defined to have context information, that information appears in this location.
Indication	The disease or disorder for which the drug was taken. This information is provided by the source application. **Note:** This field appears only for items associated with the WHO-DD or JDrug dictionary. If other dictionaries are defined to have context information, that information appears in this location.
Target(s)	A unique identifier for where the codes are to be sent. The number of targets that appear on the page depends on the mapping(s) defined in the source application.
Rule Assignment	
Rule Name	The name of the assignment rule.
Rule Text	The assignment rule, in simple syntax language, that the system evaluates.
Assignment Status	Indicates whether the request is successfully assigned to its associated assignment rule. If the request is unassigned, an error message appears.
Assigned Work Teams	The work teams to which the requests processed by the assignment rule are assigned. **Note:** This field appears only if the system successfully assigns the requests.

Request Details page	
Field	Description
Coding Definition	
Name	The name of the coding definition associated with the request.
Dictionary	The coding dictionary and version associated with the coding definition.
Algorithm	The name of the algorithm associated with the coding definition.
Stopword List	The name of the stopword list associated with the coding definition.
Synonym List	The name of the synonym list associated with the coding definition.

View Full Coding dialog box

Use the View Full Coding dialog box to view the full coding details for a coded item. The details include the dictionary name and version, the coded term and value, and the level of the dictionary hierarchy where the match was found.

Fields

View Full Coding dialog box	
Field	**Description**
Coded with	The dictionary and version number the item was coded against. This information is read only.
Is Primary Path	Indicates whether the code was found in the primary dictionary path. **Note:** This field appears only when using the MedDRA or MedDRA-J dictionary. The WHO-DD, JDrug, and custom dictionaries do not support the primary path concept.
Level	The hierarchy level in the specified dictionary.
Code	The classification level code value.
Term	The first coded term for the dictionary level.
Additional Info	Additional dictionary information.

Buttons

View Full Coding dialog box	
Button	**Description**
Previous	Navigates back to the previous view.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Reason for change dialog box

Use the Reason for Change dialog box to describe the change(s) to an item before you save it.

Fields

Reason for change dialog box	
Field	**Description**
Reason	Descriptive text about the reason for the change. 1000 characters maximum. **Note:** This field does not accept special characters. The Central Coding application cannot save the change if you leave this field blank.

Buttons

Reason for change dialog box		
Button	**Shortcut**	**Description**
Accept	Ctrl+Shift+A	Saves the changes and closes the dialog box.
Cancel		Closes the dialog box without saving any changes.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Create Query dialog box

Use the Create Query dialog box to create a query in the Open or Candidate state for a selected coding request.

Fields

Create Query dialog box	
Field	**Description**
Verbatim	The verbatim to which to associate the query.
Reason	Descriptive text about the reason for creating the query. **Note:** A Central Coding administrator can configure the default reasons, and can specify which reason appears first in the drop-down list.
Add as standard reason	Adds the text in the Other text box to the list of standard reasons that appear in the Reason drop-down list. **Note:** The Add as standard reason checkbox only appears for users who have the Manage Standard Reasons right.

Create Query dialog box	
Field	**Description**
Query State	The state to assign to the query. • **Open**—Entered in the Central Coding application by a Central Coding user to be addressed by an InForm user. • **Candidate**—Entered by a Central Coding user. A Central Coding administrator can assign a Candidate query to the Open or Deleted state. **Note:** The option to create a query in the Candidate state only appears for users who have the Issue Candidate Query right.
Auto close query upon coding complete	Automatically close the query when the associated verbatim is successfully coded and approved. This option is selected by default.
Add to auto query list	Add the verbatim associated with the query to the auto query list to indicate that you want the Central Coding application to duplicate the query and apply it to all matching verbatims in the study group that are subsequently opened in the Central Coding application. This option is selected by default.

Buttons

Create Query dialog box		
Button	**Shortcut**	**Description**
Copy ( )		Copies the text of the selected reason in the Reason drop-down list, and copies it to the Other text box for editing.
OK	Ctrl+Shift+A	Saves the changes and closes the dialog box.
Cancel	Ctrl+Shift+C	Closes the dialog box without saving any changes.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Close Query dialog box

Use the Close Query dialog box to close an open or answered query.

Fields

Close Query dialog box	
Field	**Description**
Reason	Descriptive text about the reason for closing the query. **Note:** A Central Coding administrator can configure the default reasons, and can specify which reason appears first in the drop-down list.
Add as standard reason	Adds the text in the Other text box to the list of standard reasons that appear in the Reason drop-down list. **Note:** The Add as standard reason checkbox only appears for users who have the Manage Standard Reasons right.

Buttons

Close Query dialog box	
Button	**Description**
OK	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Reissue Query dialog box

Use the Reissue Query dialog box to reissue a closed or candidate query by assigning it to the Open state.

Fields

Reissue Query dialog box	
Field	**Description**
Verbatim	The verbatim associated with the query.
Reason	Descriptive text about the reason for reissuing the query. **Note:** A Central Coding administrator can configure the default reasons, and can specify which reason appears first in the drop-down list.
Add as standard reason	Adds the text in the Other text box to the list of standard reasons that appear in the Reason drop-down list. **Note:** The Add as standard reason checkbox only appears for users who have the Manage Standard Reasons right.

Buttons

Reissue Query dialog box	
Button	**Description**
OK	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Add Notes dialog box

Use the Add Notes dialog box to add a note to a coding request.

Fields

Add Notes dialog box	
Field	**Description**
Notes	Type the text of the note that you want to associate with the coding request.
Notes History section (read-only)	
Field	**Description**
Created	Date and time when the note entry was created.
User	User name of the user who created the note entry.
Notes	Note entry text.

Buttons

Add Notes dialog box		
Button	**Shortcut**	**Description**
Accept	Ctrl+Shift+A	Saves the changes and closes the dialog box.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Notes History page

Use the Notes History page to view the details of a note.

Fields

Notes History page	
Verbatim Information section (read-only)	
Field	**Description**
Verbatim	The text of the verbatim with which the note is associated.
Study	The study in which the coding request associated with the note exists.
Site	The site at which the verbatim associated with the note was entered.
Visit	The visit in which the verbatim associated with the note was entered.
Notes History section (read-only)	
Field	**Description**
Created	Date and time when the note entry was created.
User	User name of the user who created the note entry.
Notes	Note entry text.

Actions

Notes History page		
Action	**Shortcut**	**Description**
Add Notes	Ctrl+Shift+O	Opens the Add Notes dialog box, from which you can add a note to the selected coding request.

Buttons

Notes History page		
Button	**Shortcut**	**Description**
Add Notes	Ctrl+Shift+O	Opens the Add Notes dialog box, from which you can add a note to the selected coding request.
Previous	Ctrl+Shift+P	Navigates back to the previous view.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Please select flags to add dialog box

Use the **Please select flags to add** dialog box to associate a coding flag with a coding request.

> **Note:** A Central Coding administrator can configure the meaning of each coding flag.

Fields

Please select flags to add dialog box	
Field	Description
Coding flag checkbox	Select the checkbox that corresponds to the coding flag definition to associate to the coding request.

Buttons

Please select flags to add dialog box		
Button	Shortcut	Description
Accept	Ctrl+Shift+A	Saves the changes and closes the dialog box.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Remove Flag dialog box

Use the Remove Flag dialog box to delete a flag associated with a coding request.

Buttons

Remove Flag dialog box		
Button	Shortcut	Description
OK	Ctrl+Shift+A	Saves the changes and closes the dialog box.
Cancel	Ctrl+Shift+C	Closes the dialog box without saving any changes.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Query History page

Use the Query History page to view the history for a query.

Fields

Query History page	
Field	**Description**
Verbatim	The text of the verbatim with which the query is associated.
Study	The study in which the coding request associated with the query exists.
Site	The site at which the verbatim associated with the query was entered.
Visit	The visit in which the verbatim associated with the query was entered.
Query status	The query status. • **Open ( )**—Entered in the Central Coding application by a Central Coding user to be addressed by an InForm user. • **Candidate ( )**—Entered by a Central Coding user. A Central Coding user with the Issue Candidate Query right can create a Candidate query. • **Answered ( )**—Open query that was addressed by an InForm user. • **Closed ( )**—Query on a verbatim that was successfully coded and approved. A query can enter the Closed state if it is manually closed by a Central Coding user or automatically closed by the Central Coding application. • **Deleted ( )**—Candidate query that was deleted by a Central Coding user with the Issue Candidate Query right. Only queries in the Candidate state can be deleted. • **Undeliverable, retry ( )**—The Central Coding application cannot deliver the query data to the source application because of a communication issue. The Central Coding application will retry delivery when the next Get Requests job runs. • **Undeliverable, cannot retry ( )**—The Central Coding application cannot deliver the query data to the InForm application because the form is unable to accept queries. This could happen if a form is locked or deleted in the InForm application. As a result, the query is closed in the Central Coding application.
Query text	The text of the query.
Date	The date when of each transaction related to the query..
Verbatim	The text of the verbatim with which the query is associated.
User	The user who entered or most recently modified the query in the Central Coding application.

Query History page	
Field	**Description**
Status	The status of the query: • Candidate • Open • Answered • Deleted
Closed by Client	Indicates whether the query was closed by a user in the InForm application: • Yes • No • Blank (No)
Send State	The delivery status of the query: • **Pending**—The query has not yet been delivered to the InForm application. • **Failed**—The Central Coding application could not deliver the query data to the InForm application due to an error. When you resolve the associated error, the Central Coding application will attempt to deliver the query data again. • **DUP_TXID**—The query already exists in the InForm application. This can occur in rare situations if a query was successfully created in the InForm application, but the Central Coding application did not receive a confirmation due to network issues. The Central Coding application will automatically resolve this issue. • **INVAL_REV**—Updates made to the query in the Central Coding application cannot be transferred to the InForm application. This can occur if a query was updated in the InForm application before it was updated in the Central Coding application. In this case, the updates from the InForm application overwrite the changes made in the Central Coding application.
Send Error	The text of the error that occurred when the delivery to the InForm application failed.
Reason	The reason the user entered when the query was created.

Buttons

Query History page		
Button	Shortcut	Description
Previous	Ctrl+Shift+P	Navigates back to the previous view.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Approvals folder

Approvals page

Use the Approvals page to view the list of coding requests that need to be approved.

> **Note:** Some of the information that appears on this page is configurable by an administrator through the element configuration options. The descriptions in the following table represent the default configuration.

Fields

Approvals page	
Field	Description
Verbatim	The verbatim for which you want to search. Searches are *case-insensitive*. The search supports the special characters *, %, ?, and _. The search text field can be an arbitrary text string and can contain wildcard characters to facilitate matching when the exact text is not known. The percent sign (%) or asterisk (*) matches any sequence of characters; the question mark (?) or underscore (_) matches any single character.
Subject ID	The client identifier for the subject whose coding requests you want to view.
Show filter	A filter that identifies the items you want to view, based on whether the approval is complete. • **All**—Displays all options. • **To Do**—Displays all requests that are coded but need an approval. • **Disapproved**—Displays all requests that were not approved; these requests have a status of Recode. • **Done**—Displays all requests that are approved. • **Pending Delivery**—Displays all requests that are coded, but are not yet delivered to the source application. • **Undeliverable**—Displays all requests that could not be delivered to the source application.
Study filter	A filter that identifies the items you want to view, based on the name of a study.
View filter	A filter that identifies the items you want to view, based on a coding definition. **Note:** The information that appears in this page changes depending on which coding definition you select from the filter.

Approvals page	
Field	**Description**
Apply button	Initiates the search for the text in the Verbatim field and applies the filters.
Page controls **Note:** The page controls appear only when there are multiple pages of data.	
Current page	The number of the page that currently appears in the list view.
Page count button	Click to display the total number of pages of data as of the current date and time.
✓	Selects the item(s) on which you can perform a task.
A	The autocode status. • **Autocoded ()**—The request was successfully autocoded. • **Blank**—The request was not autocoded.
Status	The coding status. • **Uncoded ( )**—The item is not coded. • **Partially coded ( )**—If coding to a primary autocode target and a secondary autocode target, the application found a single match for the primary target and multiple matches for the secondary target. You must manually select the code you want to use. • **Needs review ( )**—The request is successfully autocoded but must be reviewed. • **Recode ( )**—The request must be recoded. Requests with this status have been disapproved by an approver. By default, the disapproval reason appears in a note associated with the request. • **Coded, awaiting approval ( )**—The request is successfully coded but needs an approval. • **Completed, awaiting delivery ( )**—The request is successfully coded and approved, but is not yet delivered to the source application. • **Completed, delivered ( )**—The request is successfully coded, approved, and delivered to the source application. • **Undeliverable, retry ( )**—The request may be successfully coded and approved, but the Central Coding application cannot deliver the request to the source application because of a communication issue.

Approvals page	
Field	**Description**
Query	The query status. • **Open ()**—Entered in the Central Coding application by a Central Coding user to be addressed by an InForm user. • **Candidate ()**—Entered by a Central Coding user. A Central Coding user with the Issue Candidate Query right can create a Candidate query. • **Answered ()**—Open query that was addressed by an InForm user. • **Closed ()**—Query on a verbatim that was successfully coded and approved. A query can enter the Closed state if it is manually closed by a Central Coding user or automatically closed by the Central Coding application. • **Deleted ()**—Candidate query that was deleted by a Central Coding user with the Issue Candidate Query right. Only queries in the Candidate state can be deleted. • **Undeliverable, retry ( )**—The Central Coding application cannot deliver the query data to the source application because of a communication issue. The Central Coding application will retry delivery when the next Get Requests job runs. • **Undeliverable, cannot retry ( )**—The Central Coding application cannot deliver the query data to the InForm application because the form is unable to accept queries. This could happen if a form is locked or deleted in the InForm application. As a result, the query is closed in the Central Coding application.
Notes	Indicates that there is a note associated with the coding request.
Flag	Indicates that the coding request requires attention. A Central Coding administrator can configure the meaning of each coding flag.
Verbatim	The original reported text that describes the adverse event, disease, drug, or other item to be coded. Click the link to open the coding browser. **Note:** This information comes from the source application. **Note:** Verbatims that are updated in the source application after they are coded in the Central Coding application are highlighted in yellow for easy identification. The highlight is removed when the request status changes to **Completed, delivered**. **Note:** The first 25 characters of the context items (Indication and Route of Administration) associated with the verbatim appear below the verbatim if the **Display Context Items on Coding Requests and Approvals pages** option on the System Configuration page is selected. You can view the full Route of Administration or Indication text on the Requests Details page.

Approvals page	
Field	**Description**
Dictionary	The dictionary and version associated with the coding definition.
Code	The classification level code value. Click this link to open the View Full Coding dialog box, from which you can view the full coding details for a coded item. The details include the dictionary name and version, the coded term and value, and the level of the dictionary hierarchy where the match was found.
Dictionary-specific hierarchical levels	The terms associated with the levels of the dictionary that are displayed on the page based on your selections on the Element Configuration page.
Site	A mnemonic identifier for the subject site. **Note:** This information comes from the source application and appears in the SiteName field on the request detail pages.
Study	The name of the study. **Note:** The name is an active link if you are integrated with the InForm application. Click the link to open the InForm application login page.
Form Name	RefName of the form with which the request is associated. This information comes from the source application.
Subject ID	The client identifier for the subject.
Coder	The user who coded the request.
Date Coded	The date the request was initially coded.
Last Updated	The date the coding for the request was last updated.
Details	A link to the Request Details page, from which you can view all the information in the Central Coding application about a coding request. Click the link to open the page.

Actions

Approvals page		
Action	**Shortcut**	**Description**
Approve	Ctrl+Shift+A	Approve and propagate. Marks as approved the coding for the selected request and for all other coded requests with the same code, verbatim, coding definition, and context information. The approval propagates only to requests associated with studies that are marked as unlocked in the Central Coding application.
Approve Single	Ctrl+Shift+K	Marks the coding for only the selected request as approved.

Approvals page		
Action	**Shortcut**	**Description**
Disapprove	Ctrl+Shift+D	Disapprove and propagate. Marks as disapproved the coding for the selected request and for all other coded requests with the same code, verbatim, coding definition, and context information. The disapproval propagates only to requests associated with studies that are marked as unlocked in the Central Coding application. **Note:** Disapproved requests are returned to the coder's queue in this application with a coding status of **Recode**.
Disapprove Single	Ctrl+Shift+X	Marks the coding for only the selected request as not approved.
Code	Ctrl+Shift+C	Code and propagate. Opens the Coding Browser dialog box, from which you can interactively code and propagate the value for the selected verbatim. The application automatically propagates the selected code value to all other uncoded requests with the same verbatim, coding definition, and context information. The code is propagated only to requests associated with studies that are marked as unlocked in the Central Coding application.
Code Single		Opens the Coding Browser dialog box, from which you can interactively code the selected verbatim. The system codes only the selected item.
Clear and Propagate		Removes the code value for the selected verbatim and for all other coded requests (with a delivery status of either delivered or undelivered) with the same verbatim, code value, coding definition, and context information. A confirmation dialog box does **not** appear. The code value is cleared only for requests associated with studies that are marked as unlocked in the Central Coding application.
Clear Code		Removes the code value for the selected verbatim only. A confirmation dialog box does **not** appear.
Add Notes	Ctrl+Shift+O	Opens the Add Notes dialog box, from which you can add a note to the selected coding request.
Add Flags	Ctrl+Shift+F	Opens the Please select flags to add dialog box, from which you can add a flag to the selected coding request.

Approvals page		
Action	**Shortcut**	**Description**
Create Query Single	Ctrl+Shift+Q	Opens the Create Query dialog box, from which you can create a query associated with the selected coding request.
Approve Candidate		Opens the Approve Query dialog box, from which you can approve a query in the Candidate state, and assign it to the Open state.
Reissue Query		Opens the Reissue Query dialog box, from which you can reissue a candidate or closed query by assigning it to the Open state.
Close Query		Opens the Close Query dialog box, from which you can close an open or answered query.
Delete Query		Opens the Cancel Query dialog box, from which you can delete a candidate query.
Retry Query Delivery		Changes the delivery status for a query that failed delivery to the source application back to the previous pending state, so that the query can be resent to the source application.
Retry Delivery		Changes the delivery status for a request that failed delivery to the source application to **Completed, awaiting delivery** ( ). This allows the request to be resent to the source application.
Details		A link to the Request Details page, from which you can view all the information in the Central Coding application about a coding request. Click the link to open the page.

Buttons

Approvals page	
Button	**Description**
Approve	Approve and propagate. Marks as approved the coding for the selected request and for all other coded requests with the same code, verbatim, coding definition, and context information. The approval propagates only to requests associated with studies that are marked as unlocked in the Central Coding application.
Approve Single	Marks the coding for only the selected request as approved.

Approvals page	
Button	**Description**
Disapprove	Disapprove and propagate. Marks as disapproved the coding for the selected request and for all other coded requests with the same code, verbatim, coding definition, and context information. The disapproval propagates only to requests associated with studies that are marked as unlocked in the Central Coding application. **Note:** Disapproved requests are returned to the coder's queue in this application with a coding status of **Recode**.
Disapprove Single	Marks the coding for only the selected request as not approved.
Create Query	Opens the Create Query dialog box, from which you can create a query associated with the selected coding request.
Add Notes	Opens the Add Notes dialog box, from which you can add a note to the selected coding request.
Add Flags	Opens the Please select flags to add dialog box, from which you can add a flag to the selected coding request.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Request Details page—Approvals

Use the Request Details page to view all the information in the Central Coding application about a coding request. The information includes details about the coding method and status, assignment rule, coding definition, and identification information about the request from the source application.

Fields

Request Details page	
Field	**Description**
Request Information	
Verbatim	The original reported text that describes the adverse event, disease, drug, or other item to be coded.
Dictionary	The dictionary and version associated with the coding definition.
Status	The coding status.
Reason	Descriptive text about the reason for the change. 1000 characters maximum.
Date Coded	The date the request was initially coded.
Date Completed	The date the request was completed.

Request Details page	
Field	**Description**
Item Type	The kind of item to be coded. This information is defined in either the Central Designer or Clintrial application. Examples of item types are: • **AE**—Adverse event • **MEDPROD**—Medical product • **DISEASE**—Disease • **LABDATA**—Lab data • **Drug**
Coding Mode	The method used to code the request.
Algorithm Step	The step in the coding algorithm where the match was found. This information appears only if the request was autocoded.
Autocode Match Level	The level in the dictionary hierarchy where the coding algorithm searches for a match when performing autocoding. This information appears only if the request was autocoded.
Coder	The user who coded the request.
Auto Approve (A)	Indicates whether an autocoded request was automatically approved by the system.
Auto Approve (I)	Indicates whether a manually coded request was automatically approved by the system.
Single Coded	Indicates whether the code value was found for this request only or if the value was propagated.
Autocode Requires Review	Indicates whether the autocoded request requires a review.
Needs Delivery	Indicates whether the request has been delivered to the source application.
Query status icon	Indicates that the selected coding request has an associated query, and specifies the query state. Hold your mouse over the icon to see the query text. Click the icon to open the Query History page for the query.
Note icon ()	Indicates that the selected coding request has an associated note. Hold your mouse over the icon to see the most recent note text associated with the request. Click the icon to open the Notes History page for the note.
Number of Matches	The number of coding values found. This information appears only if the request was autocoded.
Match Text	The text to which the code value was matched. This information appears only if the request was autocoded

Request Details page	
Field	**Description**
View Codes link	Click this link to open the View Full Coding dialog box, from which you can view the full coding details for a coded item. The details include the dictionary name and version, the coded term and value, and the level of the dictionary hierarchy where the match was found. **Note:** This link appears only if the request has been coded.
Request Identification	
Client Name	The name of the source application for which the Central Coding application is coding the request.
Client Item Identifier	A unique identifier on the client for the item to be coded. This identifier is passed back with the response so that the client can update the correct records with the result. This information is provided by the source application.
Product	The product type from which the request was sent. The Central Coding application defines this property.
Host	The name of the server for the study.
Visit Name	The name of the visit. This information is provided by the source application.
URL	The URL to the page in the source application on which the request is based.
Subject ID	The client identifier for the subject. This information is provided by the source application.
Subject Initials	The subject initials of the subject. This information is provided by the source application.
Site	A unique identifier for the subject site that the Central Coding application uses internally. This information is provided by the source application.
SiteMnemonic	A mnemonic identifier for the subject site. **Note:** This information comes from the source application and appears in the Site column on the request list view pages.
SiteName	SiteMnemonic, enclosed in brackets, followed by the name of the site.
Study	The name of the study.
Visit	A data structure that describes a subject visit or a collection of monitoring forms. This information is provided by the source application.
Form Name	The form with which the request is associated. This information comes from the source application.
Mapping	The data code mapping name defined in the source application. This identifier defines the items to be returned to the source application and the location where the items are to be returned.

Request Details page	
Field	**Description**
Route of Administration	The route by which the drug was administered. This information is provided by the source application. **Note:** This field appears only for items associated with the WHO-DD or JDrug dictionary. If other dictionaries are defined to have context information, that information appears in this location.
Indication	The disease or disorder for which the drug was taken. This information is provided by the source application. **Note:** This field appears only for items associated with the WHO-DD or JDrug dictionary. If other dictionaries are defined to have context information, that information appears in this location.
Target(s)	A unique identifier for where the codes are to be sent. The number of targets that appear on the page depends on the mapping(s) defined in the source application.
Rule Assignment	
Rule Name	The name of the assignment rule.
Rule Text	The assignment rule, in simple syntax language, that the system evaluates.
Assignment Status	Indicates whether the request is successfully assigned to its associated assignment rule. If the request is unassigned, an error message appears.
Assigned Work Teams	The work teams to which the requests processed by the assignment rule are assigned. **Note:** This field appears only if the system successfully assigns the requests.
Coding Definition	
Name	The name of the coding definition associated with the request.
Dictionary	The coding dictionary and version associated with the coding definition.
Algorithm	The name of the algorithm associated with the coding definition.
Stopword List	The name of the stopword list associated with the coding definition.
Synonym List	The name of the synonym list associated with the coding definition.

Actions

Request Details page—Approvals	
Action	**Description**
Approve	Approve and propagate. Marks as approved the coding for the selected request and for all other coded requests with the same code, verbatim, coding definition, and context information. The approval propagates only to requests associated with studies that are marked as unlocked in the Central Coding application.
Approve Single	Marks the coding for only the selected request as approved.
Disapprove	Disapprove and propagate. Marks as disapproved the coding for the selected request and for all other coded requests with the same code, verbatim, coding definition, and context information. The disapproval propagates only to requests associated with studies that are marked as unlocked in the Central Coding application. **Note:** Disapproved requests are returned to the coder's queue in this application with a coding status of **Recode**.
Disapprove Single	Marks the coding for only the selected request as not approved.
Code	Code and propagate. Opens the Coding Browser dialog box, from which you can interactively code and propagate the value for the selected verbatim. The application automatically propagates the selected code value to all other uncoded requests with the same verbatim, coding definition, and context information. The code is propagated only to requests associated with studies that are marked as unlocked in the Central Coding application.
Code Single	Opens the Coding Browser dialog box, from which you can interactively code the selected verbatim. The system codes only the selected item.
Clear and Propagate	Removes the code value for the selected verbatim and for all other coded requests (with a delivery status of either delivered or undelivered) with the same verbatim, code value, coding definition, and context information. A confirmation dialog box does **not** appear. The code value is cleared only for requests associated with studies that are marked as unlocked in the Central Coding application.
Clear Code	Removes the code value for the selected verbatim only. A confirmation dialog box does **not** appear.
Retry Delivery	Changes the delivery status for a request that failed delivery to the source application to **Completed, awaiting delivery** ( ). This allows the request to be resent to the source application.

Buttons

Request Details page—Approvals	
Button	**Description**
Approve	Approve and propagate. Marks as approved the coding for the selected request and for all other coded requests with the same code, verbatim, coding definition, and context information. The approval propagates only to requests associated with studies that are marked as unlocked in the Central Coding application.
Approve Single	Marks the coding for only the selected request as approved.
Disapprove	Disapprove and propagate. Marks as disapproved the coding for the selected request and for all other coded requests with the same code, verbatim, coding definition, and context information. The disapproval propagates only to requests associated with studies that are marked as unlocked in the Central Coding application. **Note:** Disapproved requests are returned to the coder's queue in this application with a coding status of **Recode**.
Disapprove Single	Marks the coding for only the selected request as not approved.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Disapproval Reason dialog box

Use the Disapproval Reason dialog box to specify a reason for disapproving the code for a coding request.

Fields

Disapproval Reason dialog box	
Field	**Description**
Reason	The reason for disapproving the code for the selected coding request.
Add as Notes	Indicates that you want to allow users to view the disapproval reason in a note associated with the selected coding request.

Buttons

Disapproval Reason dialog box	
Button	**Description**
Accept	Saves the changes and closes the dialog box.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Queries folder

Queries page

Use the Queries page to view and manage queries.

Fields

Queries page	
Field	**Description**
Study filter	A filter that identifies the queries you want to view, based on the name of a study.
Status filter	A filter that identifies the queries you want to view, based on the status of the query. • **All**—Displays all queries. • **Candidate**—Displays only queries in the **Candidate** state. • **Opened**—Displays all queries in the **Open** state. • **Answered**—Displays all queries in the **Answered** state. • **Closed**—Displays all queries in the **Closed** state. • **Deleted**—Displays all queries in the **Deleted** state. • **Send Failed**—Displays all queries in the **Undeliverable, retry** and the **Undeliverable, cannot retry** states.
Issuer filter	A filter that identifies the queries you want to view, based on the user name of the user who entered the query.
Form filter	A filter that identifies the queries you want to view, based on the form on which the verbatim associated with the query exists.
Apply button	Initiates the search for the text in the Verbatim field and applies the filters.
✓	Selects the query or queries on which you can perform a task.
Status	The status of the query, as indicated by the status icon.
Age	The age of the query in days.
Verbatim	The original reported text associated with the query, which describes the adverse event, disease, drug, or other item to be coded. **Note:** This information comes from the InForm application.
Study	The name of the study in which the verbatim associated with the query exists. **Note:** The name is an active link if you are integrated with the InForm application. Click the link to open the InForm application login page.

Queries page	
Field	**Description**
Site	Identifier for the site at which the study in which the verbatim associated with the query exists. **Note:** This information comes from the source application and appears in the SiteName field on the request detail pages.
Subject ID	The client identifier for the subject associated with the verbatim with which the query is associated.
Visit	The visit in which the verbatim associated with the query exists.
Form	The form on which the verbatim associated with the query exists.
Issuer	The user name of the user who entered the query.
Reason	The reason text specified by the user who entered the query.

Actions

Queries page		
Action	**Shortcut**	**Description**
Approve Candidate	Ctrl+Shift+K	Opens the Approve Query dialog box, from which you can approve a query in the Candidate state, and assign it to the Open state.
Reissue Query	Ctrl+Shift+I	
Close Query	Ctrl+Shift+X	
Delete Query	Ctrl+Shift+D	Opens the Cancel Query dialog box, from which you can delete a candidate query.
Retry Query Delivery		Changes the delivery status for a query that failed delivery to the source application back to the previous pending state, so that the query can be resent to the source application.
Force Close Query	Ctrl+Shift+Delete	Opens the Force Close Query dialog box, from which you can close a query in any state. **Note:** You must have the Force Close Query right to use this option.
Manage Auto Query	Ctrl+Shift+M	Opens the Auto Query List page, from which you can manage the verbatims for which a query is automatically created in the Central Coding application.

Buttons

Queries page		
Button	Shortcut	Description
Close Query	Ctrl+Shift+X	Opens the Close Query dialog box, from which you can close queries.
Reissue Query	Ctrl+Shift+I	Opens the Reissue Query dialog box, from which you can reissue queries.
Approve Candidate	Ctrl+Shift+K	Opens the Approve Query dialog box, from which you can approve a query in the Candidate state, and assign it to the Open state.
Delete Query	Ctrl+Shift+D	Opens the Cancel Query dialog box, from which you can delete a candidate query.
Manage Auto Query	Ctrl+Shift+M	Opens the Auto Query List page, from which you can manage the verbatims for which a query is automatically created in the Central Coding application.
Apply		Initiates the search for the text in the Verbatim field and applies the filters.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Approve Query dialog box

Use the Approve Query dialog box to assign a Candidate query to the Open state.

Fields

Approve Query dialog box	
Field	Description
Reason	Descriptive text about the reason for approving the query. **Note:** A Central Coding administrator can configure the default reasons, and can specify which reason appears first in the drop-down list.
Add as standard reason	Adds the text in the Other text box to the list of standard reasons that appear in the Reason drop-down list. **Note:** The Add as standard reason checkbox only appears for users who have the Manage Standard Reasons right.
Query State	Specify the state to assign to the query that you approve. **Note:** The only available option is to assign the query to the Open state.

Approve Query dialog box	
Field	**Description**
Auto close upon query complete	Instructs the Central Coding application to close the query after its associated verbatim is coded and approved, or deleted. **Note:** This option only appears if the Auto Close Query by Default feature is enabled.
Add to auto query list	Adds the verbatim and associated query to the Auto Query List. When an instance of the verbatim is added to the Central Coding application, the application associates the query to the verbatim. **Note:** This option only appears if the Allow Auto Query by Default feature is enabled.

Buttons

Approve Query dialog box	
Button	**Description**
Copy	Copies the selected text from the Reason drop-down list to the Other text box. This allows you to expand upon the reason text as needed.
OK	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Refresh ()	Updates the information on the page.
Help ()	Opens online page-level help that describes the page function(s) and fields.

Cancel Query dialog box

Use the Cancel Query dialog box to delete a Candidate query.

Fields

Cancel Query dialog box	
Field	**Description**
Reason	Descriptive text about the reason for approving the query. **Note:** A Central Coding administrator can configure the default reasons, and can specify which reason appears first in the drop-down list.
Add as standard reason	Adds the text in the Other text box to the list of standard reasons that appear in the Reason drop-down list. **Note:** The Add as standard reason checkbox only appears for users who have the Manage Standard Reasons right.

Buttons

Cancel Query dialog box	
Button	**Description**
Copy	Copies the selected text from the Reason drop-down list to the Other text box. This allows you to expand upon the reason text as needed.
OK	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Force Close Query dialog box

Use the Force Close Query dialog box to close queries in any state.

> **Note:** This option is only available to users with the Force Close Query right.

Fields

Force Close Query dialog box	
Field	**Description**
Reason	Descriptive text about the reason for approving the query. **Note:** A Central Coding administrator can configure the default reasons, and can specify which reason appears first in the drop-down list.

Buttons

Force Close Query dialog box	
Button	**Description**
Copy	Copies the selected text from the Reason drop-down list to the Other text box. This allows you to expand upon the reason text as needed.
OK	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Auto Query List page

Use the Auto Query List page to manage the list of verbatims for which the Allow Auto Query feature is enabled, and the queries associated with the verbatims.

Fields

Auto Query List page	
Field	**Description**
Verbatim	The verbatim for which you want to search. Searches are *case-insensitive*. The search supports the special characters *, %, ?, and _. The search text field can be an arbitrary text string and can contain wildcard characters to facilitate matching when the exact text is not known. The percent sign (%) or asterisk (*) matches any sequence of characters; the question mark (?) or underscore (_) matches any single character.
Study Group filter	A filter that identifies the queries you want to view, based on the name of a study group.
✓	Selects the query or queries on which you can perform a task.
Verbatim	The original reported text associated with the query, which describes the adverse event, disease, drug, or other item to be coded. **Note:** This information comes from the InForm application.
Dictionary Type	The type of coding dictionary to which the synonym list is associated: MedDRA, MedDRA-J, WHO-DD, JDrug, or a custom type.
Dictionary Culture	The culture setting associated with the coding dictionary.
Study Group	The name of the study group in which the verbatim associated with the query exists.
Query Text	The text of the query.

Buttons

Auto Query List page		
Button	Shortcut	Description
Delete Auto Query	Ctrl+Shift+D	Removes the selected verbatim or verbatims from the list of verbatims for which to automatically create queries.
Previous	Ctrl+Shift+P	Navigates to the previous page.
Apply		Initiates the search for the text in the Verbatim field and applies the filters.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Reports folder

Report Requests page

Use the Report Requests page to view the list and status of report requests.

Fields

Report Requests page	
Field	**Description**
Job Scheduler Status	Indicates whether the job scheduler is running. • —The job scheduler is running. • —The job scheduler is not running.
Report Type filter	A filter that identifies the items you want to view, based on their report type. • **Coded Items Report**—Provides detailed information on the coded items that are associated with all studies or one study within a specified date range and/or based on the approval status of the requests. The report provides the verbatim, indication, dictionary, coder, study name, delivery status, route of administration, coding type, date coded, subject ID, level, term, code value, and total request count. • **Coding Consistency Report**—Provides detailed information on the codings for a specified dictionary type, study, verbatim, and coding mode within a specified date range. The report provides the grand total request count, and for each verbatim provides the total request count, the requested dictionary level term(s), the code value(s), and the request count per code value. • **Workteams, Roles, and Rights by User**—Provides a list of assigned work teams, roles, and rights for each active user in the system.

Report Requests page	
Field	**Description**
Status filter	A filter that identifies the items you want to view, based on a report status. • **No selection**—No filter; displays all options. • **Scheduled**—Displays only the report requests that are scheduled to be produced. • **Running**—Displays only the report requests that are in the process of generating the report results. • **Produced**—Displays only the report requests that ran successfully and for which results are available. • **Failed**—Displays only the report requests that did not run successfully.
✓	Selects the item(s) on which you can perform a task.
Report Name	A name for the report. By default, this is the same as the Report Type. You can modify the name as needed. Click this link to open the parameters page for the report, from which you can view the parameters used to run the report. **Note:** The link is active only after the report is produced.
Report Type	The name of the requested report.
Request Date	The date you requested the report.
Status	The state of the report request.
Error	Descriptive information about a report that did not run successfully.
Result	A link to the Document Viewer page, from which you can view the results of the selected report in PDF format. Click the icon to open the page.

Actions

Report Requests page		
Action	**Shortcut**	**Description**
Export	Ctrl+Shift+E	Opens the Produce Report dialog box, from which you can create a request to export reports in comma separated value (CSV) format.
New	Ctrl+Shift+N	Opens the Produce Report dialog box, from which you can create a report request.
Remove		Deletes the request from the system. **Note:** A confirmation dialog box does **not** appear.

Report Requests page		
Action	Shortcut	Description
View Results	Ctrl+Shift+V	Opens the Document Viewer page, from which you can view the results of the selected report in PDF format.

Buttons

		Report Requests page
Button		Description
Export	Ctrl+Shift+E	Opens the Produce Report dialog box, from which you can create a request to export reports in comma separated value (CSV) format.
New	Ctrl+Shift+N	Opens the Produce Report dialog box, from which you can create a report request.
View Results	Ctrl+Shift+V	Opens the Document Viewer page, from which you can view the results of the selected report in PDF format.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Produce Report dialog box—New export

Use the Produce Report dialog box to export data in comma separated value (CSV) format.

Fields

Produce Report dialog box—New export	
Field	**Description**
Export Type	The export you want to run: • **AutoCode Export**—Provides detailed information on the percentage of autocoded items for a study or all studies within a specified date range to a comma-separated value (CSV) file for use by an external application such as the Microsoft Excel spreadsheet software. • **Auto Suggestion List Export**—Provides detailed information about the auto-suggestion list for a coding definition to a comma-separated value (CSV) file for use by an external application such as the Microsoft Excel spreadsheet software. • **Coded Items Export**—Provides detailed information on the coded items that are associated with all studies or one study within a specified date range and/or based on the approval status of the requests to be exported to a comma-separated value (CSV) file for use by an external application such as the Microsoft Excel spreadsheet software. • **Coder Metrics Export**—Provides detailed information about the coding work that each coder has done in the specified time frame, including the number of verbatims manually coded, approved, and in the Awaiting Approval state, as well as the number of queries opened and closed. • **Coding Consistency Export**—Provides detailed information on the codings for a specified dictionary type, study, verbatim, and coding mode within a specified date range to be exported to a comma-separated value (CSV) file for use by an external application such as the Microsoft Excel spreadsheet software.

Produce Report dialog box—New export	
Field	**Description**
	• **Query Export**—Provides detailed information on the queries opened in the Central Coding application for a study or query status. The query listing is exported to a comma-separated value (CSV) file for use by an external application such as the Microsoft Excel spreadsheet software. • **Study Metrics Export**—Provides detailed information about the coding work in a study during the specified time frame, including the number of verbatims received, autocoded, manually coded, approved, awaiting approval, and delivered, as well as the number of opened and closed queries. • **Synonym List Export**—Provides detailed information about a synonym list to a comma-separated value (CSV) file for use by an external application such as the Microsoft Excel spreadsheet software. • **Uncoded Items Export**—Provides detailed information about the uncoded items for a study or all studies within a specified date range to a comma-separated value (CSV) file for use by an external application such as the Microsoft Excel spreadsheet software.

Buttons

Produce Report dialog box—New export		
Button	**Shortcut**	**Description**
Accept	Ctrl+Shift+A	Saves the changes and closes the dialog box.
Cancel	Ctrl+Shift+C	Closes the dialog box without saving any changes.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Produce Report dialog box—AutoCode Export

Use the Produce Report dialog box to export data about autocoded requests in comma separated value (CSV) format.

Fields

Produce Report dialog box—AutoCode Export	
Field	**Description**
Export Type	The export that you want to run: AutoCode Export.
Study	The name of the study (or all studies) whose data you want to include. To select more than one study, hold down the **Ctrl** key while selecting each study name.
Start Date	The start date for the period covered by the export. The date must be in the format that you specify on the System Configuration page. REQUIRED. **Note:** To populate a date field with the current date, insert an equal sign (=).
End Date	The end date for the period covered by the export. The date must be in the format that you specify on the System Configuration page. REQUIRED. **Note:** To populate a date field with the current date, insert an equal sign (=).

Buttons

Produce Report dialog box—AutoCode Export	
Button	**Description**
Accept	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Produce Report dialog box—Auto Suggestion List Export

Use the Produce Report dialog box to export data about auto suggestion lists in comma separated value (CSV) format.

Fields

Produce Report dialog box—Auto Suggestion Export	
Field	Description
Export Type	The export that you want to run: Auto Suggestion Export.
Coding Definition	The coding definition associated with the auto-suggestion list.

Buttons

Produce Report dialog box—Auto Suggestion Export	
Button	Description
Accept	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Produce Report dialog box—Coded Items Export

Use the Produce Report dialog box for the Coded Items Export to export coded requests in comma separated value (CSV) format.

Fields

Produce Report dialog box—Export	
Field	Description
Export Type	The export that you want to run: Coded Items Export.
Study	The name of the study (or all studies) whose data you want to include.
Coding Definition	The coding definition that you want to associate with the export.
Start Date	The start date for the period covered by the export. The date must be in the format that you specify on the System Configuration page. REQUIRED. **Note:** To populate a date field with the current date, insert an equal sign (=).

Produce Report dialog box—Export	
Field	**Description**
End Date	The end date for the period covered by the export. The date must be in the format that you specify on the System Configuration page. REQUIRED. **Note:** To populate a date field with the current date, insert an equal sign (=).
Status	The type of requests to include in the export based on their approval status. • **Coded - All Approved**—Includes all requests that are approved (including auto approved requests). • **Coded - Unapproved**—Includes only requests that are coded but have not been approved. • **Coded - Manually Approved**—Includes only manually approved requests.
Export Codes	Indicates that you want to export the code values associated with the selected study or studies and coding definition. The file is in CSV format so that you can open it in the Microsoft Excel spreadsheet software or the Microsoft Word software.

Buttons

Produce Report dialog box—Export	
Button	**Description**
Accept	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Produce Report dialog box—Coder Metrics Export

Use the Produce Report dialog box to export data about the coding workload and progress of each coder.

Fields

Produce Report dialog box—Coder Metrics Export	
Field	**Description**
Export Type	The export that you want to run: Coder Metrics Export.
Start Date	The start date for the period covered by the export. The date must be in the format that you specify on the System Configuration page. REQUIRED.
End Date	The end date for the period covered by the export. The date must be in the format that you specify on the System Configuration page. REQUIRED. **Note:** To populate a date field with the current date, insert an equal sign (=).
Show Coding Definitions	When selected, the coding definition used in each study is included.

Buttons

Produce Report dialog box—Coder Metrics Export	
Button	**Description**
Accept	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Refresh ()	Updates the information on the page.
Help ()	Opens online page-level help that describes the page function(s) and fields.

Produce Report dialog box—Coding Consistency Export

Use the Produce Report dialog box for the Coding Consistency Export to export coded requests in comma separated value (CSV) format.

Fields

Produce Report dialog box—Export	
Field	**Description**
Export Type	The export that you want to run: Coding Consistency Export.
Dictionary Type	The coding dictionary you want to associate with the export. • **JDrug** • **MedDRA** • **WHODD** • **MedDRAJ**
Study	The study that you want to search for coding information. To select more than one study, hold down the **Ctrl** key while selecting each study name.
Verbatim	The verbatim whose coding information you want to view. To see information for all verbatims, leave this field blank. Searches are *case-insensitive*. The search supports the special characters *, %, ?, and _. The search text field can be an arbitrary text string and can contain wildcard characters to facilitate matching when the exact text is not known. The percent sign (%) or asterisk (*) matches any sequence of characters; the question mark (?) or underscore (_) matches any single character.
Coding Mode	The method(s) used to code the request. • **Both**—Includes the data for both interactively and automatically coded items. • **Interactive**—Includes only the data for interactively coded items. • **Autocode**—Includes only the data for automatically coded items.
Upper Level	The upper level of the dictionary hierarchy that you want to include in the export. The available options depend on the **Dictionary Type**.
Lower Level	The lower level of the dictionary hierarchy that you want to include in the export. The available options depend on the **Dictionary Type**.
Start Date	The start date for the period covered by the export. The date must be in the format that you specify on the System Configuration page. REQUIRED. **Note:** To populate a date field with the current date, insert an equal sign (=).

Produce Report dialog box—Export	
Field	Description
End Date	The end date for the period covered by the export. The date must be in the format that you specify on the System Configuration page. REQUIRED. **Note:** To populate a date field with the current date, insert an equal sign (=).
Show only verbatims with inconsistent codes	Report only displays information about verbatims for which instances of the same verbatim were assigned different codes. • **Selected, verbatim specified**—Displays information about the specified verbatim, if instances of the verbatim are assigned different codes. • **Selected, verbatim not specified**—Displays information about all verbatims for which instances are assigned different codes.

Buttons

Produce Report dialog box—Export	
Button	Description
Accept	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Produce Report dialog box—Query Export

Use the Produce Report dialog box to export query data in comma separated value (CSV) format.

Fields

Produce Report dialog box—Query Export	
Field	**Description**
Export Type	The export that you want to run: Query Export.
Study	The name of the study (or all studies) whose data you want to include. To select more than one study, hold down the **Ctrl** key while selecting each study name.
Query Status	The type of requests to include in the export based on the status of the query associated with the request. • Candidate • Opened • Answered • Closed • Deleted

Buttons

Produce Report dialog box—Query Export	
Button	**Description**
Accept	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Produce Report dialog box—Study Metrics Export

Use the Produce Report dialog box to export data about the coding work in each study.

Fields

Produce Report dialog box—Study Metrics Export	
Field	**Description**
Export Type	The export that you want to run: Study Metrics Export.
Study	The name of the study (or all studies) whose data you want to include. To select more than one study, hold down the **Ctrl** key while selecting each study name.
Start Date	The start date for the period covered by the export. The date must be in the format that you specify on the System Configuration page. REQUIRED.
End Date	The end date for the period covered by the export. The date must be in the format that you specify on the System Configuration page. REQUIRED. **Note:** To populate a date field with the current date, insert an equal sign (=).
Show Coding Definitions	When selected, the coding definition used in each study is included.

Buttons

Produce Report dialog box—Study Metrics Export	
Button	**Description**
Accept	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Refresh ()	Updates the information on the page.
Help ()	Opens online page-level help that describes the page function(s) and fields.

Produce Report dialog box—Synonym List Export

Use the Produce Report dialog box to export data about synonym lists in comma separated value (CSV) format.

Fields

Produce Report dialog box—Synonym List Export	
Field	**Description**
Export Type	The export that you want to run: Synonym List Export.
Synonym List	The synonym list to export.

Buttons

Produce Report dialog box—Synonym List Export	
Button	**Description**
Accept	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Produce Report dialog box—Uncoded Items Export

Use the Produce Report dialog box to export data about uncoded items in comma separated value (CSV) format.

Fields

Produce Report dialog box—Uncoded Items Export	
Field	**Description**
Export Type	The export that you want to run: Uncoded Items Export.
Study	The name of the study (or all studies) whose data you want to include. To select more than one study, hold down the **Ctrl** key while selecting each study name.
Start Date	The start date for the period covered by the export. The date must be in the format that you specify on the System Configuration page. REQUIRED. **Note:** To populate a date field with the current date, insert an equal sign (=).
End Date	The end date for the period covered by the export. The date must be in the format that you specify on the System Configuration page. REQUIRED. **Note:** To populate a date field with the current date, insert an equal sign (=).
Status	The type of requests to include in the export based on the Uncoded or Recode status associated with the request. • Uncoded • Recode • Uncoded or Recode

Buttons

Produce Report dialog box—Uncoded Items Export	
Button	**Description**
Accept	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Produce Report dialog box—New request

Use the Produce Report dialog box to create a report request.

Fields

Produce Report dialog box—New request	
Field	**Description**
Report Type	The report you want to run. • **Coded Items Report**—Provides detailed information on the coded items that are associated with all studies or one study within a specified date range and/or based on the approval status of the requests. The report provides the verbatim, indication, dictionary, coder, study name, delivery status, route of administration, coding type, date coded, subject ID, level, term, code value, and total request count. • **Coding Consistency Report**—Provides detailed information on the codings for a specified dictionary type and coding mode within a specified date range. The report provides the grand total request count, and for each verbatim provides the total request count, the requested dictionary level term(s), the code value(s), and the request count per code value. • **Workteams, Roles, and Rights by User**—Provides a list of assigned work teams, roles, and rights for each active user in the system. **Note:** All the reports require parameters with the exception of the **Workteams, Roles, and Rights by User** report. **Note:** The Central Coding application automatically generates the data for the Verify Codes Report when it updates the codes for all coded requests against a new dictionary. Therefore, the report is not available in the **Report Type** field.
Report Name	A name for the report. By default, this is the same as the Report Type. You can modify the name as needed.

Buttons

Produce Report dialog box—New request	
Button	**Description**
Accept	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Refresh ( )	Updates the information on the page.

Produce Report dialog box—New request	
Button	**Description**
Help (?)	Opens online page-level help that describes the page function(s) and fields.

Produce Report dialog box—Coded Items Report

Use the Produce Report dialog box to enter the parameters for a Coded Items report. This report provides detailed information on the coded items that are associated with all studies or one study within a specified date range and/or based on the approval status of the requests. The details include the verbatim, dictionary, coder, study name, coding type, date coded, subject ID, level, term, code value, and associated request count.

Fields

Produce Report dialog box—Coded Items Report	
Field	**Description**
Report Type	The report that you want to run: Coded Items Report.
Report Name	A name for the report. By default, this is the same as the Report Type. You can modify the name as needed.
Study	The name of the study (or all studies) whose data you want to include.
Start Date	The start date for the period covered by the report. The date must be in the format DD-MON-YYYY. REQUIRED. **Note:** To populate a date field with the current date, insert an equal sign (=).
End Date	The end date for the period covered by the report. The date must be in the format DD-MON-YYYY. REQUIRED. **Note:** To populate a date field with the current date, insert an equal sign (=).
Status	The type of requests to include in the report based on their approval status. • **Coded - All Approved**—Includes all requests that are approved (including auto approved requests). • **Coded - Unapproved**—Includes only requests that are coded but have not been approved. • **Coded - Manually Approved**—Includes only manually approved requests.

Produce Report dialog box—Coded Items Report	
Field	**Description**
Cumulative	• **Selected**—Report includes all the items coded in the system through the specified end date. All items within the specified date range appear in the report highlighted in pink. All items outside of the date range appear in the report but are not highlighted. • **Not selected**—Report includes only the items that were coded within the specified date range.

Buttons

Produce Report dialog box—Coded Items Report	
Button	**Description**
Accept	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

View Report Request dialog box—Coded Items Report

Use the View Report Request dialog box to view the parameters for a Coded Items report.

> **Note:** The information on this page is read only.

Fields

Produce Report dialog box—Coded Items Report	
Field	**Description**
Report Type	The report for which you are viewing the parameters: Coded Items Report.
Report Name	The name of the report. By default, this is the same as the Report Type; however, it could have been modified.
Study	The name of the study (or all studies) whose data you want to include.
Start Date	The start date for the period covered by the report.
End Date	The end date for the period covered by the report.

Produce Report dialog box—Coded Items Report	
Field	**Description**
Status	The type of requests to include in the report. • **Coded - All Approved**—Includes all requests that are approved (including auto approved requests). • **Coded - Unapproved**—Includes only requests that are coded but have not been approved. • **Coded - Manually Approved**—Includes only manually approved requests.
Cumulative	• **Selected**—Report includes all the items coded in the system through the specified end date. All items within the specified date range appear in the report highlighted in pink. All items outside of the date range appear in the report but are not highlighted. • **Not selected**—Report includes only the items that were coded within the specified date range.

Buttons

Produce Report dialog box—Coded Items Report	
Button	**Description**
OK	Closes the dialog box.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Produce Report dialog box—Coding Consistency Report

Use the Produce Report dialog box to enter the parameters for a Coding Consistency report. This report provides detailed information on the codings for a specified dictionary type, study, verbatim, and coding mode within a specified date range. The report provides the grand total request count, and for each verbatim provides the total request count, the requested dictionary level term(s), the code value(s), and the request count per code value.

Fields

Produce Report dialog box—Coding Consistency Report	
Field	**Description**
Report Type	The report that you want to run: Coding Consistency Report.
Report Name	A name for the report. By default, this is the same as the Report Type. You can modify the name as needed.

Produce Report dialog box—Coding Consistency Report	
Field	Description
Dictionary Type	The coding dictionary you want to associate with the report. REQUIRED. • **JDrug** • **MedDRA** • **WHODD** • **MedDRAJ**
Study	The study that you want to search for coding information. To select more than one study, hold down the **Ctrl** key while selecting each study name.
Verbatim	The verbatim whose coding information you want to view. To see information for all verbatims, leave this field blank. Searches are *case-insensitive*. The search supports the special characters *, %, ?, and _. The search text field can be an arbitrary text string and can contain wildcard characters to facilitate matching when the exact text is not known. The percent sign (%) or asterisk (*) matches any sequence of characters; the question mark (?) or underscore (_) matches any single character.
Coding Mode	The method(s) used to code the request. • **Both**—Includes the data for both interactively and automatically coded items. • **Interactive**—Includes only the data for interactively coded items. • **Autocode**—Includes only the data for automatically coded items.
Upper Level	The upper level of the dictionary hierarchy that you want to include in the report. The available options depend on the **Dictionary Type**.
Lower Level	The lower level of the dictionary hierarchy that you want to include in the report. The available options depend on the **Dictionary Type**.
Start Date	The start date for the period covered by the report. The date must be in the format that you specify on the System Configuration page. REQUIRED. **Note:** To populate a date field with the current date, insert an equal sign (=).
End Date	The end date for the period covered by the report. The date must be in the format that you specify on the System Configuration page. REQUIRED. **Note:** To populate a date field with the current date, insert an equal sign (=).

Produce Report dialog box—Coding Consistency Report	
Field	Description
Show only verbatims with inconsistent codes	Report only displays information about verbatims for which instances of the same verbatim were assigned different codes. • **Selected, verbatim specified**—Displays information about the specified verbatim, if instances of the verbatim are assigned different codes. • **Selected, verbatim not specified**—Displays information about all verbatims for which instances are assigned different codes.

Buttons

Produce Report dialog box—Coding Consistency Report	
Button	Description
Accept	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

View Report Request—Coding Consistency Report

Use the View Report Request dialog box to view the parameters for a Coding Consistency report.

Fields

View Report dialog box—Coding Consistency Report	
Field	Description
Report Type	The report for which you are viewing the parameters: Coding Consistency Report.
Report Name	The name of the report. By default, this is the same as the Report Type; however, it could have been modified.
Dictionary Type	The coding dictionary you want to associate with the report. • **JDrug** • **MedDRA** • **WHODD** • **MedDRAJ**

View Report dialog box—Coding Consistency Report	
Field	**Description**
Study	The study that you want to search for coding information. To select more than one study, hold down the **Ctrl** key while selecting each study name.
Verbatim	The verbatim whose coding information you want to view. To see information for all verbatims, leave this field blank.
Coding Mode	The method(s) used to code the request. • **Both**—Includes the data for both interactively and automatically coded items. • **Interactive**—Includes only the data for interactively coded items. • **Autocode**—Includes only the data for automatically coded items.
Upper Level	The upper level of the dictionary hierarchy that you want to include in the report.
Lower Level	The lower level of the dictionary hierarchy that you want to include in the report.
Start Date	The start date for the period covered by the report.
End Date	The end date for the period covered by the report.
Show only verbatims with inconsistent codes	Report only displays information about verbatims for which instances of the same verbatim were assigned different codes. • **Selected, verbatim specified**—Displays information about the specified verbatim, if instances of the verbatim are assigned different codes. • **Selected, verbatim not specified**—Displays information about all verbatims for which instances are assigned different codes.

Buttons

Produce Report dialog box—Coding Consistency Report	
Button	**Description**
OK	Closes the dialog box.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Produce Report dialog box—Workteams, Roles, and Rights by User

Use the Produce Report dialog box to enter the parameters for a Workteams, Roles, and Rights by User report. This report provides a list of assigned work teams, roles, and rights for each active user in the system.

Fields

Produce Report dialog box—Workteams, Roles, and Rights by User Report	
Field	**Description**
Report Type	The report that you want to run: Workteams, Rights, and Roles by User Report.
Report Name	A name for the report. By default, this is the same as the Report Type. You can modify the name as needed.

Buttons

Produce Report dialog box—Workteams, Roles, and Rights by User Report	
Button	**Description**
Accept	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

View Report Request dialog box—Workteams, Roles, and Rights by User

Use the Produce Report dialog box to view the parameters for a Workteams, Roles, and Rights by User report.

Fields

View Report Request dialog box—Workteams, Roles, and Rights by User	
Field	**Description**
Report Type	The report that you want to run: Workteams, Rights, and Roles by User Report.
Report Name	A name for the report. By default, this is the same as the Report Type. You can modify the name as needed.

Buttons

View Report Request dialog box—Workteams, Roles, and Rights by User	
Button	**Description**
OK	Closes the dialog box.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

View Report Request dialog box—Verify Codes Report

Use the View Report Request dialog box to view the parameters for a Verify Codes Report.

> **Note:** The information on this page is read only.

Fields

View Report Request dialog box—Verify Codes Report	
Field	**Description**
Report Type	The report for which you are viewing the parameters: Verify Codes Report.
Report Name	The name of the report. By default, this is the same as the Report Type; however, it could have been modified.

Buttons

View Report Request dialog box—Verify Codes Report	
Button	**Description**
OK	Closes the dialog box.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Document Viewer page

Use the Document Viewer page to view a report in PDF format.

Buttons

Document Viewer page	
Button	Description
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Coding Setup folder

Dictionaries tab

Dictionaries page

Use the Dictionaries page to view the list of installed dictionaries.

Fields

Dictionaries page	
Field	Description
✓	Selects the item(s) on which you can perform a task.
Type	The installed dictionary. Click this link to open the **[Dictionary Name]** page, from which you can view details about the dictionary. The information that appears on this page is defined when you load the dictionary.
Version	The version of the coding dictionary.
Culture	A combination of attributes including, but not limited to, language, date formats, and currency.
Status	The state of the dictionary. Only dictionaries with a status of **ACTIVE** appear on the page and are available for coding. **Note:** The status is defined in the Dictionary Loader tool. For more information, see the *Installation Guide*.

Actions

Dictionaries page		
Action	Shortcut	Description
View Details	Ctrl+Shift+V	Opens the [Dictionary Name] page, from which you can view details about the dictionary. The information that appears on this page is defined when you load the dictionary.
Element Configuration		Opens the Element Configuration page, from which you can specify the dictionary elements that you want to use to control which coding features and information are available to users in the Central Coding user interface.
Browse Dictionary		Opens the Coding Browser dialog box, from which you can familiarize yourself with the coding browser and view the terms associated with the selected dictionary.

Dictionaries page		
Action	Shortcut	Description
View Dictionary Changes	Ctrl+Shift+D	Opens the Dictionary Changes page, from which you can view the complete list of source and target dictionary versions that have been compared.

Buttons

Dictionaries page	
Button	Description
View Details	Opens the [Dictionary Name] page, from which you can view details about the dictionary. The information that appears on this page is defined when you load the dictionary.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

[Dictionary Name] page

Use the [Dictionary Name] page to view details about the dictionary. The information that appears on this page is defined when you load the dictionary.

> **Note:** The information on this page is read only.

Fields

[Dictionary Name] page	
Field	Description
Dictionary Information	
Type	The installed dictionary.
Version	The version of the coding dictionary.
Culture	A combination of attributes including, but not limited to, language, date formats, and currency.
Adapter Type	The type of dictionary to be used by the coding engine. The standard adapters are MedDRA, WHO-DD, and JDrug. For custom dictionaries, the adapter is Custom.
Levels	The number of hierarchy levels in the dictionary.

[Dictionary Name] page	
Field	**Description**
Punctuation String	The punctuation to be removed by a step in the coding algorithm, to help increase the chance of a coding match. **Note:** An Installer typically defines the punctuation string using the Dictionary Loader tool.
Status	The state of the dictionary. Only dictionaries with a status of **ACTIVE** appear in the page and are available for coding. **Note:** The status is defined in the Dictionary Loader tool. For more information, see *About the Dictionary Loader tool* in the *Installation Guide*.
Supports	Indicates the dictionary items the Central Coding application supports. • Supports Stopwords • Supports Synonyms • Uses PF Algorithm • Supports Search • Supports Browse • Supports Autocode • Supports Primary Path • Supports Term 2 • Terms Only • Requires Schema • Requires Load • Supports AutoSuggestion • Supports InSearch
Levels	
Level Abbreviation	The abbreviation for the level in the dictionary hierarchy.
Term Label	The full name for the level in the dictionary hierarchy.
Additional Information Label	Additional dictionary information.

Actions

[Dictionary Name] page	
Action	**Description**
Previous	Navigates back to the previous view.

Buttons

[Dictionary Name] page	
Button	**Description**
Previous	Navigates back to the previous view.
Refresh ()	Updates the information on the page.
Help ()	Opens online page-level help that describes the page function(s) and fields.

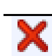
Element Configuration page

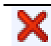
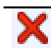
Use the Element Configuration page to specify the dictionary elements that you want to use to control which coding features and information are available to users in the Central Coding user interface. The element configuration settings determine the:

- Autocode target(s).
- Information that appears on the request list view pages and the coding browser displays.
- Dictionary elements that are returned to the source application.
- Dictionary elements that can be exported to the Microsoft Excel spreadsheet software with the request.
- Data items to be reconciled during impact analysis.

> **Note: The dictionary elements that appear on this page depend on the dictionary type. For more information, see *Dictionary elements—MedDRA and MedDRA-J* (on page 30), *Dictionary elements—WHO-DD* (on page 31), and *Dictionary elements—JDrug* (on page 32).**

Fields

Element Configuration page	
Field	**Description**
Request List Page Display	
Note: The items in this section appear on the Coding Requests, Approvals, and All Requests pages.	
Name	The hierarchy level in the specified dictionary.
	Moves the position of the item in this configuration section up, and in the page display to the left.
	Moves the position of the item in this configuration section down, and in the page display to the right.
	Removes the item from this configuration section so that it does not appear in the page display.
Search Page Display	

Element Configuration page	
Field	**Description**
Note: The items in this section appear in the coding browser when it is in the Search mode.	
Name	The hierarchy level in the specified dictionary.
In Field	Indicates whether to include the associated **Name** in the **In field** drop-down list in the coding browser.
	Moves the position of the item in this configuration section up, and in the page display to the left.
	Moves the position of the item in this configuration section down, and in the page display to the right.
	Removes the item from this configuration section so that it does not appear in the page display.
Browse Page Display	
Note: The items in this section appear in the coding browser when it is in the Browse mode.	
Name	The hierarchy level in the specified dictionary.
Include Code	Indicates, for each element, whether to display the code with the term in the coding browser display. This option appears only for each element that represents the term for a level in the dictionary.
Include Label	Indicates, for each element, whether to include the label in the coding browser display. This option appears only for the elements that represent additional information on a level.
	Removes the item from this configuration section so that it does not appear in the page display.
Elements	
Note: The items in this section depend on the associated dictionary.	
Name	The hierarchy level in the specified dictionary.
Autocode Target	Indicates that you want the application to autocode to this dictionary level as the primary autocode target.
Secondary Target	Indicates that you want the application to autocode to this dictionary level as the secondary target. The secondary target is a term level in the coding dictionary that is higher than the primary autocode target. The Central Coding application uses the secondary target to find all the secondary nodes that the primary autocode node connects to. **Note:** Use a secondary target if you want to autocode to something other than the primary autocode target (a non-primary path for MedDRA or MedDRA-J, or to include the ATC codes 1-4 for WHO-DD).
Return	Indicates that you want the data to be returned to the source application and saved in the Central Coding database.

Element Configuration page	
Field	**Description**
Exportable	Indicates that you want the data associated with the dictionary level to be exportable. If this option is not selected, the export option in the Reports folder is not available.
Search Term	Adds the item to the **Search Page Display** section on this page. **Note:** When the plus sign is grey ( ) , the corresponding item appears in the **Search Page Display** section. When the plus sign is green ( ), the item is available to be added to the **Search Page Display** section.
Search Code	Adds the item to the **Search Page Display** section on this page. **Note:** When the plus sign is grey ( ) , the corresponding item appears in the **Search Page Display** section. When the plus sign is green ( ), the item is available to be added to the **Search Page Display** section.
Browse	Adds the item to the **Browse Page Display** section on this page. **Note:** When the plus sign is grey ( ), the corresponding item appears in the **Browse Page Display** section. When the plus sign is green ( ), the item is available to be added to the **Browse Page Display** section.
Request List	Adds the item to the **Request List Page Display** section on this page. **Note:** When the plus sign is grey ( ), the corresponding item appears in the **Request List Page** section. When the plus sign is green ( ), the item is available to be added to the **Request List Page** section.
Requires Reconciliation	Select the checkbox if any difference in the term or the code of the level, or the text of an Additional Information element, will require reconciliation. By default, the items that are selected in the Return column are also selected in this column. You can edit the selections as needed. New codings that differ from the original codings only in elements that do not have this checkbox selected do not appear on the Reconcile Verbatims page. However, they are included in the Impact Analysis Report. **Note:** If the **Auto Reconcile Terms** checkbox on the Source And Target Coding Definitions dialog box is selected, only the code will require autoreconciliation.

Actions

Element Configuration page	
Action	**Description**
Clear Phase 2 Target	Clears the selection of the **Secondary Target** option(s) in the **Elements** section of the page.

Element Configuration page	
Action	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.

Buttons

Element Configuration page	
Button	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Dictionary Changes page

Use the Dictionary Changes page to view the complete list of source and target dictionary versions that have been compared. This list includes the dictionary type, the source and target dictionary versions, the dictionary culture, and the status of the comparison.

> **Note:** This page is used only during impact analysis.

Fields

Dictionary Changes page	
Field	**Description**
✓	Selects the dictionary version set(s) on which you can perform a task.
Dictionary Type	The type of coding dictionary: MedDRA, WHO-DD, or custom.
Source Dictionary Version	The version of the original (source) coding dictionary. **Note:** This is the dictionary the study has been coded to.
Target Dictionary Version	The version of the new (target) coding dictionary. **Note:** This is the dictionary you want to upgrade the study to.
Dictionary Culture	The culture setting associated with the coding dictionary.
Status	The state of the comparison between the two dictionary versions.
Error	Descriptive information about a dictionary comparison that did not run successfully.

Actions

Dictionary Changes page	
Action	**Description**
New	Opens the Dictionary Selection dialog box, from which you can select two dictionary versions to compare.
Rerun	Reruns the dictionary comparison for the selected dictionary set. You can rerun the comparison only if the Status is **Failed**.
Delete	Removes the selected dictionary set from the system. **Note:** A confirmation dialog box appears.
View Term Changes	Opens the Term Changes page, from which you can view the term changes between two dictionary versions.
View Path Changes	Opens the Path Changes page, from which you can view the path changes between two dictionary versions.

Buttons

Dictionary Changes page	
Button	**Description**
New	Opens the Dictionary Selection dialog box, from which you can select two dictionary versions to compare.
View Term Changes	Opens the Term Changes page, from which you can view the term changes between two dictionary versions.
View Path Changes	Opens the Path Changes page, from which you can view the path changes between two dictionary versions.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Dictionary Selection dialog box

Use the Dictionary Selection dialog box to select two dictionary versions to compare.

> **Note:** This page is used only during impact analysis.

Fields

Dictionary Selection dialog box	
Field	Description
Old Dictionary	The version of the original (source) coding dictionary.
New Dictionary	The version of the new (target) coding dictionary.

Buttons

Dictionary Selection dialog box		
Button	Shortcut	Description
OK	Ctrl+Shift+A	Saves the changes, initiates the comparison, and closes the dialog box.
Cancel	Ctrl+Shift+C	Closes the dialog box without saving any changes.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Term Changes page

Use the Term Changes page to view the term changes between two dictionary versions.

> **Note:** This page is used only during impact analysis.

Fields

Term Changes page	
Field	**Description**
Level filter	A filter that identifies the items you want to view, based on the dictionary level. For the MedDRA or MedDRA-J dictionary, the options are: • **No selection**—No filter; displays all options. • System Organ Class • High Level Group Term • High Level Term • Preferred Term • Low Level Term For the WHO-DD dictionary, the options are: • **No selection**—No filter; displays all options. • ATC1 • ATC2 • ATC3 • ATC4 • Preferred Name • Trade Name • Medicinal Product For the JDrug dictionary, the options are: • **No selection**—No filter; displays all options. • TC1 • TC2 • TC3 • TC4 • Generic Name • Trade Name • Case Name

Term Changes page	
Field	**Description**
Change filter	A filter that identifies the items you want to view, based on the changes made to the dictionary terms. For the MedDRA dictionary, the options are: • **No selection**—No filter; displays all options. • **Add**—Displays only the terms that have been added to the dictionary. • **Delete or Non-current**—Displays only the terms that have been deleted from the dictionary or displays only the terms that are non-current (valid for LLT only). • **Update**—Displays only the terms that have been updated in the dictionary. For the WHO-DD or JDrug dictionary, the options are: • **No selection**—No filter; displays all options. • **Add**—Displays only the terms that have been added to the dictionary. • **Delete**—Displays only the terms that have been deleted from the dictionary. • **Update**—Displays only the terms that have been updated in the dictionary.
Dictionary Level	The level of the coding dictionary on which the path originates.
Term	The dictionary term that has changed.
Change	The change made to the dictionary term. • **Add**—The term was added to the dictionary. • **Delete**—The term was deleted from the dictionary. • **Non-current**—The term is not current in the dictionary (MedDRA only). • **Update—**The term was updated in the dictionary.

Actions

Term Changes page	
Action	**Description**
Export	Opens the Windows **File Download** dialog box, from which you can choose to open or save the term changes in comma separated value (CSV) format.

Buttons

Term Changes page	
Button	**Description**
Export	Opens the Windows **File Download** dialog box, from which you can choose to open or save the term changes in comma separated value (CSV) format.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Export Result Viewer—Term Changes page

Use the Export Result Viewer—Term Changes page to access the dictionary term changes. You can choose to view the changes in the Microsoft Excel spreadsheet software or you can save the changes in comma separated value (CSV) format.

> **Note:** This page is used only during impact analysis.

Buttons

Export Result Viewer—Term Changes page	
Button	**Description**
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Path Changes page

Use the Path Changes page to view the path changes between two dictionary versions.

> **Note:** This page is used only during impact analysis.

Fields

Path Changes page	
Field	**Description**
Level filter	A filter that identifies the items you want to view, based on the dictionary level. For the MedDRA or MedDRA-J dictionary, the options are: • **No selection**—No filter; displays all options. • Preferred Term • Low Level Term For the WHO-DD dictionary, the options are: • **No selection**—No filter; displays all options. • Trade Name • Medicinal Product For the JDrug dictionary, the options are: • **No selection**—No filter; displays all options. • Generic Name • Trade Name • Case Name
✓	Selects the item(s) on which you can perform a task.
Dictionary Level	The level of the coding dictionary on which the path originates.
Term	The dictionary term that has changed.
Path Changes	A link that opens the View Path Changes Detail dialog box, from which you can view a summary of the path changes between dictionary versions.

Actions

Path Changes page	
Action	**Description**
Export	Opens the Windows File Download dialog box, from which you can choose to open or save the path changes in comma separated value (CSV) format.

Buttons

Path Changes page	
Button	**Description**
View Path Changes Detail	Opens the View Path Changes Detail dialog box, from which you can view a summary of the path changes between dictionary versions.
Export	Opens the Windows File Download dialog box, from which you can choose to open or save the path changes in comma separated value (CSV) format.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Export Result Viewer—Path Changes page

Use the Export Result Viewer—Path Changes page to access the dictionary path changes. You can choose to view the changes in the Microsoft Excel spreadsheet software or you can save the changes in comma separated value (CSV) format.

> **Note:** This page is used only during impact analysis.

Buttons

Export Result Viewer—Path Changes page	
Button	**Description**
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

View Path Changes Detail dialog box

Use the View Path Changes Detail dialog box to view a summary of the path changes between dictionary versions. The page shows the old, new, and unchanged paths for a particular term.

> **Note:** This page is used only during impact analysis.

Fields

View Path Changes Detail dialog box	
Field	**Description**
Dictionary Level	The level of the coding dictionary on which the path originates.
Code	The classification level code value.
Term	The standardized word or phrase.
Old Paths	
Note: This section displays paths that exist only in the source dictionary version.	
P	Indicates whether the path is the primary path. **Note:** This information appears only for the MedDRA or MedDRA-J dictionary.
Level	The level of the coding dictionary on which the path originates.
Code	The classification level code value.
Term	The standardized word or phrase associated with the code.
New Paths	
Note: This section displays paths that exist only in the target dictionary version.	
P	Indicates whether the path is the primary path. **Note:** This information appears only for the MedDRA or MedDRA-J dictionary.
Level	The level of the coding dictionary on which the path originates.
Code	The classification level code value.
Term	The standardized word or phrase.
Unchanged Paths	
Note: This section displays paths that exist in both the source and target dictionary versions.	
P	Indicates whether the path is the primary path. **Note:** This information appears only for the MedDRA or MedDRA-J dictionary.
Level	The level of the coding dictionary on which the path originates.
Code	The classification level code value.
Term	The standardized word or phrase.

Buttons

View Path Changes Detail dialog box	
Button	Description
OK	Closes the dialog box.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Synonym Lists tab

Synonym Lists page

Use the Synonym Lists page to view the list of synonym lists in the Central Coding application.

Fields

Synonym Lists page	
Field	Description
Dictionary filter	A filter that identifies the items you want to view, based on the dictionary they are defined against. If left blank, all items appear.
✓	Selects the item(s) on which you can perform a task.
	• If the flag icon appears, there is at least one proposed synonym in the associated synonym list. • If the icon does not appear, there are no proposed synonyms in the associated synonym list.
Name	The name of the synonym list. Click this link to open the [Synonym List Name] page, from which you can view, add, accept, reject, activate, deactivate, promote, mask, and unmask the stopwords in the list.
Dictionary Type	The type of coding dictionary to which the synonym list is associated: MedDRA, MedDRA-J, WHO-DD, JDrug, or a custom type.
Version	The version of the coding dictionary to which the synonym list is associated.
Culture	The culture setting associated with the coding dictionary.
Status	The status of the synonym list. • Active • Inactive

Synonym Lists page	
Field	**Description**
Parent Synonym List Name	The name of the synonym list from which the selected list is inherited. If blank, the list is not inherited.

Actions

Synonym Lists page		
Action	**Shortcut**	**Description**
New	Ctrl+Shift+N	Opens the New Synonym List page, from which you can create a new synonym list.
Copy		Opens the New Synonym List page, from which you can create a new synonym list that is a copy of an existing synonym list.
Edit	Ctrl+Shift+E	Opens the [Synonym List Name] page, from which you can edit the name of the synonym list.
Upgrade		Opens the Upgrade Synonym List dialog box, from which you can create a new synonym list that is a copy of an existing synonym list for use in impact analysis.
View Upgrade Process		Opens the Upgrade Synonym List In Process dialog box, from which you can view the status of the synonym upgrade process, initiate the synonym reconciliation process, generate the Synonym Reconciliation Report, and commit synonym changes to the database.
Activate		Changes the state of the selected synonym list to **Active**. Opens the Reason for Change dialog box, from which you can describe the change(s) to an item before you save it.
Deactivate		Changes the state of the selected synonym list to **Inactive**. Opens the Reason for Change dialog box, from which you can describe the change(s) to an item before you save it.
Delete		Removes the selected item from the system. A confirmation box appears. **Note:** You can only delete a synonym list that is empty (does not contain any synonyms) and is not used in a coding definition.

Synonym Lists page		
Action	**Shortcut**	**Description**
Manage	Ctrl+Shift+M	Opens the [Synonym List Name] page, from which you can view, add, accept, reject, activate, deactivate, promote, mask, and unmask the synonyms in the list.

Buttons

Synonym Lists page		
Button	**Shortcut**	**Description**
New	Ctrl+Shift+N	Opens the New Synonym List page, from which you can create a new synonym list.
Edit	Ctrl+Shift+E	Opens the [Synonym List Name] page, from which you can edit the name of the synonym list.
Activate	Ctrl+Shift+A	Changes the state of the selected synonym list to **Active**. Opens the Reason for Change dialog box, from which you can describe the change(s) to an item before you save it.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

New Synonym List page

Use the New Synonym List page to create a new synonym list.

Fields

New Synonym List page	
Field	**Description**
Synonym List Information	
Name	The name of the synonym list. REQUIRED.
Dictionary	The coding dictionary, version, and culture associated with the synonym list. REQUIRED.
Parent	The name of the synonym list that you want to inherit.
Status	The status of the synonym list.

Actions

New Synonym List page	
Action	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.

Buttons

New Synonym List page	
Button	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

[New Synonym List Name] page—Copied

Use the [New Synonym List Name] page—Copied to create a new synonym list that is a copy of an existing synonym list.

> **Note:** A copied synonym list is based on a snapshot of the existing list that you copy at the time you create the new list. Changes you make to the new list are not made to the original copied list.

Fields

[New Synonym List Name] page—Copied	
Field	**Description**
Synonym List Information	
Name	The name of the synonym list. REQUIRED.
Dictionary	The coding dictionary, version, and culture associated with the synonym list.
Parent	The name of the synonym list from which the selected list is inherited. **Note:** This field appears only if the list being copied is an inherited list.
Status	The status of the synonym list.

[New Synonym List Name] page—Copied	
Field	**Description**
Include children?	Indicates whether to copy the child synonym lists of the selected Parent synonym list. **Note:** This field appears only if the list being copied is a parent synonym list.

Actions

[New Synonym List Name] page—Copied	
Action	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.

Buttons

[New Synonym List Name] page—Copied	
Button	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

[Synonym List Name] page—Change name

Use the [Synonym List Name] page—Change name to edit the name of the synonym list.

Fields

[Synonym List Name] page—Change name	
Field	**Description**
Synonym List Information	
Name	The name of the synonym list. REQUIRED.
Dictionary	The coding dictionary, version, and culture associated with the synonym list. This field is read-only.
Parent	The name of the synonym list from which the selected list is inherited. **Note:** This field appears only if the list is inherited.

[Synonym List Name] page—Change name	
Field	**Description**
Status	The status of the synonym list. This field is read-only. The name of the synonym list from which the selected list is inherited.

Actions

[Synonym List Name] page—Change name	
Action	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.

Buttons

[Synonym List Name] page—Change name	
Button	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.
Help (?)	Opens online page-level help that describes the page function(s) and fields.

Upgrade Synonym List dialog box

Use the Upgrade Synonym List dialog box to create a new synonym list that is a copy of an existing synonym list for use in impact analysis.

> **Note:** This page is used only during impact analysis.

Fields

Upgrade Synonym List dialog box	
Field	**Description**
Original	
Synonym List	The name of the synonym list.
Parent Synonym List	The name of the synonym list from which the selected list is inherited. If blank, the list is not inherited.
Dictionary Type	The type of coding dictionary to which the synonym list is associated: MedDRA, MedDRA-J, WHO-DD, JDrug, or a custom type.

Upgrade Synonym List dialog box	
Field	**Description**
Dictionary Culture	The culture setting associated with the coding dictionary.
Dictionary Version	The version of the coding dictionary to which the synonym list is associated.
New	
Note: You can only upgrade a synonym list to a new dictionary version of the same type and culture.	
Synonym List	The name of the new synonym list that you want to upgrade. REQUIRED. **Note:** The synonym list name must be unique.
Parent Synonym List	The name to give the parent synonym list if the source synonym list is inherited and the parent has not yet been upgraded.
Dictionary Type	The type of coding dictionary to associate with the new synonym list: MedDRA, WHO-DD, JDrug, or a custom type. This field is read-only.
Dictionary Culture	The culture setting associated with the new coding dictionary. This field is read-only. **Note:** The culture setting associated with the dictionary must be the same for the source and target dictionary versions.
Dictionary Version	The version of the coding dictionary for the synonym list to upgrade to. REQUIRED. **Note:** The application checks to see if the source synonym list has been upgraded to this dictionary version already. If so, the upgraded synonym list is populated and a warning message appears.
Auto Reconcile Term Capitalization Differences	Select this option so that verbatim capitalization matches the Preferred Name for the WHO-DD format.

Buttons

Upgrade Synonym List dialog box		
Button	**Shortcut**	**Description**
OK	Ctrl+Shift+A	Saves the changes, initiates the Prepare step, and closes the dialog box.
Cancel	Ctrl+Shift+C	Closes the dialog box without saving any changes.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Upgrade Synonym List In Process page

Use the Upgrade Synonym List In Process page to view the status of the synonym upgrade process, initiate the synonym reconciliation process, generate the Synonym Reconciliation Report, and commit synonym changes to the database.

> **Note:** This page is used only during impact analysis.

Fields

Upgrade Synonym List In Process page	
Field	**Description**
✓	Selects the item(s) on which you can perform a task.
Source Name	The source synonym list.
Source Type	The type of the source coding dictionary: MedDRA, WHO-DD, or custom.
Source Culture	The culture setting associated with the source coding dictionary.
Source Version	The version of the original (source) coding dictionary.
Target Name	The target synonym list.
Target Version	The version of the new (target) coding dictionary.
Step	The current processing step of the synonym list upgrade. • Prepare • Reconcile • Update
Status	The status of the processing step. • In Process • Not Started • Scheduled • Running • Complete
Error	Descriptive information about a synonym list upgrade that did not run successfully.
Report	A link to the Document Viewer page, from which you can view the results of the Synonym Reconciliation report in PDF format. Click the icon to open the page.

Actions

Upgrade Synonym List In Process page		
Action	**Shortcut**	**Description**
Cancel		Stops a synonym list upgrade that is in process. **Note:** The application deletes the data and any report that has been created by the process. A warning message appears if the upgrade process has already started the Update step.
Rerun		Reruns the synonym list upgrade for the selected synonym list set. You can rerun the upgrade only if the Status is **Failed**.
Reconcile	Ctrl+Shift+R	Opens the Reconcile Synonyms page, from which you can reconcile the synonym differences between dictionary versions. **Note:** This action is available only when there are synonyms to reconcile.
Update	Ctrl+Shift+U	Commits all approved synonym changes to the database. **Note:** A confirmation dialog box appears.

Buttons

Upgrade Synonym List In Process page		
Button	**Shortcut**	**Description**
Generate Report	Ctrl+Shift+G	Runs the Synonym Reconciliation Report, which provides a snapshot of the synonym upgrade and reconciliation process at the time you run the report.
Reconcile	Ctrl+Shift+R	Opens the Reconcile Synonyms page, from which you can reconcile the synonym differences between dictionary versions. **Note:** This button is available only when there are synonyms to reconcile.
Update	Ctrl+Shift+U	Commits all approved synonym changes to the database. **Note:** A confirmation dialog box appears.
Previous		Navigates back to the previous view.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Reconcile Synonyms page

Use the Reconcile Synonyms page to reconcile the synonym differences between dictionary versions. If the code and term pair associated with any synonym no longer exists in the new dictionary, you must reassign or delete the synonyms.

> **Note:** It is the combination of the code and term that must exist in the new dictionary. If the code still exists but the term associated with that code has changed in the new version of the dictionary, the synonym must be reconciled.

The page lists all terms that no longer exist, or are no longer current, in the new dictionary version. You can:

- Select another term for that synonym set.
- Choose not to select another term for that synonym set, in which case all synonyms in the set will be removed from the synonym list(s).

> **Note:** This page is used only during impact analysis.

Fields

Reconcile Synonyms page	
Field	**Description**
Deleted Term	The term and code from the old dictionary version. The status of the old term can be Not Current (it is not current in the new dictionary version) or Deleted.
New Term	The term from the new dictionary version chosen to replace the non-current or deleted term from the old dictionary version. Click the **Code** link to open the Coding Browser dialog box, from which you can interactively recode the synonym.
Synonyms	The synonyms in the source synonym list(s) that are associated with the Deleted Term.

Reconcile Synonyms page	
Field	**Description**
Action	Indicates the action that you want to perform on the Deleted Term. • If you select the **Delete** option, the associated Deleted Term will not be copied to the new synonym list; it is deleted when you approve all changes. • If you do not select this option, the associated **Deleted Term** is not deleted when you approve all changes. When you deselect the option, the coding browser opens and you can recode the term. **Note:** You can also click the **Code** link in the New Term column to open the Coding Browser dialog box, from which you can interactively code the synonym. **Note:** If an administrator selects the **Set Delete Synonym as Default** option on the System Configuration page, the **Delete** option is selected by default for all deleted terms (synonyms). You can deselect the option.

Actions

Reconcile Synonyms page		
Action	**Shortcut**	**Description**
Approve All	Ctrl+Shift+A	Saves and applies the selected actions for every synonym. Select this action when you consider synonym reconciliation to be complete. The Upgrade Synonym List In Process page reappears, and any terms that have the Delete action selected are not copied to the new synonym list when Update is initiated. An error message appears if the Allow Uncode option is not available on the page and all synonyms are not reconciled. You must reconcile all synonyms before you can approve the changes.
Previous	Ctrl+Shift+P	Navigates back to the previous view.

Buttons

Reconcile Synonyms page		
Button	**Shortcut**	**Description**
Approve All	Ctrl+Shift+A	Saves and applies the selected actions for every synonym.
Previous	Ctrl+Shift+P	Navigates back to the previous view.

Reconcile Synonyms page		
Button	**Shortcut**	**Description**
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

[Synonym List Name] page—Manage synonyms

Use the [Synonym List Name] page—Manage synonyms to view, add, accept, reject, activate, deactivate, promote, mask, and unmask the synonyms in the list.

Fields

[Synonym List Name] page—Manage synonyms	
Field	**Description**
Synonym	A filter that identifies the items you want to view, based on the name of the synonym. Searches are *case-insensitive*. The search supports the special characters *, %, ?, and _. The search text field can be an arbitrary text string and can contain wildcard characters to facilitate matching when the exact text is not known. The percent sign (%) or asterisk (*) matches any sequence of characters; the question mark (?) or underscore (_) matches any single character.
Status filter	A filter that identifies the items you want to view, based on the status of the synonyms. • **No selection**—No filter; displays all options. • **ACTIVE**—Displays all of the synonyms in the list that are active. • **INACTIVE**—Displays all of the synonyms in the list that are not active. • **MASKED**—Displays all of the synonyms in the list that are masked from the parent synonym list. • **PROPOSED**—Displays all of the synonyms in the list that are proposed and not yet accepted.
Inheritance filter	A filter that identifies the items you want to view, based on whether the list is inherited. • **All**—Displays both the inherited and non-inherited synonyms in the list. • **Show Inherited**—Displays only the inherited synonyms. • **Show Non-inherited**—Displays only the non-inherited synonyms.

[Synonym List Name] page—Manage synonyms	
Field	**Description**
Apply button	Initiates the search for the text in the **Synonym** field and applies the filters.
Synonym List Information	
Name	The name of the synonym list.
Dictionary	The coding dictionary, version, and culture associated with the synonym list.
Parent	The name of the synonym list from which the selected list is inherited. **Note:** This field appears only if the list is inherited. When you create a synonym list by inheriting the contents of another list, it always appears to contain the synonyms from both lists. However, the parent synonym list contains only its own synonyms; it does not include the synonyms from the child (inherited) list.
Status	The status of the synonym list.
Synonyms	
✓	Selects the item(s) on which you can perform a task.
Synonym	The synonym for a term.
Term	The coded term.
Code	The classification level code value. Click this link to open the View Full Coding dialog box, from which you can view the full coding details for a coded item. The details include the dictionary name and version, the coded term and value, and the level of the dictionary hierarchy where the match was found.
Level	The hierarchy level in the specified dictionary.
Status	The state of the synonym.
Inherited	Indicates whether the synonym was inherited from another list. The options are Yes and No.

Actions

[Synonym List Name] page—Manage synonyms	
Action	**Description**
New	Opens the New Synonym page, from which you can create and code a new synonym.
Accept	Accepts the proposed synonym, activates it, and adds it to the synonym list.
Reject	Rejects the proposed synonym and removes it from the list of synonyms.

[Synonym List Name] page—Manage synonyms	
Action	Description
Activate	Changes the state of the selected synonym to **Active**. Opens the Reason for Change dialog box, from which you can describe the change(s) to an item before you save it.
Deactivate	Changes the state of the selected synonym to **Inactive**. Opens the Reason for Change dialog box, from which you can describe the change(s) to an item before you save it.
Promote	Adds the selected synonym to the Parent Synonym List. This option is available only for inherited synonym lists.
Mask	Hides the selected synonym from the Parent Synonym List. This option is available only for inherited synonym lists.
Unmask	Shows the selected synonym to the Parent Synonym List. This option is available only for inherited synonym lists.
Previous	Navigates back to the previous view.

Buttons

[Synonym List Name] page—Manage synonyms	
Button	Description
New	Opens the New Synonym page, from which you can create and code a new synonym.
Edit	Opens the [Synonym Name] page, from which you can review the details for the synonym including information on the synonym list, the dictionary level where the term was found, and its current associated term and code.
Accept	Accepts the proposed synonym, activates it, and adds it to the synonym list. Opens the Reason for Change dialog box, from which you can describe the change made to an item before it is saved.
Reject	Rejects the proposed synonym and removes it from the list of synonyms. Opens the Reason for Change dialog box, from which you can describe the change made to an item before it is saved.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

New Synonym page

Use the New Synonym page to create and code a new synonym.

Fields

New Synonym page	
Field	**Description**
Synonym List Information	
Name	The name of the synonym list. This field is read-only.
Dictionary	The coding dictionary, version, and culture associated with the synonym list. This field is read-only.
Parent	The name of the synonym list from which the selected list is inherited. This field is read-only. **Note:** This field appears only if the list is inherited.
Status	The status of the synonym list. This field is read-only.
Synonym	
Level	The hierarchy level in the associated dictionary where the code value was found. REQUIRED.
Synonym	The synonym for a term. REQUIRED.
Term	The coded term. This field is blank until you code and save the new synonym.
Code	The classification level code value. This field is blank until you code and save the new synonym.

Actions

New Synonym page	
Action	**Description**
Code	Opens the Coding Browser dialog box, from which you can interactively code the proposed synonym.
Save	Saves the changes.
Previous	Navigates back to the previous view.

Buttons

New Synonym page	
Button	Description
Code	Opens the Coding Browser dialog box, from which you can interactively code the proposed synonym.
Save	Saves the changes.
Previous	Navigates back to the previous view.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

[Synonym Name] page

Use the [Synonym Name] page to review the details for the synonym including information on the synonym list, the dictionary level where the term was found, and its current associated term and code.

> **Note:** The information on this page is read only.

Fields

[Synonym Name] page	
Field	Description
Synonym List Information	
Name	The name of the synonym list.
Dictionary	The coding dictionary, version, and culture associated with the synonym list.
Parent	The name of the synonym list from which the selected list is inherited. **Note:** This field appears only if the list is inherited.
Status	The status of the synonym list.
Synonym	
Level	The hierarchy level in the associated dictionary where the code value was found.
Synonym	The synonym for a term.
Term	The coded term.

[Synonym Name] page	
Field	**Description**
Code	The classification level code value. Click this link to open the View Full Coding dialog box, from which you can view the full coding details for a coded item. The details include the dictionary name and version, the coded term and value, and the level of the dictionary hierarchy where the match was found.

Actions

[Synonym Name] page	
Action	**Description**
Code	Opens the Coding Browser dialog box, from which you can interactively code the proposed synonym.
Save	Saves the changes.
Previous	Navigates back to the previous view.

Buttons

[Synonym Name] page	
Button	**Description**
Code	Opens the Coding Browser dialog box, from which you can interactively code the proposed synonym.
Save	Saves the changes.
Previous	Navigates back to the previous view.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Stopword Lists tab

Stopword Lists page

Use the Stopword Lists page to view the list of stopword lists in the Central Coding application.

Fields

Stopword Lists page	
Field	Description
✓	Selects the item(s) on which you can perform a task.
Name	The name of the stopword list. Click this link to open the [Stopword List Name] page, from which you can view, add, accept, reject, activate, deactivate, promote, mask, and unmask the stopwords in the list.
Status	The state of the stopword list. • Active • Inactive
Parent Stopword List Name	The name of the stopword list from which the selected list is inherited. If blank, the list is not inherited.

Actions

Stopword Lists page		
Action	Shortcut	Description
New	Ctrl+Shift+N	Opens the New Stopword List page, from which you can create a new stopword list.
Copy		Opens the New Stopword List page, from which you can create a new stopword list that is a copy of an existing stopword list.
Edit	Ctrl+Shift+E	Opens the [Stopword List Name] page, from which you can edit the name of the stopword list.
Activate		Changes the state of the selected deactivated stopword list to **Active**. Opens the Reason for Change dialog box, from which you can describe the change(s) to an item before you save it.
Deactivate		Changes the state of the selected active stopword list to **Inactive**. Opens the Reason for Change dialog box, from which you can describe the change(s) to an item before you save it.
Delete		Removes the selected item from the system. A confirmation dialog box appears.

Stopword Lists page		
Action	**Shortcut**	**Description**
Manage		Opens the [Stopword List Name] page, from which you can view, add, accept, reject, activate, deactivate, promote, mask, and unmask the stopwords in the list.

Buttons

Stopword Lists page		
Button	**Shortcut**	**Description**
New	Ctrl+Shift+N	Opens the New Stopword List page, from which you can create a new stopword list.
Edit	Ctrl+Shift+E	Opens the [Stopword List Name] page, from which you can edit the name of the stopword list.
Activate		Changes the state of the selected deactivated stopword list to **Active**. Opens the Reason for Change dialog box, from which you can describe the change(s) to an item before you save it.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

New Stopword List page

Use the New Stopword List page to create a new stopword list.

Fields

New Stopword List page	
Field	**Description**
Stopword List Information	
Name	The name of the stopword list. REQUIRED.
Parent	The name of the stopword list that you want to inherit. **Note:** When you create a stopword list by inheriting the contents of another list, the new list always appears to contain the stopwords from both lists. However, the parent stopword list contains only its stopwords, not the stopwords from the child (inherited) list.
Status	The state of the stopword list.

Actions

New Stopword List page	
Action	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.

Buttons

New Stopword List page	
Button	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.
Help (?)	Opens online page-level help that describes the page function(s) and fields.

[New Stopword List Name] page—Copied

Use the [New Stopword List Name] page—Copied to create a new stopword list that is a copy of an existing stopword list.

> **Note:** A copied stopword list is based on a snapshot of the existing list that you copy at the time you create the new list. Changes you make to the new list are not made to the original copied list.

Fields

[New Stopword List Name] page—Copied	
Field	**Description**
Stopword List Information	
Name	The name of the stopword list. REQUIRED.
Parent	The name of the stopword list from which the selected list is inherited. **Note:** This field appears only if the list is inherited.
Status	The state of the stopword list. This field is read-only.

Actions

[New Stopword List Name] page—Copied

Action	Description
Save	Saves the changes.
Previous	Navigates back to the previous view.

Buttons

[New Stopword List Name] page—Copied	
Button	Description
Save	Saves the changes.
Previous	Navigates back to the previous view.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

[Stopword List Name] page—Change name

Use the [Stopword List Name] page to edit the name of the stopword list.

Fields

[Stopword List Name] page—Change name	
Field	Description
Stopword List Information	
Name	The name of the stopword list. REQUIRED.
Parent	The name of the stopword list from which the selected list is inherited. **Note:** This field appears only if the list is inherited.
Status	The state of the stopword list.

Actions

[Stopword List Name] page—Change name	
Action	Description
Save	Saves the changes.
Previous	Navigates back to the previous view.

Buttons

[Stopword List Name] page—Change name

Button	Description
Save	Saves the changes.
Previous	Navigates back to the previous view.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

[Stopword List Name] page—Manage stopwords

Use the [Stopword List Name] page to view, add, accept, reject, activate, deactivate, promote, mask, and unmask the stopwords in the list.

Fields

[Stopword List Name] page—Manage stopwords	
Field	**Description**
Status filter	A filter that identifies the items you want to view, based on the status of the stopwords. • **No selection**—No filter; displays all options. • **ACTIVE**—Displays all of the stopwords in the list that are active. • **INACTIVE**—Displays all of the stopwords in the list that are not active. • **MASKED**—Displays all of the stopwords in the list that are masked from the parent stopwords list.
Inheritance filter	A filter that identifies the items you want to view, based on whether the list is inherited. • **All**—Displays both the inherited and non-inherited stopwords in the list. • **Show Inherited**—Displays only the inherited stopwords. • **Show Non-inherited**—Displays only the non-inherited stopwords.
Stopword List Information	
Name	The name of the stopword list.

[Stopword List Name] page—Manage stopwords	
Field	**Description**
Parent	The name of the stopword list from which the selected list is inherited. **Note:** This field appears only if the list is inherited.
Status	The state of the stopword list.
Stopwords	
✓	Selects the item(s) on which you can perform a task.
Stopword	The stopword text.
Status	The state of the stopword.
Inherited	Indicates whether the stopword was inherited from another list. The options are Yes and No.

Actions

[Stopword List Name] page—Manage stopwords	
Action	**Description**
New	Opens the New Stopword page, from which you can add a stopword to the list.
Activate	Changes the state of the selected deactivated stopword to **Active**. Opens the Reason for Change dialog box, from which you can describe the change(s) to an item before you save it.
Deactivate	Changes the state of the selected active stopword to **Inactive**. Opens the Reason for Change dialog box, from which you can describe the change(s) to an item before you save it.
Promote	Adds the selected stopword to the Parent Stopword List. This option is available only for inherited stopword lists.
Mask	Hides the selected stopword from the Parent Stopword List. This option is available only for inherited stopword lists.
Unmask	Shows the selected stopword to the Parent Stopword List. This option is available only for inherited stopword lists.
Previous	Navigates back to the previous view.

Buttons

[Stopword List Name] page—Manage stopwords	
Button	**Description**

[Stopword List Name] page—Manage stopwords	
Button	**Description**
New	Opens the New Stopword page, from which you can add a stopword to the list.
Previous	Navigates back to the previous view.
Activate	Changes the state of the selected deactivated stopword to **Active**. Opens the Reason for Change dialog box, from which you can describe the change(s) to an item before you save it.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

New Stopword page

Use the New Stopword page to create a new stopword.

Fields

New Stopword page	
Field	**Description**
Stopword List Information	
Name	The name of the stopword list. This field is read-only.
Parent	The name of the stopword list from which the selected list is inherited. **Note:** This field appears only if the list is inherited.
Status	The state of the stopword list. This field is read-only.
Stopword	
Stopword	The stopword text. REQUIRED.

Actions

New Stopword page	
Action	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.

Buttons

New Stopword page

Button	Description
Save	Saves the changes.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Algorithms tab

Algorithms page

Use the Algorithms page to view the list of algorithms in the Central Coding application.

Fields

Algorithms page	
Field	**Description**
✓	Selects the item(s) on which you can perform a task.
Name	The name of the algorithm. Click this link to open the [Algorithm Name] page, from which you can view, reorder, add, or remove steps in the algorithm.
Description	Descriptive information about the algorithm.
Status	The state of the algorithm. • Active • Inactive

Actions

Algorithms page		
Action	**Shortcut**	**Description**
New	Ctrl+Shift+N	Opens the New Algorithm page, from which you can create a new algorithm.
Activate		Changes the state of the selected algorithm to **Active**. Opens the Reason for Change dialog box, from which you can describe the change(s) to an item before you save it.

Algorithms page		
Action	Shortcut	Description
Deactivate		Changes the state of the selected algorithm to **Inactive**. Opens the Reason for Change dialog box, from which you can describe the change(s) to an item before you save it.
Delete		Removes the selected item from the system.
Manage		Opens the [Algorithm Name] page, from which you can reorder, add, or remove steps in the algorithm.

Buttons

		Algorithms page
Button	Shortcut	Description
New	Ctrl+Shift+N	Opens the New Algorithm page, from which you can create a new algorithm.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

New Algorithm page

Use the New Algorithm page to create a new algorithm.

Fields

New Algorithm page	
Field	Description
Coding Algorithm Information	
Name	The name of the algorithm. REQUIRED. **Note:** You cannot modify this information after you save the algorithm.
Description	Descriptive information about the algorithm. **Note:** You cannot modify this information after you save the algorithm.
Status	The state of the algorithm.

Actions

New Algorithm page

Action	Description
Save	Saves the changes.
Previous	Navigates back to the previous view.

Buttons

New Algorithm page	
Button	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

[Algorithm Name] page—View mode

Use the [Algorithm Name] page—View mode to view information about the coding algorithm.

> **Note:** The information on this page is read only.

Fields

[Algorithm Name] page—View mode	
Field	**Description**
Coding Algorithm Information	
Name	The name of the algorithm.
Description	Descriptive information about the algorithm.
Status	The state of the algorithm.
Steps	
✓	Selects the item(s) on which you can perform a task.
Order	The order the system runs the steps in the algorithm.
Name	The name of the algorithm step.
Description	Descriptive information about the algorithm step.

Actions

[Algorithm Name] page—View mode

Action	Description
Edit	Puts the [Algorithm Name] page into Edit mode, from which you can reorder, add, or remove steps in the algorithm.
Previous	Navigates back to the previous view.

Buttons

[Algorithm Name] page—View mode	
Button	**Description**
Edit	Puts the [Algorithm Name] page into Edit mode, from which you can reorder, add, or remove steps in the algorithm.
Previous	Navigates back to the previous view.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

[Algorithm Name] page—Edit mode

Use the [Algorithm Name] page—Edit mode to reorder, add, or remove steps in the algorithm.

Fields

[Algorithm Name] page—Edit mode	
Field	**Description**
Coding Algorithm Information	
Name	The name of the algorithm. This field is read-only.
Description	Descriptive information about the algorithm. This field is read-only.
Status	The state of the algorithm. This field is read-only.
Steps	
✓	Selects the item(s) on which you can perform a task.
Order	The order the system runs the steps in the algorithm.
Name	The name of the algorithm step.
Description	Descriptive information about the algorithm step.

Actions

[Algorithm Name] page—Edit mode	
Action	**Description**

[Algorithm Name] page—Edit mode	
Action	Description
Add	Opens the Add Actions to Algorithm page, from which you can add and manage the steps in the algorithm.
Remove	Deletes the selected algorithm step from the algorithm. A confirmation dialog box appears.
Save	Saves the changes.
Previous	Navigates back to the previous view.

Buttons

[Algorithm Name] page—Edit mode	
Action	Description
Add	Opens the Add Actions to Algorithm page, from which you can add and manage the steps in the algorithm.
Remove	Deletes the selected algorithm step from the algorithm. A confirmation dialog box appears.
Save	Saves the changes.
Previous	Navigates back to the previous view.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Add Actions to Algorithm dialog box

Use the Add Actions to Algorithm dialog box to add and manage the steps in the algorithm. For more information, see ***Available algorithm steps*** (on page 162).

Fields

Add Actions to Algorithm dialog box	
Field	Description
✓	Selects the item(s) on which you can perform a task.
Name	The name of the algorithm step.
Description	Descriptive information about the algorithm step.

Buttons

Add Actions to Algorithm dialog box

Button	Description
Accept	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Coding Definitions tab

Coding Definitions page

Use the Coding Definitions page to view the list of coding definitions in the Central Coding application.

Fields

Coding Definitions page	
Field	Description
✓	Selects the item(s) on which you can perform a task.
Name	The name of the coding definition. Click this link to open the [Coding Definition Name] page, from which you can view or edit the details of a coding definition.
Description	Descriptive information about the coding definition.
Dictionary	The coding dictionary and version associated with the coding definition.
Synonym List	The name of the synonym list associated with the coding definition.
Stopword List	The name of the stopword list associated with the coding definition.
Coding Algorithm	The name of the algorithm associated with the coding definition.
Comments	System generated information about the coding definition.

Actions

Coding Definitions page		
Action	Shortcut	Description
New	Ctrl+Shift+N	Opens the New Coding Definition page, from which you can create a new coding definition.
Edit	Ctrl+Shift+E	Puts the [Coding Definition Name] page into Edit mode, from which you can edit the name of the stopword list.

Coding Definitions page		
Action	**Shortcut**	**Description**
Upgrade	Ctrl+Shift+U	Used during impact analysis only. Opens the Upgrade Coding Definition dialog box, from which you can create a new coding definition that is a copy of an existing coding definition.
Rerun		Used during impact analysis only. Reruns the upgrade coding definition process. You can rerun the process only if the Status is Failed.
Element Configuration		Opens the Element Configuration page, from which you can specify the dictionary elements that you want to use to control which coding features and information are available to users in the Central Coding user interface.
Reset Element Configuration		Resets all of the element configuration settings for the selected coding definition to the settings for its associated dictionary. A confirmation dialog box appears.
Manage Auto Suggestions		Opens the Auto Suggestions page, from which you can view the auto-suggested codes for terms that are associated with a coding definition and specified verbatim.
Delete		Removes the selected item from the system. A confirmation dialog box appears.
Verify and Update Codes		Instructs the Central Coding system to review the codes for all coded requests against a new dictionary. Changes are tracked in the audit history. For more information, see ***Verifying and updating codes after changing a dictionary*** (on page 582).
View Verify and Update Job Log		Opens the View Job Log page, from which you can view the results of updating the codes for all coded requests against a new dictionary.
Run Impact Analysis		Used during impact analysis only. Opens the Choose Source And Target Coding Definitions dialog box, from which you can select two coding definitions to compare for impact analysis.
View Impact Analysis Process		Used during impact analysis only. Opens the In Process page, from which you can view the status of the verbatim upgrade process, initiate the verbatim reconciliation process, generate the Impact Analysis Report, export data, and commit verbatim changes to the database.

Buttons

Coding Definitions page		
Button	**Shortcut**	**Description**
New	Ctrl+Shift+N	Opens the New Coding Definition page, from which you can create a new coding definition.
Edit	Ctrl+Shift+E	Puts the [Coding Definition Name] page into Edit mode, from which you can edit the name of the stopword list.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

New Coding Definition page

Use the New Coding Definition page to create a new coding definition.

Fields

New Coding Definition page	
Field	**Description**
Coding Definition Information	
Name	The name of the coding definition. REQUIRED.
Description	Descriptive information about the coding definition.
Dictionary	The coding dictionary and version associated with the coding definition. REQUIRED.
Synonym List	The name of the synonym list associated with the coding definition. REQUIRED.
Stopword List	The name of the stopword list associated with the coding definition. REQUIRED.
Coding Algorithm	The name of the algorithm associated with the coding definition. REQUIRED.

Actions

New Coding Definition page	
Action	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.

Buttons

New Coding Definition page	
Button	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.
Help (?)	Opens online page-level help that describes the page function(s) and fields.

[Coding Definition Name] page

Use the [Coding Definition Name] page to view or edit the details of a coding definition.

Fields

[Coding Definition Name] page	
Field	**Description**
Coding Definition Information	
Name	The name of the coding definition. This field is read-only.
Description	Descriptive information about the coding definition.
Dictionary	The coding dictionary and version associated with the coding definition. REQUIRED.
Synonym List	The name of the synonym list associated with the coding definition. REQUIRED.
Stopword List	The name of the stopword list associated with the coding definition. REQUIRED.
Coding Algorithm	The name of the algorithm associated with the coding definition. REQUIRED.

Actions

[Coding Definition Name] page	
Action	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.

Buttons

[Coding Definition Name] page	
Button	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.
Help (?)	Opens online page-level help that describes the page function(s) and fields.

Upgrade Coding Definition dialog box

Use the Upgrade Coding Definition dialog box to create a new coding definition that is a copy of an existing coding definition.

> **Note:** This page is used only during impact analysis.

Fields

Upgrade Coding Definition dialog box	
Field	**Description**
Original	
Note: *This column provides information on the source coding definition.*	
Coding Definition Name	The name of the coding definition that you want to copy.
Dictionary Type	The type of coding dictionary to which the coding definition is associated: MedDRA, WHO-DD, or custom.
Dictionary Culture	The culture setting associated with the coding dictionary.
Dictionary Version	The version of the coding dictionary to which the coding definition is associated.
Synonym List	The name of the synonym list associated with the coding definition.
Coding Algorithm	The name of the algorithm associated with the coding definition.
Stopword List	The name of the stopword list associated with the coding definition.

Upgrade Coding Definition dialog box	
Field	**Description**
Update assignment rules with new coding definition	• Select to replace the source coding definition with the target coding definition for all existing assignment rules. • Use this option to assign any future requests that would have been assigned to the source coding definition to the new coding definition. • During the upgrade process, all assignment rules that were assigned to the source coding definition will be assigned to the new upgraded coding definition. **Note:** All new requests that meet the rules will be assigned to the new coding definition during the next run of assignment rules.
Copy assignment rules and use new coding definition	• Select to make a copy of the assignment rules associated with the source coding definition for the new (target) coding definition, so that you can edit them based on the set of verbatims you want coded with the new dictionary version. • The original assignment rules will continue to assign future requests to the old coding definition. **Note:** During the upgrade process, all assignment rules that were assigned to the source coding definition will be copied to another rule and the new rule will be assigned to the upgraded coding definition.
No changes to assignment rules	• Select to create a new set of assignment rules from scratch. • The assignment rules are not touched during the upgrade process. You must create assignment rules for the new coding definition after the upgrade. **Note:** The original assignment rules will continue to assign future requests to the old coding definition.
New	
Note: *This column provides information for the target coding definition.*	
Coding Definition Name	The name you want to give to the new coding definition. REQUIRED. If the source coding definition has already been upgraded to the selected dictionary version, the new **Coding Definition Name** field is populated and a warning message appears.
Dictionary Type	The type of coding dictionary to which the coding definition is associated: MedDRA, WHO-DD, or custom. This field is read-only.
Dictionary Culture	The culture setting associated with the coding dictionary. This field is read-only.
Dictionary Version	The version of the dictionary to associate with the new coding definition. REQUIRED. The synonym lists that are available for the dictionary version you select populate the new **Synonym List** field.

Upgrade Coding Definition dialog box	
Field	**Description**
Synonym List	The synonym list to associate with the new coding definition. REQUIRED.

Buttons

Upgrade Coding Definition dialog box		
Button	**Shortcut**	**Description**
OK	Ctrl+Shift+A	Saves the changes, initiates the copying of the valid autosuggestions, and closes the dialog box.
Cancel	Ctrl+Shift+C	Closes the dialog box without saving any changes.

Auto Suggestions page

 Use the Auto Suggestions page to view the auto-suggested codes for terms that are associated with a coding definition and specified verbatim.

An auto-suggestion is a manually selected unique coding response for requests with the same verbatim, coding definition, and context information that maps to a dictionary path.

> **Note: All available auto-suggested codes appear on the page. If the page is blank there are no auto-suggested codes.**

Fields

Auto Suggestions page	
Field	**Description**
Search for Verbatim	
Verbatim	The verbatim for which you want to view the available autocode suggestions. Searches are *case-insensitive*. The search supports the special characters *, %, ?, and _. The search text field can be an arbitrary text string and can contain wildcard characters to facilitate matching when the exact text is not known. The percent sign (%) or asterisk (*) matches any sequence of characters; the question mark (?) or underscore (_) matches any single character.
	Initiates the search. Click the icon to start the search.
	Clears the auto-suggestion search.
✓	Selects the item(s) on which you can perform a task.

Auto Suggestions page	
Field	Description
Verbatim	The original reported text that describes the adverse event, disease, drug, or other item to be coded.
Indication	The disease or disorder for which the drug was taken. **Note:** This field appears only for items associated with the WHO-DD or JDrug dictionary. If other dictionaries are defined to have context information, that information appears in this location.
Route of Administration	The route by which the drug was administered. **Note:** This field appears only for items associated with the WHO-DD or JDrug dictionary. If other dictionaries are defined to have context information, that information appears in this location.
Target Code	The code value for the primary autocode target.
Target Term	The coded term for the primary autocode target.
Secondary Code	The code value for the secondary autocode target.
Secondary Term	The coded term for the secondary autocode target.

Actions

Auto Suggestions page	
Action	Description
Delete	Removes the selected item from the system.
Previous	Navigates back to the previous view.

Buttons

Auto Suggestions page	
Button	Description
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Choose Source And Target Coding Definitions dialog box

Use the Choose Source And Target Coding Definitions dialog box to select two coding definitions to compare for impact analysis.

> **Note:** This page is used only during impact analysis.

Fields

Choose Source And Target Coding Definitions dialog box	
Field	**Description**
Source Coding Definition Name	The original (source) coding definition.
Target Coding Definition Name	The new (target) coding definition that you want to use for impact analysis.
Auto Reconcile Terms	Indicates whether you do not want to consider any changes in the terms on any level. You select this option when choosing the coding definitions during impact analysis. If you select this option, any changes in the terms on any level are not considered. The Central Coding application autoreconciles only the terms and requires manual reconciliation only of the codes. **Note:** The application autoreconciles the term, even if the **Requires Reconciliation** option is selected for an element on the Element Configuration page.

Buttons

Choose Source And Target Coding Definitions dialog box		
Button	**Shortcut**	**Description**
OK	Ctrl+Shift+A	Saves the changes, initiates the impact analysis, and closes the dialog box.
Cancel	Ctrl+Shift+C	Closes the dialog box without saving any changes.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Impact Analysis tab

In Process page

Use the In Process page to view the status of the verbatim upgrade process, initiate the verbatim reconciliation process, generate the Impact Analysis Report, export data, and commit verbatim changes to the database.

> **Note:** This page is used only during impact analysis.

Fields

In Process page	
Field	Description
✓	Selects the item(s) on which you can perform a task.
Source Name	The original (source) coding definition.
Type	The type of the source coding dictionary: MedDRA, WHO-DD, or custom.
Culture	The culture setting associated with the source coding dictionary.
Source Version	The version of the original (source) coding dictionary.
Target Name	The new (target) coding definition that you want to use for impact analysis.
Target Version	The version of the new (target) coding dictionary.
Auto Reconcile Term Changes	A checkmark indicates that the **Auto Reconcile Terms** checkbox on the Choose Source And Target Coding Definitions dialog box was selected when the impact analysis process was initiated.
Affected Study(s)	The studies affected by the dictionary change.
Requests Analyzed	The number of coding requests the system has analyzed during the impact analysis process.
Requests Impacted	The number of coding requests that are affected by dictionary version changes.
Step	The current processing step of the impact analysis process. • Prepare • Reconcile • Update

In Process page	
Field	**Description**
Status	The status of the processing step. • In Process • Not Started • Scheduled • Running • Complete
Error	Descriptive information about an impact analysis process that did not run successfully.
Report	A link to the Document Viewer page, from which you can view the results of the Impact Analysis report in PDF format. Click the icon to open the page.

Actions

In Process page		
Action	**Shortcut**	**Description**
Cancel		Stops an impact analysis job that is in process. **Note:** The application deletes the data and any report that has been created by the process. A warning message appears if the upgrade process has already started the Update step.
Rerun		Reruns the impact analysis process for the selected coding definition set. You can rerun the comparison only if the Status is **Failed**.
Reconcile	Ctrl+Shift+R	Opens the Reconcile Verbatims page, from which you can reconcile the verbatims after running impact analysis. **Note:** This action is available only when there are verbatims to reconcile.
Update	Ctrl+Shift+U	Commits all approved verbatim changes to the database. **Note:** A confirmation dialog box appears. You cannot undo this action.

Buttons

In Process page		
Button	**Shortcut**	**Description**

In Process page		
Button	**Shortcut**	**Description**
Generate Report	Ctrl+Shift+G	Runs the Impact Analysis Report, which provides a snapshot of the impact analysis and verbatim reconciliation process at the time you run the report.
Export	Ctrl+Shift+E	Exports the impact analysis data and opens the Windows File Download dialog box, from which you can choose to open or save the reconciled verbatims in comma separated value (CSV) format.
Reconcile	Ctrl+Shift+R	Opens the Reconcile Verbatims page, from which you can reconcile the verbatims after running impact analysis. **Note:** This button is available only when there are verbatims to reconcile.
Update	Ctrl+Shift+U	Commits all approved verbatim changes to the database. **Note:** A confirmation dialog box appears. You cannot undo this action.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Reconcile Verbatims page

Use the Reconcile Verbatims page to reconcile the verbatims after running impact analysis. This page lists each verbatim target for which there is an impact due to the dictionary upgrade.

Depending on your configuration:

- If there are two possible actions, the default action is set based on the default action configuration.

  The default action is applied if you choose to complete verbatim reconciliation without individually selecting actions.

- You are provided with the Uncode option.

  An administrator might decide that coded requests cannot leave Impact Analysis in an uncoded state. In this case, the Central Coding application can be configured so that the Uncode option does not appear on the page. This is set by a configuration setting on the System Configuration page.

> **Note:** The options that are selected on this page by default are set by an administrator on the Reconciliation Options page. For more information, see ***Reconciliation Options page—View mode*** (on page 510). You can change the selections as needed.

Note: This page is used only during impact analysis.

Fields

Reconcile Verbatims page	
Field	**Description**
Reason filter	A filter that identifies the items you want to view, based on the reason for a code and term change between dictionary versions. • **No selection**—No filter; displays all options. • Deleted Terms • Path Change • Possible Better Choice • Path Change Same Primary SOC (MedDRA only) • Path Change New Primary SOC (MedDRA only)
Reason	The cause of the difference between the dictionary versions for the associated verbatim.
Verbatim	The original reported text that describes the adverse event, disease, drug, or other item to be coded.
Context Items	Information from the source application such as the indication and route of administration for drugs. **Note:** This column appears only when using the WHO-DD or JDrug dictionary, or a dictionary for which context items have been defined.
Original Coding Type	The type of coding originally performed on the verbatim. • **I**—Interactive • **A**—Automatic
Original Code and Term	The code and term from the source dictionary version. Click the **Code and Term** link to open the Compare Coding Results dialog box, from which you can view the differences in the coding results between the source and target dictionary versions. **Note:** If the original code, term, and path exist in the new dictionary, you can click the radio button to accept the original code and term. **Note:** If the application is configured for impact analysis to consider something other than the complete result to be what matters, the autocoder can find a unique result that is indicated by a red asterisk (*). For more information, see ***When the autocoder returns a unique result*** (on page 556).

Reconcile Verbatims page	
Field	**Description**
New Code and Term	The code and term from the target dictionary version. • Click the **Code and Term** link to open the Compare Coding Results dialog box, from which you can view the differences in the coding results between the source and target dictionary versions. • Click the **Code** link to open the Coding Browser dialog box, from which you can interactively code or recode the verbatim. **Note:** If the new code and term exist in the new dictionary, you can click the radio button to accept the new code and term.
Algorithm Step	The algorithm step (and its order in the algorithm) where the New Code and Term were found.
Done	Indicates whether all decisions for the verbatim are complete. **Note:** This feature is designed to help you keep track of the work to be done on the verbatim. It has no affect on the Approve All action.
Accept Uncode	Select the **Uncode** option if you do not want to accept the original or new coding, and do not want to manually recode the verbatim. The verbatim is returned to the coder's queue. **Note:** The Accept Uncode column appears only if an administrator selects the Allow Uncode option on the System Configuration page.

Actions

Reconcile Verbatims page		
Action	**Shortcut**	**Description**
Approve All	Ctrl+Shift+A	Confirms the selected actions for every verbatim. Select this action when you consider verbatim reconciliation to be complete. The In Process page reappears.
Previous	Ctrl+Shift+P	Navigates back to the previous view.

Buttons

Reconcile Verbatims page		
Button	**Shortcut**	**Description**
Approve All	Ctrl+Shift+A	Confirms the selected actions for every verbatim. Click this button when you consider verbatim reconciliation to be complete. The In Process page reappears.
Previous	Ctrl+Shift+P	Navigates back to the previous view.

Reconcile Verbatims page		
Button	Shortcut	Description
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Compare Coding Results dialog box

Use the Compare Coding Results dialog box to view the differences in the coding results between the source and target dictionary versions.

> **Note: The differences between the original and new coding results are highlighted in yellow.**

> **Note: This page is used only during impact analysis.**

Fields

Compare Coding Results dialog box	
Field	Description
Original Path	
Primary Path?	Indicates whether the path is the primary path. **Note:** This information appears only for the MedDRA or MedDRA-J dictionary.
Level	The level in the source coding dictionary where the term appeared.
Code	The classification level code value for the term in the source dictionary version.
Term	The standardized word or phrase associated with the code in the source dictionary version.
Additional Info	Any additional information associated with the dictionary level in the source version.
New Path	
Primary Path?	Indicates whether the path is the primary path. **Note:** This information appears only for the MedDRA or MedDRA-J dictionary.
Level	The level in the target coding dictionary where the term now appears.
Code	The classification level code value for the term in the target dictionary version. Indicates whether the path is the primary path.

Compare Coding Results dialog box	
Field	Description
Term	The standardized word or phrase associated with the code in the target dictionary version.
Additional Info	Any additional information associated with the dictionary level in the target version.

Buttons

Compare Coding Results dialog box	
Button	Description
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Assignment Rules tab

Assignment Rules page

Use the Assignment Rules page to view the list of assignment rules in the Central Coding application.

Fields

Assignment Rules page	
Field	Description
✓	Selects the item(s) on which you can perform a task.
Order	The order the system runs the assignment rules. **Note:** The Central Coding application runs the assignment rules in the order they appear on the Assignment Rules page.
Name	The name of the assignment rule. Click this link to open the [Assignment Rule Name] page, from which you can edit the details for the assignment rule. **Note:** A red exclamation mark (!) appears next to the name of any assignment rule that does not have a coding definition or work team selected.
Description	Descriptive information about the assignment rule.

Actions

Assignment Rules page		
Action	**Shortcut**	**Description**
New	Ctrl+Shift+N	Opens the New Assignment Rule page, from which you can create a new assignment rule.
Edit	Ctrl+Shift+E	Opens the [Assignment Rule Name] page, from which you can edit the details for the assignment rule.
Delete	Ctrl+Shift+C	Removes the selected item from the system.

Buttons

Assignment Rules page		
Button	**Shortcut**	**Description**
New	Ctrl+Shift+N	Opens the New Assignment Rule page, from which you can create a new assignment rule.
Edit	Ctrl+Shift+E	Opens the [Assignment Rule Name] page, from which you can edit the details for the assignment rule.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

New Assignment Rule page

Use the New Assignment Rule page to create a new assignment rule.

Fields

New Assignment Rule /[Assignment Rule Name] page	
Field	**Description**
Rule Properties	
Name	The name of the assignment rule. REQUIRED. **Note:** The assignment rule name must be unique.
Description	Descriptive information about the assignment rule.
Coding Definition	The coding definition to use when coding requests are processed by this assignment rule.

New Assignment Rule /[Assignment Rule Name] page	
Field	**Description**
Attempt autocode	Indicates whether you want the system to always attempt to autocode incoming requests. By default, this option is selected.
Autocoding requires approval	Indicates whether you want all autocoded values to require an approval. If you select this option, the application routes all autocoded requests to the Approvals page so that the approver can approve them. By default, this option is **not** selected.
Autocoding requires review	Indicates whether you want all autocoded values to require a review. If you select this option, the application routes all autocoded requests to the Coding Requests page and sets the status to **Needs Review** so that the coder can review them. By default, this option is **not** selected.
Interactive coding requires approval	Indicates whether you want all interactively coded values to require an approval. After a request is manually coded, the application identifies it as being **Complete, awaiting delivery** or **Complete, awaiting approval**. If you select this option, requests that require an approval are routed to the Approvals page so that the approver can review them. By default, this option is **not** selected.
Coding result requires delivery	Indicates whether you want the coded values to be returned to the InForm application. By default, this option is selected.
Delete request after delivery	Indicates that you want the Central Coding application to delete, for a specified assignment rule, all coding requests that have been coded in the Central Coding application and delivered to the source application. **Note:** This option is only available if you select the **Show Delete Request After Delivery Option** checkbox on the System Configuration page.
Rule Text and Workteam Assignment	

New Assignment Rule /[Assignment Rule Name] page	
Field	**Description**
Request property	The property on which to base the assignment rule. • **ClientName**—The name of the source application for which the Central Coding application is coding the request. • **Product**—The product type from which the request was sent. The Central Coding application defines this property. • **ClientHost**—The name of the server for the study. • **Verbatim**—The original reported text that describes the adverse event, disease, drug, or other item to be coded. This information is defined in the source application. • **DictType**—The dictionary type. • **StudyName**—The name of the study. • **Site**—A mnemonic identifier for the subject site. • **VisitName**—The name of the visit. This information is defined in the source application. • **ItemType**—The kind of item to be coded. This information is defined in the source application. • **FormName**—The form RefName. This information is defined in the source application.
Operators	The comparison value. • = • ! = • < = • > =
Value	The value for the Request property.
	Adds the value to the **Rule text** box.
Rule text	The assignment rule, in simple syntax language, that the system evaluates. **Note:** The maximum size of an assignment rule is 64K.
	Checks the syntax of the rule text. **Caution:** If the system verifies the syntax but the data in the **Value** field is not valid, the system cannot assign incoming requests using this rule.
Select work teams	
✓	Indicates the work teams to which the requests that are processed by this assignment rule are assigned.

Actions

New Assignment Rule page	
Action	Description
Save	Saves the changes.
Previous	Navigates back to the previous view.

Buttons

New Assignment Rule page	
Button	Description
Save	Saves the changes.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

[Assignment Rule Name] page

Use the [Assignment Rule Name] page to edit the details for the assignment rule.

Fields

New Assignment Rule /[Assignment Rule Name] page	
Field	Description
Rule Properties	
Name	The name of the assignment rule. REQUIRED. **Note:** The assignment rule name must be unique.
Description	Descriptive information about the assignment rule.
Coding Definition	The coding definition to use when coding requests are processed by this assignment rule.
Attempt autocode	Indicates whether you want the system to always attempt to autocode incoming requests. By default, this option is selected.
Autocoding requires approval	Indicates whether you want all autocoded values to require an approval. If you select this option, the application routes all autocoded requests to the Approvals page so that the approver can approve them. By default, this option is **not** selected.

New Assignment Rule /[Assignment Rule Name] page	
Field	**Description**
Autocoding requires review	Indicates whether you want all autocoded values to require a review. If you select this option, the application routes all autocoded requests to the Coding Requests page and sets the status to **Needs Review** so that the coder can review them. By default, this option is **not** selected.
Interactive coding requires approval	Indicates whether you want all interactively coded values to require an approval. After a request is manually coded, the application identifies it as being **Complete, awaiting delivery** or **Complete, awaiting approval**. If you select this option, requests that require an approval are routed to the Approvals page so that the approver can review them. By default, this option is **not** selected.
Coding result requires delivery	Indicates whether you want the coded values to be returned to the InForm application. By default, this option is selected.
Delete request after delivery	Indicates that you want the Central Coding application to delete, for a specified assignment rule, all coding requests that have been coded in the Central Coding application and delivered to the source application. **Note:** This option is only available if you select the **Show Delete Request After Delivery Option** checkbox on the System Configuration page.
Rule Text and Workteam Assignment	

New Assignment Rule /[Assignment Rule Name] page	
Field	**Description**
Request property	The property on which to base the assignment rule. • **ClientName**—The name of the source application for which the Central Coding application is coding the request. • **Product**—The product type from which the request was sent. The Central Coding application defines this property. • **ClientHost**—The name of the server for the study. • **Verbatim**—The original reported text that describes the adverse event, disease, drug, or other item to be coded. This information is defined in the source application. • **DictType**—The dictionary type. • **StudyName**—The name of the study. • **Site**—A mnemonic identifier for the subject site. • **VisitName**—The name of the visit. This information is defined in the source application. • **ItemType**—The kind of item to be coded. This information is defined in the source application. • **FormName**—The form RefName. This information is defined in the source application.
Operators	The comparison value. • = • ! = • < = • > =
Value	The value for the Request property.
	Adds the value to the **Rule text** box.
Rule text	The assignment rule, in simple syntax language, that the system evaluates. **Note:** The maximum size of an assignment rule is 64K.
	Checks the syntax of the rule text. **Caution:** If the system verifies the syntax but the data in the **Value** field is not valid, the system cannot assign incoming requests using this rule.
Select work teams	
✓	Indicates the work teams to which the requests that are processed by this assignment rule are assigned.

Actions

[Assignment Rule Name] page	
Action	Description
Save	Saves the changes.
Previous	Navigates back to the previous view.

Buttons

[Assignment Rule Name] page	
Button	Description
Save	Saves the changes.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Unassigned Requests tab

Unassigned Requests page

Use the Unassigned Requests page to view the requests that are not being distributed by the assignment rules.

When the requests and assignment rules are set up correctly, no requests appear on the Unassigned Requests page. Requests that appear on the Unassigned Requests page are not assigned to a work team, or are not being routed by the existing assignment rules.

Fields

Unassigned Requests page	
Field	Description
Study filter	A filter that identifies the items you want to view, based on the name of a study.
✓	Selects the item(s) on which you can perform a task.

Unassigned Requests page	
Field	**Description**
Verbatim	The original reported text that describes the adverse event, disease, drug, or other item to be coded. **Note:** This information comes from the source application. **Note:** The first 25 characters of the context items (Indication and Route of Administration) associated with the verbatim appear below the verbatim if the **Display Context Items on Coding Requests and Approvals pages** option on the System Configuration page is selected. You can view the full Route of Administration or Indication text on the Requests Details page.
Dictionary	The dictionary and version associated with the coding definition.
Coding Definition	The name of the coding definition.
Site	A mnemonic identifier for the subject site. **Note:** This information comes from the source application and appears in the SiteName field on the request detail pages.
Study	The name of the study. **Note:** The name is an active link if you are integrated with the InForm application. Click the link to open the InForm application login page.
Form Name	RefName of the form with which the request is associated. This information comes from the source application.
Subject ID	The client identifier for the subject.
Received	The date the coding request was received from the source application.
Last Updated	The date the coding for the request was last updated.
Details	A link to the Request Details page, from which you can view all the information in the Central Coding application about a coding request. Click the link to open the page.

Actions

Unassigned Requests page		
Action	**Shortcut**	**Description**
Run Assignment Rules	Ctrl+Shift+R	Runs the assignment rules for the selected request. All requests that are not routed by the rules appear on the Unassigned Requests page. **Note:** When the requests and assignment rules are set up correctly, no requests appear on the Unassigned Requests page. Requests that appear on the Unassigned Requests page are not assigned to a work team, or are not being routed by the existing assignment rules.

Unassigned Requests page		
Action	**Shortcut**	**Description**
Details	Ctrl+Shift+V	A link to the Request Details page, from which you can view all the information in the Central Coding application about a coding request. Click the link to open the page.

Buttons

Unassigned Requests page		
Button	**Shortcut**	**Description**
Run Assignment Rules	Ctrl+Shift+R	Runs the assignment rules for the selected request. All requests that are not routed by the rules appear on the Unassigned Requests page. **Note:** When the requests and assignment rules are set up correctly, no requests appear on the Unassigned Requests page. Requests that appear on the Unassigned Requests page are not assigned to a work team, or are not being routed by the existing assignment rules.
Details	Ctrl+Shift+V	A link to the Request Details page, from which you can view all the information in the Central Coding application about a coding request. Click the link to open the page.
Help ( )		Updates the information on the page.
Refresh ( )		Opens online page-level help that describes the page function(s) and fields.

Request Details page—Unassigned Requests

Use the Request Details page to view all the information in the Central Coding application about a coding request. The information includes details about the coding method and status, assignment rule, coding definition, and identification information about the request from the source application.

Fields

Request Details page	
Field	**Description**
Request Information	
Verbatim	The original reported text that describes the adverse event, disease, drug, or other item to be coded.
Dictionary	The dictionary and version associated with the coding definition.

Request Details page	
Field	**Description**
Status	The coding status.
Reason	Descriptive text about the reason for the change. 1000 characters maximum.
Date Coded	The date the request was initially coded.
Date Completed	The date the request was completed.
Item Type	The kind of item to be coded. This information is defined in either the Central Designer or Clintrial application. Examples of item types are: • **AE**—Adverse event • **MEDPROD**—Medical product • **DISEASE**—Disease • **LABDATA**—Lab data • **Drug**
Coding Mode	The method used to code the request.
Algorithm Step	The step in the coding algorithm where the match was found. This information appears only if the request was autocoded.
Autocode Match Level	The level in the dictionary hierarchy where the coding algorithm searches for a match when performing autocoding. This information appears only if the request was autocoded.
Coder	The user who coded the request.
Auto Approve (A)	Indicates whether an autocoded request was automatically approved by the system.
Auto Approve (I)	Indicates whether a manually coded request was automatically approved by the system.
Single Coded	Indicates whether the code value was found for this request only or if the value was propagated.
Autocode Requires Review	Indicates whether the autocoded request requires a review.
Needs Delivery	Indicates whether the request has been delivered to the source application.
Query status icon	Indicates that the selected coding request has an associated query, and specifies the query state. Hold your mouse over the icon to see the query text. Click the icon to open the Query History page for the query.

Request Details page	
Field	**Description**
Note icon ( )	Indicates that the selected coding request has an associated note. Hold your mouse over the icon to see the most recent note text associated with the request. Click the icon to open the Notes History page for the note.
Number of Matches	The number of coding values found. This information appears only if the request was autocoded.
Match Text	The text to which the code value was matched. This information appears only if the request was autocoded.
View Codes link	Click this link to open the View Full Coding dialog box, from which you can view the full coding details for a coded item. The details include the dictionary name and version, the coded term and value, and the level of the dictionary hierarchy where the match was found. **Note:** This link appears only if the request has been coded.
Request Identification	
Client Name	The name of the source application for which the Central Coding application is coding the request.
Client Item Identifier	A unique identifier on the client for the item to be coded. This identifier is passed back with the response so that the client can update the correct records with the result. This information is provided by the source application.
Product	The product type from which the request was sent. The Central Coding application defines this property.
Host	The name of the server for the study.
Visit Name	The name of the visit. This information is provided by the source application.
URL	The URL to the page in the source application on which the request is based.
Subject ID	The client identifier for the subject. This information is provided by the source application.
Subject Initials	The subject initials of the subject. This information is provided by the source application.
Site	A unique identifier for the subject site that the Central Coding application uses internally. This information is provided by the source application.
Site Name	A mnemonic identifier for the subject site. **Note:** This information comes from the source application and appears in the Site column on the request list view pages.
Study	The name of the study.

Request Details page	
Field	**Description**
Visit	A data structure that describes a subject visit or a collection of monitoring forms. This information is provided by the source application.
Form Name	The form with which the request is associated. This information comes from the source application.
Mapping	The data code mapping name defined in the source application. This identifier defines the items to be returned to the source application and the location where the items are to be returned.
Route of Administration	The route by which the drug was administered. This information is provided by the source application. **Note:** This field appears only for items associated with the WHO-DD or JDrug dictionary. If other dictionaries are defined to have context information, that information appears in this location.
Indication	The disease or disorder for which the drug was taken. This information is provided by the source application. **Note:** This field appears only for items associated with the WHO-DD or JDrug dictionary. If other dictionaries are defined to have context information, that information appears in this location.
Target(s)	A unique identifier for where the codes are to be sent. The number of targets that appear on the page depends on the mapping(s) defined in the source application. This information is defined in the source application.
Rule Assignment	
Rule Name	The name of the assignment rule.
Rule Text	The assignment rule, in simple syntax language, that the system evaluates.
Assignment Status	Indicates whether the request is successfully assigned to its associated assignment rule. If the request is unassigned, an error message appears.
Assigned Work Teams	The work teams to which the requests processed by the assignment rule are assigned. **Note:** This field appears only if the system successfully assigns the requests.
Coding Definition	
Name	The name of the coding definition associated with the request.
Dictionary	The coding dictionary and version associated with the coding definition.
Algorithm	The name of the algorithm associated with the coding definition.
Stopword List	The name of the stopword list associated with the coding definition.
Synonym List	The name of the synonym list associated with the coding definition.

Actions

Request Details page—Unassigned Requests	
Action	Description
Run Assignment Rules	Runs the assignment rules for the selected request. All requests that are not routed by the rules appear on the Unassigned Requests page.

Buttons

Request Details page—Unassigned Requests	
Button	Description
Run Assignment Rules	Runs the assignment rules for the selected request. All requests that are not routed by the rules appear on the Unassigned Requests page.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Coding Definition dialog box

Use the Coding Definition dialog box to view the details of the coding definition. The details include the dictionary name and version, the culture, the associated algorithm, stopword list, and synonym list, and the level of the dictionary hierarchy where the match was found.

Fields

Coding Definition dialog box	
Field	Description
Dictionary Type	The installed dictionary.
Version	The version of the coding dictionary.
Culture	A combination of attributes including, but not limited to, language, date formats, and currency.
Algorithm	The name of the algorithm associated with the coding definition.
Stopword List	The name of the stopword list associated with the coding definition.
Synonym List	The name of the synonym list associated with the coding definition.
Autocode Match Level	The level in the dictionary hierarchy where the coding algorithm searches for a match when performing autocoding. This information appears only if the request was autocoded.

Buttons

Coding Definition dialog box	
Button	**Description**
OK	Closes the dialog box.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Administration folder

Management subfolder

Users

Users page

Use the Users page to view information about the users that are defined in the application, and activate, deactivate, and terminate users.

Fields

Users page	
Field	Description
Status filter	A filter that identifies the items you want to view, based on the status of the user.
Type filter	A filter that identifies the items you want to view, based on the type of user.
✓	Selects the item(s) on which you can perform a task.
Status	The status of the user account. • **Active** ( )—The user exists in the system and can access the application. New accounts must be activated before they can be used. • **Active Never Used** ( )—The user profile is active, but it has not been used. • **Inactive** ( )—The user exists in the system but cannot access the application. Inactive accounts can be activated. • **Inactive Never Used** ( )—The user profile exists, but it has not been activated or used. • **Terminated** ( )—The user can no longer access the application. Terminated accounts cannot be activated.
Name	The system logon name for the user. Click the link to open the User Details page, from which you can view or edit information for the selected user.
Display Name	The screen name for the user. The display name appears in the upper-left corner of the user interface.

Users page	
Field	**Description**

Type	The kind of user account.
	• **User**—An account associated with a person. This option is the system default.
	• **Machine**—An account not associated with a person, such as the account used by the job scheduler. Passwords for these accounts never expire.
	  ▪ If you select this account type you cannot select the **User must change password** option.
	• **SuperUser**—An account that is associated with a person and that never locks out after the configured number of failed login attempts.
	  ▪ This account type has access to all users, roles, rights, and work teams.
	  ▪ You cannot inactivate the last SuperUser account.

Roles	The roles assigned to the user.
Work Teams	The work teams to which the user is assigned.

Actions

Users page		
Action	**Shortcut**	**Description**
New	Alt+N	Opens the New User page, from which you can create a new user.
View Details	Alt+W	Opens the User Details page, from which you can view or edit information for the selected user.
Activate		Changes the status of the selected user to **Active** ( ). Active users exist in the system and can access the application.
Deactivate		Changes the status of the selected user to **Inactive** ( ). Inactive users exist in the system but cannot access the application. Inactive accounts can be activated.
Terminate		Changes the status of the user to **Terminated** ( ). Terminated users can no longer access the application. Terminated accounts cannot be activated.

Buttons

Users page

Button	Shortcut	Description
New	Alt+N	Opens the New User page, from which you can create a new user.
View Details	Alt+W	Opens the User Details page, from which you can view or edit information for the selected user.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

New User/User Details page

Use the New User/User Details page to add a new user, or to view or edit information for an existing user.

Fields

New User/User Details page	
Field	**Description**
User Information	
Display name	The screen name for the user. The display name appears in the upper-left corner of the user interface. REQUIRED. **Note:** You cannot modify this field after you create the user.
Status	The status of the user account. • **Invalid** ( )—The user profile is being entered and is not saved. This status appears only when you are creating a new user profile. • **Inactive Never Used** ( )—The user profile exists, but it has not been activated or used. • **Active Never Used** ( )—The user profile is active, but it has not been used. • **Active** ( )—The user profile is in the system and can access the application. • **Inactive** ( )— The user profile is in the system but cannot access the application. Inactive accounts can be activated. • **Terminated** ( )—The user profile can no longer access the application. Terminated accounts cannot be activated.

New User/User Details page	
Field	**Description**
Account name	The system logon name for the user. REQUIRED. **Note:** You cannot modify this field after you create the user.
Failed logon count	The number of failed logon attempts.
Authentication	The type of authentication required for the user. • **Native**—The system uses the Central Coding application user name and password. This option is the system default. • **Windows**—The system checks the Windows registry for a user name and password. • **Certificate**—The system checks a digital certificate for a valid user name and password.

Type	The kind of user account.
	• **User**—An account associated with a person. This option is the system default.
	• **Machine**—An account not associated with a person, such as the account used by the job scheduler. Passwords for these accounts never expire.
	  ▪ If you select this account type you cannot select the **User must change password** option.
	• **SuperUser**—An account that is associated with a person and that never locks out after the configured number of failed login attempts.
	  ▪ This account type has access to all users, roles, rights, and work teams.
	  ▪ You cannot inactivate the last SuperUser account.

Password	The logon password for the user. This password is used in conjunction with the Account name to authenticate the user to the system. **Note:** Passwords can be from 6 to 32 characters. For security purposes, Oracle recommends using a combination of letters and numbers. Passwords are case-sensitive.
Verify password	The logon password for the user.
Password last updated	The timestamp and date the password was last modified.
User must change password	Indicates that the user must change the password at the next logon. **Note:** Any change to this option takes effect the next time the user logs on.
Roles	
Roles	The roles that contain rights and are assigned to the user.
Work Teams	

New User/User Details page	
Field	**Description**
Work Teams	The work teams to which the user is assigned.
Personal Information	
First name	The first name of the user.
Last name	The last name of the user.
Title	The title of the user, such as Dr., Mr., or Mrs.
Culture	A combination of attributes including, but not limited to, language, date formats, and currency.
Address	The street address of the user.
City	The city where the user lives.
State/Province	The state or province where the user lives.
Postal code	The postal code of the user.
Country	The country where the user lives.
Company	The name of the company where the user works.
Department	The department where the user works.
Position	The job or company position of the user.
Home page	The Web page address of the user.
Email	The email address of the user.
Telephone	The telephone number of the user.
Mobile	The cellular telephone number of the user.
Pager	The pager number of the user.
Fax	The fax number of the user.
Description	Descriptive information about the user.

Actions

New User/User Details page		
Action	**Shortcut**	**Description**
Save		Saves the changes.
Assign Roles	Ctrl+Shift+R	Opens the Assign Roles to User: [User Name] dialog box, from which you can assign or modify the roles associated with the selected user. **Note:** This option appears only on the User Details page.

New User/User Details page		
Action	**Shortcut**	**Description**
Assign Work Teams	Ctrl+Shift+W	Opens the Assign Work Teams to User: [User Name] dialog box, from which you can assign or modify the work teams associated with the selected user. **Note:** This option appears only on the User Details page.

Buttons

New User/User Details page		
Button	**Shortcut**	**Description**
Assign Roles	Ctrl+Shift+R	Opens the Assign Roles to User: [User Name] dialog box, from which you can assign or modify the roles associated with the selected user. **Note:** This option appears only on the User Details page.
Assign Work Teams	Ctrl+Shift+W	Opens the Assign Work Teams to User: [User Name] dialog box, from which you can assign or modify the work teams associated with the selected user. **Note:** This option appears only on the User Details page.
Save		Saves the changes.
Previous		Navigates back to the previous view.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Assign Roles to User: [User Name] dialog box

Use the Assign Roles to User: [User Name] dialog box to assign or modify the roles associated with the selected user.

Fields

Assign Roles to User: [User Name] dialog box	
Field	**Description**
Available Roles	
Action	A button that adds a role to the **Selected Roles** section. Click **[Select]** to move the associated role to the **Selected Roles** section.
Name	The roles available for assignment to the user.

Assign Roles to User: [User Name] dialog box	
Field	Description
Description	Descriptive information about the role.
Selected Roles	
Action	A button that removes a role from the **Selected Roles** section. Click **[Remove]** to return the associated role to the **Available Roles** section.
Name	The role(s) assigned to the user.
Description	Descriptive information about the role.

Buttons

Assign Roles to User: [User Name] dialog box	
Button	Description
Save	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Assign Work Team to User: [User Name] dialog box

Use the Assign Work Team to User: [User Name] dialog box to assign or modify the work teams associated with the selected user.

Fields

Assign Work Team to User: [User Name] dialog box	
Field	Description
Available Work Teams	
Action	A button that adds a work team to the **Selected Work Teams** section. Click **[Select]** to move the associated work team to the **Selected Work Teams** section.
Name	The work teams available for assignment to the user.
Description	Descriptive information about the work team.
Selected Work Teams	
Action	A button that removes a work team from the **Selected Work Teams** section. Click **[Remove]** to return the associated work team to the **Available Work Teams** section.
Name	The work teams assigned to the user.

Assign Work Team to User: [User Name] dialog box	
Field	Description
Description	Descriptive information about the work team.

Buttons

Assign Work Team to User: [User Name] dialog box	
Button	Description
Save	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Roles

Roles page

Use the Roles page to view information about the roles defined in the application, and remove roles from the application.

Fields

Roles page	
Field	Description
✓	Selects the item(s) on which you can perform a task.
Name	The name of the role. Click the link to open the Role Details page, from which you can view or edit information for the selected role.
Display Name	The role name that you want to appear on the screen.
Description	Descriptive information about the role.
Active Users	The number of active users assigned to the role.

Actions

Roles page		
Action	Shortcut	Description
New	Alt+N	Opens the New Role page, from which you can create a new role.
View Details	Alt+W	Opens the Role Details page, from which you can view or edit information for the selected role.

Roles page		
Action	**Shortcut**	**Description**
Delete	Ctrl+D	Removes the selected item from the system.

Buttons

Roles page	
Button	**Description**
New	Opens the New Role page, from which you can create a new role.
View Details	Opens the Role Details page, from which you can view or edit information for the selected role.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

New Role/Role Details page

Use the New Role/Role Details page to add a new role to the system, or to view or edit information for an existing role.

Fields

New Role/Role Details page	
Field	**Description**
Role	
Name	The name of the role. REQUIRED.
Display Name	The role name that you want to appear on the screen. REQUIRED.
Description	Descriptive information about the role. REQUIRED.
Assigned Rights	
Category	The type or grouping of the rights available in the system.
Rights	Descriptive information about the right.

Actions

New Role/Role Details page		
Action	**Shortcut**	**Description**
Save		Saves the changes.

New Role/Role Details page		
Action	**Shortcut**	**Description**
Assign Rights	Ctrl+Shift+R	Opens the Assign Rights to Role: [Role Name] dialog box, from which you can assign or modify the rights associated with the selected role. **Note:** This option appears only on the Role Details page.

Buttons

New Role/Role Details page		
Button	**Shortcut**	**Description**
Assign Rights	Ctrl+Shift+R	Opens the Assign Rights to Role: [Role Name] dialog box, from which you can assign or modify the rights associated with the selected role. Note: This option appears only on the Role Details page.
Save		Saves the changes.
Previous		Navigates back to the previous view.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Assign Rights to Role: [Role Name] dialog box

Use the Assign Rights to Role: [Role Name] dialog box to assign or modify the rights associated with the selected role. For more information, see ***Default roles and rights*** (on page 541).

Fields

Assign Rights to Role: [Role Name] dialog box	
Field	**Description**
✓	Selects the item(s) on which you can perform a task.
Category	The type or grouping of the rights available in the system. Select the check box to assign all the associated rights to the role.
Rights	Descriptive information about the right. • Select the check box for each right that you want to assign to the role. • Deselect the check box for each right that you do not want to assign to the role.

Buttons

Assign Rights to Role: [Role Name] dialog box	
Button	**Description**
Select All	Selects all of the items at one time.
Clear All	Deselects all of the items at one time.
Save	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Work teams

Work Teams page

Use the Work Teams page to view information about the work teams defined in the application, and remove work teams from the application.

Fields

Work Teams page	
Field	**Description**
✓	Selects the item(s) on which you can perform a task.
Name	The name of the work team. Click this link to open the [Work Team Name] page, from which you can view or edit information about the work team.
Description	Descriptive information about the work team.
Assigned Users	The number of users assigned to the work team.
Assigned Work Items	The number of requests assigned to the work team.

Actions

Work Teams page		
Action	**Shortcut**	**Description**
New	Alt+N	Opens the New Workteam page, from which you can create a new work team.
View Details	Alt+W	Opens the Work Team Details page, from which you can view or edit information about the work team.
Delete	Ctrl+D	Removes the selected item from the system.

Buttons

Work Teams page		
Button	**Shortcut**	**Description**
New	Alt+N	Opens the New Workteam page, from which you can create a new work team.
View Details	Alt+W	Opens the Work Team Details page, from which you can view or edit information about the work team.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

New Work Team/Work Team Details page

Use the New Work Team/Work Team Details page to add a new work team to the system, or to view or edit information for an existing work team.

Fields

New Work Team/Work Team Details page	
Field	**Description**
Work Team	
Name	The name of the work team. REQUIRED.
Description	Descriptive information about the work team. REQUIRED.
Assigned Users	
Account Name	The system logon name of the user.
Display Name	The screen name of the user.

Actions

New Work Team/Work Team Details page		
Action	**Shortcut**	**Description**
Save		Saves the changes.
Assign Users	Ctrl+Shift+U	Opens the Assign Users to Work Team dialog box, from which you can assign or modify the users associated with the work team. **Note:** This option appears only on the Work Team Details page.

Buttons

New Work Team/Work Team Details page		
Button	**Shortcut**	**Description**
Assign Users	Ctrl+Shift+U	Opens the Assign Users to Work Team dialog box, from which you can assign or modify the users associated with the work team. **Note:** This option appears only on the Work Team Details page.
Save		Saves the changes.
Previous		Navigates back to the previous view.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Assign Users to Work Team: [Work Team Name] dialog box

Use the Assign Users to Work Team: [Work Team Name] dialog box to assign or modify the users associated with the work team.

Fields

Assign Users to Work Team: [Work Team Name] dialog box	
Field	**Description**
Available Users	
All	A link that resets the view to show all users.
A to Z	Links to the user names. Click a letter to scroll to the users in the list whose names start with that letter. Click on the letter link a second time to reset the list and show all users.
Action	A button that adds a user to the **Selected Users** section. Click the **[Select]** button to move the associated user to the **Selected Users** section.
Account Name	The users available for assignment to the work team. The system logon name for the user appears in the list.
Display Name	The users available for assignment to the work team. The screen name for the user appears in the list.
Selected Users	
Action	A button that removes a user from the **Selected Users** section. Click the **[Remove]** button to return the associated user to the **Available Users** section.

Assign Users to Work Team: [Work Team Name] dialog box	
Field	**Description**
Account Name	The users available for assignment to the work team. The system logon name for the user appears in the list.
Display Name	The users available for assignment to the work team. The screen name for the user appears in the list.

Buttons

Assign Users to Work Team: [Work Team Name] dialog box	
Button	**Description**
Save	Saves the changes and closes the dialog box.
Cancel	Closes the dialog box without saving any changes.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Requests

All Requests page

Use the All Requests page to view the complete list of coding requests in the Central Coding application, view the work teams assigned to requests, and run an audit history report for a request. This list includes the requests assigned to all work teams, and requests in studies marked as either locked or unlocked in the Central Coding application.

> **Note: Some of the information that appears on this page is configurable by an administrator through the element configuration options. The descriptions in the following table represent the default configuration.**

Fields

All Requests page	
Field	**Description**
Verbatim	The verbatim for which you want to search. Searches are *case-insensitive*. The search supports the special characters *, %, ?, and _. The search text field can be an arbitrary text string and can contain wildcard characters to facilitate matching when the exact text is not known. The percent sign (%) or asterisk (*) matches any sequence of characters; the question mark (?) or underscore (_) matches any single character.
Subject ID	The client identifier for the subject whose coding requests you want to view.

All Requests page	
Field	**Description**
Show filter	A filter that identifies the items you want to view, based on the coding request status, delivery status, or autocode status. • **All**—Displays all options. • **Uncoded**—Displays only the requests that are not coded. • **Partially coded**—If coding to a primary and secondary target, displays only the requests for which the system has found a single match for the primary autocode target and multiple matches for the secondary target. A user must interactively code the request. • **Recode**—Displays only the requests that must be recoded. Requests with this status have been disapproved by an approver. • **Needs Review**—Displays only the requests that have been successfully autocoded but must be reviewed. • **Coded**—Displays only the requests that have been successfully coded. • **Completed**—Displays only the requests that have been successfully coded and approved. • **Delivered**—Displays only the requests that have been successfully returned to the source application. • **Undeliverable, retry**—Displays only the requests for which the attempt to return the request to the source application was unsuccessful. • **Autocoded**—Displays only the requests that have been autocoded. • **Deleted**—Displays only the requests that have been deleted.
Study filter	A filter that displays the studies associated with the Central Coding instance.
View filter	A filter that identifies the items you want to view, based on a coding definition.
Apply button	Initiates the search for the text in the Verbatim field and applies the filters.
Page controls **Note:** The page controls appear only when there are multiple pages of data.	
Current page	The number of the page that currently appears in the list view.
Page count button	Click to display the total number of pages of data as of the current date and time.
✓	Selects the item(s) on which you can perform a task.

All Requests page	
Field	**Description**
A	The autocode status. • **Autocoded ()**—The request was successfully autocoded. • **Blank**—The request was not autocoded.
Status	The coding status. • **Uncoded ( )**—The item is not coded. • **Partially coded ( )**—If coding to a primary autocode target and a secondary autocode target, the application found a single match for the primary target and multiple matches for the secondary target. You must manually select the code you want to use. • **Needs review ( )**—The request is successfully autocoded but must be reviewed. • **Recode ( )**—The request must be recoded. Requests with this status have been disapproved by an approver. By default, the disapproval reason appears in a note associated with the request. • **Coded, awaiting approval ( )**—The request is successfully coded but needs an approval. • **Completed, awaiting delivery ( )**—The request is successfully coded and approved, but is not yet delivered to the source application. • **Completed, delivered ( )**—The request is successfully coded, approved, and delivered to the source application. • **Undeliverable, retry ( )**—The request may be successfully coded and approved, but the Central Coding application cannot deliver the request to the source application because of a communication issue.

All Requests page	
Field	**Description**
Query	The query status. • **Open ( )**—Entered in the Central Coding application by a Central Coding user to be addressed by an InForm user. • **Candidate ( )**—Entered by a Central Coding user. A Central Coding user with the Issue Candidate Query right can create a Candidate query. • **Answered ( )**—Open query that was addressed by an InForm user. • **Closed ( )**—Query on a verbatim that was successfully coded and approved. A query can enter the Closed state if it is manually closed by a Central Coding user or automatically closed by the Central Coding application. • **Deleted ( )**—Candidate query that was deleted by a Central Coding user with the Issue Candidate Query right. Only queries in the Candidate state can be deleted. • **Undeliverable, retry ( )**—The Central Coding application cannot deliver the query data to the source application because of a communication issue. The Central Coding application will retry delivery when the next Get Requests job runs. • **Undeliverable, cannot retry ( )**—The Central Coding application cannot deliver the query data to the InForm application because the form is unable to accept queries. This could happen if a form is locked or deleted in the InForm application. As a result, the query is closed in the Central Coding application.
Notes	Indicates that there is a note associated with the coding request. Hover help displays the date, time, and note text for each note entry associated with the coding request. The note entries are sorted from newest to oldest.
Flag	Indicates that the coding request requires attention.
Verbatim	The original reported text that describes the adverse event, disease, drug, or other item to be coded. **Note:** This information comes from the source application. **Note:** The first 25 characters of the context items (Indication and Route of Administration) associated with the verbatim appear below the verbatim if the **Display Context Items on Coding Requests and Approvals pages** option on the System Configuration page is selected. You can view the full Route of Administration or Indication text on the Requests Details page.
Dictionary	The coding dictionary type associated with the term.

All Requests page	
Field	**Description**
Code	The classification level code value. Click this link to open the View Full Coding dialog box, from which you can view the full coding details for a coded item. The details include the dictionary name and version, the coded term and value, and the level of the dictionary hierarchy where the match was found.
Dictionary-specific hierarchical levels	The terms associated with the levels of the dictionary that are displayed on the page based on your selections on the Element Configuration page.
Site	A mnemonic identifier for the subject site. **Note:** This information comes from the source application and appears in the SiteName field on the request detail pages.
Study	The name of the study. **Note:** The name is an active link if you are integrated with the InForm application. Click the link to open the InForm application login page.
Form Name	RefName of the form with which the request is associated. This information comes from the source application.
Subject ID	The client identifier for the subject.
Coder	The user who coded the request.
Date Coded	The date the request was initially coded.
Last Updated	The date the coding for the request was last updated.
Details	A link to the Request Details page, from which you can view all the information in the Central Coding application about a coding request. Click the link to open the page.

Actions

All Requests page		
Action	**Shortcut**	**Description**
View Work Team Assignments	Ctrl+Shift+W	Opens the Work Team Assignment page, from which you can view the list of work teams assigned to a request.
View Audit History	Ctrl+Shift+G	Opens the Audit History Report page, from which you can view the audit history for a request in PDF format.
Details	Ctrl+Shift+V	Opens the Request Details page, from which you can view all the information in the Central Coding application about a coding request.

All Requests page		
Action	**Shortcut**	**Description**
Retry Delivery for All		Changes the delivery status of all requests with a failed delivery to the source application to **Complete, awaiting delivery**. This allows the request(s) to be resent to the source application.

Buttons

All Requests page		
Button	**Shortcut**	**Description**
View Work Team Assignments	Ctrl+Shift+W	Opens the Work Team Assignment page, from which you can view the list of work teams assigned to a request.
View Audit History	Ctrl+Shift+G	Opens the Audit History Report page, from which you can view the audit history for a request in PDF format.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Workteam Assignment page—View mode

Use the Workteam Assignment page—View mode to view the list of work teams assigned to a request.

Fields

Workteam Assignment page—View mode	
Field	**Description**
✓	Selects the item(s) on which you can perform a task.
Name	The name of the work team.
Description	Descriptive information about the work team.

Actions

Workteam Assignment page—View mode	
Action	**Description**
Edit	Puts the Work Team Assignment page into Edit mode, from which you can edit the work team assignments.

Buttons

Workteam Assignment page—View mode	
Button	Description
Edit	Puts the Work Team Assignment page into Edit mode, from which you can edit the work team assignments.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Workteam Assignment page—Edit mode

Use the Workteam Assignment page—Edit mode to edit the list of work teams assigned to a request.

Fields

Workteam Assignment page—Edit mode	
Field	Description
✓	Selects the item(s) on which you can perform a task.
Name	The name of the work team.
Description	Descriptive information about the work team.

Actions

Workteam Assignment page—Edit mode	
Action	Description
Save	Saves the changes.

Buttons

Workteam Assignment page—Edit mode	
Button	Description
Save	Saves the changes.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.

Workteam Assignment page—Edit mode	
Button	Description
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Audit History Report page

Use the Audit History Report page to view the audit history for a request in PDF format.

Buttons

Audit History Report page	
Button	Description
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Request Details page—All Requests

Use the Request Details page to view all the information in the Central Coding application about a coding request. The information includes details about the coding method and status, assignment rule, coding definition, and identification information about the request from the source application.

Fields

Request Details page	
Field	Description
Request Information	
Verbatim	The original reported text that describes the adverse event, disease, drug, or other item to be coded.
Dictionary	The dictionary and version associated with the coding definition.
Status	The coding status.
Reason	Descriptive text about the reason for the change. 1000 characters maximum.
Date Coded	The date the request was initially coded.
Date Completed	The date the request was completed.

Request Details page	
Field	**Description**
Item Type	The kind of item to be coded. This information is defined in either the Central Designer or Clintrial application. Examples of item types are: • **AE**—Adverse event • **MEDPROD**—Medical product • **DISEASE**—Disease • **LABDATA**—Lab data • **Drug**
Coding Mode	The method used to code the request.
Algorithm Step	The step in the coding algorithm where the match was found. This information appears only if the request was autocoded.
Autocode Match Level	The level in the dictionary hierarchy where the coding algorithm searches for a match when performing autocoding. This information appears only if the request was autocoded.
Coder	The user who coded the request.
Auto Approve (A)	Indicates whether an autocoded request was automatically approved by the system.
Auto Approve (I)	Indicates whether a manually coded request was automatically approved by the system.
Single Coded	Indicates whether the code value was found for this request only or if the value was propagated.
Autocode Requires Review	Indicates whether the autocoded request requires a review.
Needs Delivery	Indicates whether the request has been delivered to the source application.
Query status icon	Indicates that the selected coding request has an associated query, and specifies the query state. Hold your mouse over the icon to see the query text. Click the icon to open the Query History page for the query.
Note icon ( )	Indicates that the selected coding request has an associated note. Hold your mouse over the icon to see the most recent note text associated with the request. Click the icon to open the Notes History page for the note.
Number of Matches	The number of coding values found. This information appears only if the request was autocoded.
Match Text	The text to which the code value was matched. This information appears only if the request was autocoded

Request Details page	
Field	**Description**
View Codes link	Click this link to open the View Full Coding dialog box, from which you can view the full coding details for a coded item. The details include the dictionary name and version, the coded term and value, and the level of the dictionary hierarchy where the match was found. **Note:** This link appears only if the request has been coded.
Request Identification	
Client Name	The name of the source application for which the Central Coding application is coding the request.
Client Item Identifier	A unique identifier on the client for the item to be coded. This identifier is passed back with the response so that the client can update the correct records with the result. This information is provided by the source application.
Product	The product type from which the request was sent. The Central Coding application defines this property.
Host	The name of the server for the study.
Visit Name	The name of the visit. This information is provided by the source application.
URL	The URL to the page in the source application on which the request is based.
Subject ID	The client identifier for the subject. This information is provided by the source application.
Subject Initials	The subject initials of the subject. This information is provided by the source application.
Site	A unique identifier for the subject site that the Central Coding application uses internally. This information is provided by the source application.
SiteMnemonic	A mnemonic identifier for the subject site. **Note:** This information comes from the source application and appears in the Site column on the request list view pages.
SiteName	SiteMnemonic, enclosed in brackets, followed by the name of the site.
Study	The name of the study.
Visit	A data structure that describes a subject visit or a collection of monitoring forms. This information is provided by the source application.
Form Name	The form with which the request is associated. This information comes from the source application.
Mapping	The data code mapping name defined in the source application. This identifier defines the items to be returned to the source application and the location where the items are to be returned.

Route of Administration	The route by which the drug was administered. This information is provided by the source application. **Note:** This field appears only for items associated with the WHO-DD or JDrug dictionary. If other dictionaries are defined to have context information, that information appears in this location.
Indication	The disease or disorder for which the drug was taken. This information is provided by the source application. **Note:** This field appears only for items associated with the WHO-DD or JDrug dictionary. If other dictionaries are defined to have context information, that information appears in this location.
Target(s)	A unique identifier for where the codes are to be sent. The number of targets that appear on the page depends on the mapping(s) defined in the source application.
Rule Assignment	
Rule Name	The name of the assignment rule.
Rule Text	The assignment rule, in simple syntax language, that the system evaluates.
Assignment Status	Indicates whether the request is successfully assigned to its associated assignment rule. If the request is unassigned, an error message appears.
Assigned Work Teams	The work teams to which the requests processed by the assignment rule are assigned. **Note:** This field appears only if the system successfully assigns the requests.
Coding Definition	
Name	The name of the coding definition associated with the request.
Dictionary	The coding dictionary and version associated with the coding definition.
Algorithm	The name of the algorithm associated with the coding definition.
Stopword List	The name of the stopword list associated with the coding definition.
Synonym List	The name of the synonym list associated with the coding definition.

Buttons

Request Details page—All Requests	
Button	**Description**
View Work Team Assignments	Opens the Work Team Assignment page, from which you can view the list of work teams assigned to a request.

Request Details page—All Requests	
Button	**Description**
View Audit History	Opens the Audit History Report page, from which you can view the audit history for a request in PDF format.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Studies

Study Information page

Use the Study Information page to view and manage information about the adapters in the application and their associated studies.

Fields

Study Information page	
Field	**Description**
✓	Selects the item(s) on which you can perform a task.
Study	The name of the study. Click the link to open the InForm application login page.
Study Group	Name of the study group to which the study belongs. A study group specifies auto close and auto query settings for a subset of studies in the Central Coding instance. **Note:** The Central Coding application includes a default study group called System.
Application	The name of the application that is integrated with the Central Coding application.
Locked	An icon that indicates whether the study is locked ( ) or unlocked ( ) in the Central Coding application. **Note:** Because requests associated with locked studies cannot have any actions performed on them, they do not appear on the Coding Requests or Approvals pages. However, they do appear on the All Requests page.
Adapter	The name of the adapter.

Study Information page	
Field	**Description**
Get Requests	Information about the Get Requests job schedule, and access to the job log and status for the associated adapter and study. • Select the checkbox to add the study to the Get Requests job schedule. • Click the **Log** icon ( ) to open the View Job Log page, from which you can view information about the Get Requests jobs. • Click the **Run** icon ( ) to manually run the Get Requests jobs.
Return Codes	Information about the Return Codes job schedule, and access to the job log and status for the associated adapter and study. • Select the checkbox to add the study to the Return Codes job schedule. • Click the **Log** icon ( ) to open the View Job Log page, from which you can view information about the Return Codes jobs. • Click the **Run** icon ( ) to manually run the Return Codes jobs.
Exchange Query Updates	Information about the Exchange Query Updates jobs, and access to the job log and status for the associated job. • Click the **Log** icon ( ) to open the View Job Log page, from which you can view information about the Exchange Query Updates jobs.
Status	The status of the **Delete Study and All Data** action. Click the link to open the View Job Log page.

Actions

Study Information page		
Action	**Shortcut**	**Description**
New	Ctrl+Shift+N	Opens the New Study Information page, from which you can add a study and its associated information to the Central Coding application.
Edit	Ctrl+Shift+E	Opens the [Study Name] Study Information page, from which you can edit the information for the selected study.
Delete Study Information	Ctrl+Shift+Delete	Removes only the study information for the selected study from the system. **Note:** A confirmation dialog box does **not** appear.

Study Information page		
Action	**Shortcut**	**Description**
Reset		Resets the bookmark attribute for the InForm Adapter application. The bookmark attribute is an index number that identifies the last verbatim stored in the cache. It is set in the GETCODINGDATAREQ element in the GETCODINGDATAREQ web method in the InForm Adapter application. For more information, see the InForm Adapter *Interfaces Guide*.
Delete Study and All Data		Removes all information associated with the selected study, including all requests and audit data. **Note:** This functionality may be limited using the **Delete Trial Mask** field on the System Configuration page. The field is populated with **UAT** by default, to allow deletion of studies with **UAT** in the study name only. For more information, see ***Configuring study deletion settings*** (on page 122).
Decommission a Study		Archives coding data for a study that is complete. The Central Coding application moves all request-related data from the current database tables to the history database tables.

Buttons

Study Information page		
Button	**Shortcut**	**Description**
New	Ctrl+Shift+N	Opens the New Study Information page, from which you can add a study and its associated information to the Central Coding application.
Edit	Ctrl+Shift+E	Opens the [Study Name] Study Information page, from which you can edit the information for the selected study.
Delete Study Information	Ctrl+Shift+Delete	Removes only the study information for the selected study from the system. **Note:** A confirmation dialog box does **not** appear.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

New Study Information page

Use the New Study Information page to add a study and its associated information to the Central

Coding application.

Fields

New Study Information page	
Field	**Description**
Source Application	The name of the application that is integrated with the Central Coding application.
Adapter	The name of the adapter. REQUIRED.
Trial	The unique name of the study. REQUIRED. **Note:** The Central Coding application does not support multiple studies with the same study name. **Note:** Only the studies associated with the selected adapter appear in the list.
PutCodes Client Audit User	User name for the audit records that are created in the InForm application to record the codes that are returned by the Central Coding application.
URL	The base URL for the study. REQUIRED.
Study Group	The study group to which to add the study. Use a study group to specify auto close and auto query settings for a subset of studies in the Central Coding instance. **Note:** The Central Coding application includes a default study group called System.
Support Query	Whether the study supports query management. **Note:** Select this option only when the InForm application is the source application. Deselect this option when another application, such as the Clintrial application, is the source application.
Study Locked	Select to lock the study in the Central Coding application. For more information, see ***Locking a study in the Central Coding application*** (on page 211). **Note:** Because requests associated with locked studies cannot have any actions performed on them, they do not appear on the Coding Requests or Approvals pages. However, they do appear on the All Requests page.

Actions

New Study Information page	
Action	**Description**
Save	Saves the changes.

Buttons

New Study Information page	
Button	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

[Study Name] Study Information page

Use the [Study Name] Study Information page to view the information associated with a study.

Fields

[Study Name] Study Information page	
Field	**Description**
Source Application	The name of the application that is integrated with the Central Coding application.
Adapter	The name of the physical server where the study is installed. This field is read only.
Trial	The name of the study. This field is read only.
PutCodes Client Audit User	User name for the audit records that are created in the InForm application to record the codes that are returned by the Central Coding application.
URL	The base URL for the study.
Study Group	Name of the study group to which the study belongs. A study group specifies auto close and auto query settings for a subset of studies in the Central Coding instance. **Note:** The Central Coding application includes a default study group called System.
Support Query	Whether the study supports query management. **Note:** Select this option only when the InForm application is the source application. Deselect this option when another application, such as the Clintrial application, is the source application.

[Study Name] Study Information page	
Field	**Description**
Study Locked	Select to lock the study in the Central Coding application. For more information, see ***Locking a study in the Central Coding application*** (on page 211). **Note:** Because requests associated with locked studies cannot have any actions performed on them, they do not appear on the Coding Requests or Approvals pages. However, they do appear on the All Requests page.

Actions

[Study Name] Study Information page	
Action	**Description**
Save	Saves the changes.

Buttons

[Study Name] Study Information page	
Button	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Study Groups

Study Group List page

Use the Study Group List page to create and edit study groups. Use study groups to configure the auto query and auto close settings for a subset of studies in the Central Coding instance.

> **Note:** This is especially useful for CROs who manage several customers conducting studies.

Fields

Study Group List page	
Field	**Description**
✓	Selects the query or queries on which you can perform a task.

Study Group List page	
Field	**Description**
Name	The name of the study group. **Note:** By default, the Central Coding application includes a study group called System. This group contains all studies in the instance of the Central Coding application.
Allow Auto Query By Default	Instructs the Central Coding application to duplicate an existing query and apply it to all matching verbatims in the study group that are subsequently entered in the Central Coding application. This option is selected by default.
Allow Auto Close Query By Default	Instructs the Central Coding application to automatically close a query if the verbatim associated with the query is successfully coded and approved. This option is selected by default.

Buttons

Study Group List page		
Button	**Shortcut**	**Description**
Add	Ctrl+Shift+A	Opens the Study Group Detail page, from which you can create a new study group.
Edit	Ctrl+Shift+E	Opens the Study Group Detail page, from which you can edit the selected study group.
Delete	Ctrl+Shift+D	Deletes the selected study group. A confirmation dialog box does **not** appear.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Study Group Detail page

Use the Study Group Detail page to create a new study group or edit an existing study group.

Fields

Study Group Detail page	
Field	**Description**
Name	The name of the study group you are creating or editing.
Allow Auto Query by Default	Instructs the Central Coding application to duplicate an existing query and apply it to all matching verbatims in the study group that are subsequently entered in the Central Coding application. This option is selected by default.

Study Group Detail page	
Field	**Description**
Allow Auto Close Query by Default	Instructs the Central Coding application to automatically close a query if the verbatim associated with the query is successfully coded and approved. This option is selected by default.

Buttons

Study Group Detail page	
Button	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

System subfolder

Jobs

View Job Log page

Use the View Job Log page to view detailed information about the get verbatims or return codes jobs, and to stop a running job.

> **Note:** Entries 45 days old are automatically deleted from the Central Coding database.

Fields

View Job Log page	
Field	**Description**
Job filter	A filter that identifies the data you want to view, based on the Job Name. To view all jobs, leave the filter blank.
Start date after	The start date (as DD-MON-YYYY) of the period for which you want to view the job log.
End date before	The end date (as DD-MON-YYYY) of the period for which you want to view the job log.
Apply button	Initiates the search for the jobs and applies the filter.
✓	Selects the item(s) on which you can perform a task.

View Job Log page	
Field	**Description**
Job Name	A system-generated identifier for the job.
Start Time	The date and time the job started to run.
End Time	The date and time the job was completed.
Progress	General text about a job that is in progress. • While getting verbatims, displays In Process. • While returning codes, displays the percentage of completed requests.
Status	The status of the job.
Error	Descriptive information about a job that did not run successfully. • If the **ExceptionMaps.xml** file does not contain an entry on the error, only the error message appears. • If the **ExceptionMaps.xml** file contains an entry for the error, a description of the issue and a possible solution appear as part of the error message. The **ExceptionMaps.xml** file is similar to a knowledge base. It contains specific information about call stacks in the event log and how to interpret and troubleshoot them. For certain errors, the file provides a description of the issue and a solution as part of the error message. You can add entries to the file as you learn from the system. If you change the **ExceptionMaps.xml** file, you must restart the job scheduler for the new entry to take effect.

Actions

View Job Log page		
Action	**Shortcut**	**Description**
Delete	Ctrl+Shift+Delete	Removes the selected item from the system.
Stop Job	Ctrl+Shift+X	Stops the selected job from running.

Buttons

View Job Log page		
Button	**Shortcut**	**Description**
Delete	Ctrl+Shift+Delete	Removes the selected item from the system.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Locks

Locks page

Use the Locks page to view the list of items in the application that are locked. Items are considered to be locked when they are being edited by a logged on user. The application unlocks objects when a user is done editing.

Fields

Locks page	
Field	**Description**
✓	Selects the item(s) on which you can perform a task.
Object Type	A system-created description of the item that is locked.
Object Identification	A system-created identifier for the Object Type.
User Name	The account name of the user who has locked the item.
Session ID	A system-created identifier.
Expiration	The date and time that the lock expires.

Actions

Locks page		
Action	**Shortcut**	**Description**
Revoke	Ctrl+Shift+Delete	Clears the system lock on the selected item. Any unsaved changes made to the object are lost.

Buttons

Locks page		
Button	**Shortcut**	**Description**
Revoke	Ctrl+Shift+Delete	Clears the system lock on the selected item. Any unsaved changes made to the object are lost.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Adapters

Adapters page

Use the Adapters page to view information about the InForm Adapters that are defined in the application.

The InForm Adapter provides an interface to web services that support the secure transfer of data between an InForm study and the Central Coding application.

Fields

Adapters page	
Field	**Description**
✓	Selects the item(s) on which you can perform a task.
Name	The name of the adapter. Click the link to open the [Adapter Name] page, from which you can view or edit information about the InForm Adapter.
Get Requests Schedule	Access to the Get Requests job schedule for the associated adapter. Click the **Schedule** icon ( ) to open the Schedule [Adapter Name]—Basic page, from which you can create a schedule for running the Get Requests jobs for the associated adapter. The icon is blue when a schedule exists ( ).
Return Codes Schedule	Access to the Return Codes job schedule for the associated adapter. Click the **Schedule** icon ( ) to open the Schedule [Adapter Name]—Basic page, from which you can create a schedule for running the Return Codes jobs for the associated adapter. The icon is colored when a schedule exists ( ).
Adapter Type	The product type from which the request was sent. The Central Coding application defines this property.

Actions

Adapters page		
Action	**Shortcut**	**Description**
Add	Ctrl+Shift+N	Opens the New Adapter page, from which you can add information about an InForm Adapter to the Central Coding application.
Delete	Ctrl+Shift+Delete	Removes the selected adapter from the system. **Caution:** A confirmation dialog box does **not** appear.
Clear Get Verbatims		Clears the Get Requests job schedule for the selected adapter.

Adapters page		
Action	**Shortcut**	**Description**
Clear Return Codes		Clears the Return Codes job schedule for the selected adapter.

Buttons

Adapters page		
Button	**Shortcut**	**Description**
Add	Ctrl+Shift+N	Opens the New Adapter page, from which you can add information about an InForm Adapter to the Central Coding application.
Delete	Ctrl+Shift+Delete	Removes the selected adapter from the system. **Caution:** A confirmation dialog box does **not** appear.
Refresh ()		Updates the information on the page.
Help ()		Opens online page-level help that describes the page function(s) and fields.

New Adapter page

Use the New Adapter page to add information about an InForm Adapter to the Central Coding application.

Fields

New Adapter page	
Field	**Description**
Adapter name	The name of the adapter.
Adapter type	The product type from which the request was sent. The Central Coding application defines this property.
Adapter URL	The URL for the server where the InForm Adapter software is installed.
Test button	Initiates a test of the connection to the adapter. • If the test is successful, the name of the study or studies that are associated with the adapter appear on the page. • If the test is not successful, an error message appears on the page.
Call AdapterAdmin Interface	The default authentication method for calling the InForm Adapter Admin interface when the Adapter URL starts with https.

New Adapter page	
Field	Description
Call Coding Interface	Selects the authentication method for calling the InForm Adapter Coding interface when the Adapter URL starts with https. **Note:** If you select User Name/Password, you must enter the InForm user name and password in the Get/Put Job options section on the ***System Configuration page*** (on page 529).
Call Discrepancy Interface	Selects the authentication method for calling the InForm Adapter Discrepancy when the Adapter URL starts with https. **Note:** If you select User Name/Password, you must enter the InForm user name and password in the Get/Put Job options section on the ***System Configuration page*** (on page 529).

Actions

New Adapter page	
Action	Description
Save	Saves the changes.
Previous	Navigates back to the previous view.

Buttons

New Adapter page	
Button	Description
Save	Saves the changes.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

[Adapter Name] page

Use the [Adapter Name] page to view or edit information about the InForm Adapter.

Fields

[Adapter Name] page	
Field	Description
Adapter name	The name of the adapter.

[Adapter Name] page	
Field	**Description**
Adapter type	The type of adapter; it is always INFORM.
Adapter URL	The URL for the server where the InForm Adapter software is installed. **NOTE:** If you are using authentication to call the InForm Adapter web services, you must use a secure SSL connection (https).
Test button	Tests the connection to the adapter. • If the test is successful, the names of the trials that are associated with the adapter display on the page. • If the test is not successful, a message appears.
Call AdapterAdmin Interface	The default authentication method for calling the InForm Adapter Admin interface when the Adapter URL starts with https.
Call Coding Interface	Selects the authentication method for calling the InForm Adapter Coding interface when the Adapter URL starts with https. **Note:** If you select User Name/Password, you must enter the InForm user name and password in the Get/Put Job options section on the ***System Configuration page*** (on page 529).
Call Discrepancy Interface	Selects the authentication method for calling the InForm Adapter Discrepancy when the Adapter URL starts with https. **Note:** If you select User Name/Password, you must enter the InForm user name and password in the Get/Put Job options section on the ***System Configuration page*** (on page 529).

Buttons

[Adapter Name] page	
Button	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Schedule [Adapter Name] Job—Basic page

Use the Schedule [Adapter Name] Job—Basic page to create a job schedule based on the days of the week and time.

Fields

Schedule [Adapter Name] Job—Basic page	
Field	Description
Days of week	
Sunday to Saturday	Indicates the day(s) of the week on which you want the job queue to run.
All	Selects all the days. Indicates that you want the job queue to be run every day.
Time span	
Every minute	Indicates that you want the job queue to run every minute of the selected hour(s).
Every 5 minutes	Indicates that you want the job queue to run every 5 minutes of the selected hour(s).
Every 15 minutes	Indicates that you want the job queue to run every 15 minutes of the selected hour(s).
Every 30 minutes	Indicates that you want the job queue to run every 30 minutes of the selected hour(s).
No time span	Indicates that you want the job queue to run only on the selected hour(s).
Hours	
12 to 11 A.M.	Indicates the morning hour(s) on which you want the job queue to run.
12 to 11 P.M.	Indicates the afternoon and evening hour(s) on which you want the job queue to run.
All	Selects all the hours in the day. Indicates that you want the job queue to be run every hour in the day.

Actions

Schedule [Adapter Name] Job—Basic page	
Action	Description
Save	Saves the changes.
Previous	Navigates back to the previous view.

Buttons

Schedule [Adapter Name] Job—Basic page	
Button	**Description**
Advanced	Opens the Schedule [Job Name] Job—Advanced page, from which you can create a detailed job schedule based on months, days, and time.
Save	Saves the changes.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Schedule [Adapter Name] Job—Advanced page

Use the Schedule [Adapter Name] Job—Advanced page to create a detailed job schedule based on months, days, and time.

Fields

Schedule [Adapter Name] Job—Advanced page	
Field	**Description**
Months	
January to December	Indicates the month(s) in which you want the job queue to run.
All	Selects all of the months. Indicates that you want the job queue to be run in every month.
Days	
1 to 31	Indicates the days in the month(s) on which you want the job queue to run.
All	Selects all of the days. Indicates that you want the job queue to be run on every day in the selected month(s).
Time span	
Every minute	Indicates that you want the job queue to run every minute of the selected hour(s).
Every 5 minutes	Indicates that you want the job queue to run every 5 minutes of the selected hour(s).
Every 15 minutes	Indicates that you want the job queue to run every 15 minutes of the selected hour(s).

Schedule [Adapter Name] Job—Advanced page	
Field	**Description**
Every 30 minutes	Indicates that you want the job queue to run every 30 minutes of the selected hour(s).
Custom	Indicates that you want the job queue to be run at the specified interval in the selected hour(s). **Notes:** The valid text is a single value or a comma separated list of values in the following format: • The time in 24 hour clock format when the queue should start to be processed (the hour as an integer between 0 and 23 inclusive, a colon, and the minute as an integer between 0 and 59 inclusive). • A dash ('-'). • The time in 24 hour clock format when the queue should no longer be processed (the hour as an integer between 0 and 23 inclusive, a colon, and the minute as an integer between 0 and 59 inclusive). • The number of minutes between the last time that the queue was processed and the next time that it should be processed as an integer greater than zero enclosed in square brackets ('[','']'). It is assumed that the start time is earlier in real time than the stop time. This will result in the stop time occurring during the day following the start time when the stop time is less than the start time. If the start time and the stop time are the same, the time span is exactly 24 hours. Examples: • 12:30-13:15[5] (Process the queue every five minutes from 12:30 PM until 1:15 PM.) • 23:30-3:45[10],5:15-7:59[20] (Process the queue every 10 minutes from 11:30 PM until 3:45 AM as well as every 20 minutes from 5:15 AM until 7:59 AM.) If TimeSpans overlap (contain some period of time in common), if the current time matches the pattern defined in either TimeSpan, the queue will be processed. For example, for the TimeSpan value "7:00-13:00[4],12:00-14:00[9]" for the period between noon and 1:00 PM, if it has been an even multiple of four minutes since 7:00 AM or it has been an even multiple of 9 minutes since noon, the queue for this schedule will be processed. The example Schedule definition above specifies that the queue will be processed every day at 3 am and every 15 minutes between 12:45 AM and 1:15 AM and every 30 minutes between 1:00 AM and 1:15 PM during January, February, March, and July.

Schedule [Adapter Name] Job—Advanced page	
Field	Description
Hours	
12 to 11 A.M.	Indicates the morning hour(s) on the selected day(s) on which you want the job queue to run.
12 to 11 P.M.	Indicates the afternoon and evening hour(s) on the selected day(s) on which you want the job queue to run.
All	Selects all the hours in the day. Indicates that you want the job queue to be run on every hour in the selected day(s).
Minutes	
0 to 59	Indicates the minutes in selected hour(s) that you want the job queue to be run.
All	Selects all the minutes in an hour. Indicates that you want the job queue to be run every minute in the selected hour(s).

Actions

Schedule [Adapter Name] Job—Advanced page	
Action	Description
Save	Saves the changes.
Previous	Navigates back to the previous view.

Buttons

Schedule [Adapter Name] Job—Advanced page	
Button	Description
Basic	Opens the Schedule [Job Name] Job—Basic page, from which you can create a job schedule based on the days of the week and time.
Save	Saves the changes.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Reconciliation Options

Reconciliation Options page—View mode

Use the Reconciliation Options—View mode page to view the default selection options that appear on the Reconcile Verbatims page, which you use to reconcile the verbatims after running impact analysis.

> **Note:** The Reason, Difference, and Default Actions options that appear on the Reconciliation Options page vary depending on whether the Allow Uncode option is selected on the System Configuration page.

Fields

<table>
<tr><th colspan="2">Reconciliation Options page</th></tr>
<tr><th>Field</th><th>Description</th></tr>
<tr><td>Reason</td><td>The cause of the difference between the dictionary versions for the associated verbatim.
Path Change New Primary SOC (MedDRA only)
Possible Better Choice (4 choices defined in the Differences column)</td></tr>
<tr><td>Difference</td><td>The difference in dictionary versions, which produce different codings for a given verbatim that requires a user to select an action on the Reconcile Verbatims page.
Path Change New Primary SOC—The original term and path exist in the new version. It now autocodes to the same term with a different path to a different primary SOC.
Possible Better Choice:
1—The original term and path exist in the new version. Autocoding results coding to a different term with multiple possible paths.
2—The original term and path exist in the new version. Autocoding results coding to the same term with additional path choices.
3—The original term and path exist in the new version. It now autocodes to a different term and path.
4—The original term and path exist in the new version. It now autocodes to the same term but a different path.</td></tr>
<tr><td>Original Coding Mode</td><td>The type of coding originally performed on the verbatim.
I—Interactive
A—Automatic
I/A—Interactive or automatic</td></tr>
</table>

Reconciliation Options page	
Field	**Description**
Default Action	The actions available to be selected by default on the Reconcile Verbatims page. When the **Allow Uncode** option on the System Configuration page is selected, the options in the Default Actions column are: • **Accept New**—The new autocode result (code, term, and path represented by the code and term) displays in the **New Code and Term** column and is selected by default. • **Keep Original**—The coding (code, term, and path represented by the code and term) in the **Original Code and Term** column is selected by default. • **Uncoded**—The **Uncode** option in the **Accept Uncode** column is selected by default. When the **Allow Uncode** option on the System Configuration page is **not** selected, the options in the Default Action column are: • **Accept New**—The new autocode result (code, term, and path represented by the code and term) displays in the **New Code and Term** column and is selected by default. • **Keep Original**—The coding (code, term, and path represented by the code and term) in the **Original Code and Term** column is selected by default.

Actions

Reconciliation Options page—View mode		
Action	**Shortcut**	**Description**
Edit	Ctrl+Shift+E	Puts the Reconciliation Options page into the Edit mode, from which you can edit the default selection options that appear on the Reconcile Verbatims page, which you use to reconcile the verbatims after running impact analysis.

Buttons

Reconciliation Options page—View mode		
Button	**Shortcut**	**Description**
Edit	Ctrl+Shift+E	Puts the Reconciliation Options page into the Edit mode, from which you can edit the default selection options that appear on the Reconcile Verbatims page, which you use to reconcile the verbatims after running impact analysis.

Reconciliation Options page—View mode		
Button	Shortcut	Description
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Reconciliation Options page—Edit mode

Use the Reconciliation Options page—Edit mode to modify the default selection options that appear on the Reconcile Verbatims page, which you use to reconcile the verbatims after running impact analysis. The choices you make determine which options are automatically selected on the Reconcile Verbatims page. You can choose to modify the default selections, or you can change individual selections as needed when you reconcile the verbatims.

> **Note: The Reason, Difference, and Default Actions options that appear on the Reconciliation Options page vary depending on whether the Allow Uncode option is selected on the System Configuration page.**

Fields

Reconciliation Options page	
Field	Description
Reason	The cause of the difference between the dictionary versions for the associated verbatim. • Path Change New Primary SOC (MedDRA only) • Possible Better Choice (4 choices defined in the **Differences** column)

Reconciliation Options page	
Field	Description

Difference	The difference in dictionary versions, which produce different codings for a given verbatim that requires a user to select an action on the Reconcile Verbatims page.
	• **Path Change New Primary SOC**—The original term and path exist in the new version. It now autocodes to the same term with a different path to a different primary SOC.
	• **Possible Better Choice**:
	  • **1**—The original term and path exist in the new version. Autocoding results coding to a different term with multiple possible paths.
	  • **2**—The original term and path exist in the new version. Autocoding results coding to the same term with additional path choices.
	  • **3**—The original term and path exist in the new version. It now autocodes to a different term and path.
	  • **4**—The original term and path exist in the new version. It now autocodes to the same term but a different path.

Original Coding Mode	The type of coding originally performed on the verbatim. • **I**—Interactive • **A**—Automatic • **I/A**—Interactive or automatic

Reconciliation Options page	
Field	Description
Default Action	The actions available to be selected by default on the Reconcile Verbatims page. When the **Allow Uncode** option on the System Configuration page is selected, the options in the Default Actions column are: • **Accept New**—The new autocode result (code, term, and path represented by the code and term) displays in the **New Code and Term** column and is selected by default. • **Keep Original**—The coding (code, term, and path represented by the code and term) in the **Original Code and Term** column is selected by default. • **Uncoded**—The **Uncode** option in the **Accept Uncode** column is selected by default. When the **Allow Uncode** option on the System Configuration page is **not** selected, the options in the Default Action column are: • **Accept New**—The new autocode result (code, term, and path represented by the code and term) displays in the **New Code and Term** column and is selected by default. • **Keep Original**—The coding (code, term, and path represented by the code and term) in the **Original Code and Term** column is selected by default.

Actions

Reconciliation Options page—Edit mode	
Action	Description
Save	Saves the changes.
Cancel	Returns the page to the view mode without saving any changes.

Buttons

Reconciliation Options page—Edit mode	
Button	Description
Save	Saves the changes.
Cancel	Returns the page to the view mode without saving any changes.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Query Standard Reasons

Query Standard Reason List page

Use the Query Standard Reason List page to manage the reasons that appear in the Reason drop-down list in the Create Query, Cancel Query, Close Query, and Reissue Query dialog boxes.

Fields

Query Standard Reason List page	
Field	Description
Action Type filter	The query action whose associated standard reasons you want to view. • **Create**—Standard reasons that are available for use when you create an open or candidate query. • **Close**—Standard reasons that are available for use when you close a query. • **Reissue**—Standard reasons that are available for use when you reissue a query. • **Delete**—Standard reasons are available for use when you delete a query.
✓	Selects the item(s) on which you can perform a task.
Action Type	The query action with which to associate the standard reason. • **Create**—Standard reasons appear in the Create Query and Approve Query dialog box. • **Close**—Standard reasons appear in the Close Query and Force Close Query dialog boxes. • **Reissue**—Standard reasons appear in the Reissue Query dialog box. • **Delete**—Standard reasons appear in the Cancel Query dialog box.
Update Date	The most recent date the reason was modified.
Reason	The text of the reason.
Set as Default Reason	Select to set the reason as the first to appear in the Reason drop-down list in the appropriate dialog box.

Actions

Query Standard Reason List page		
Action	Shortcut	Description
Add	Ctrl+Shift+A	Opens the Add [Action Type] Query Standard Reason page, from which you can add a standard query reason for the action type that is selected in the Action Type drop-down list on the Query Standard Reason List page.
Edit	Ctrl+Shift+E	Opens the Edit [Action Type] Query Standard Reason page, from which you can edit the selected standard reason.
Delete	Ctrl+Shift+D	Deletes the selected query reason. **Note:** A confirmation dialog box does **not** appear.

Buttons

Query Standard Reason List page		
Button	Shortcut	Description
Add	Ctrl+Shift+A	Opens the Add [Action Type] Query Standard Reason page, from which you can add a standard query reason for the action type that is selected in the Action Type drop-down list on the Query Standard Reason List page.
Edit	Ctrl+Shift+E	Opens the Edit [Action Type] Query Standard Reason page, from which you can edit the selected standard reason.
Delete	Ctrl+Shift+D	Deletes the selected query reason. **Note:** A confirmation dialog box does **not** appear.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Add [Action Type] Standard Reason page

Use the Add [Action Type] Standard Reason page to add a standard query reason for the action type that is selected in the Action Type drop-down list on the Query Standard Reason List page.

Fields

Add [Action Type] Standard Reason page	
Field	**Description**
Standard Reason	The text of the default query reason you want to add to the standard reasons list for the action type you specified on the Query Standard Reason List page.

Buttons

Add [Action Type] Standard Reason page	
Button	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Edit [Action Type] Standard Reason page

Use the Edit [Action Type] Standard Reason page to edit the selected default query reason.

Fields

Edit [Action Type] Standard Reason page	
Field	**Description**
Standard Reason	The text of the default query reason you want to edit.

Buttons

Edit [Action Type] Standard Reason page	
Button	**Description**
Save	Saves the changes.
Previous	Navigates back to the previous view.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

Coding flags

Coding Flags—View mode

Use the Coding Flags—View mode page to view the definitions associated with each coding flag.

> **Note:** A Central Coding administrator can configure the meaning of each coding flag.

Fields

Coding Flags—View mode	
Field	**Description**
Icon	The coding flag icon for which a Central Coding administrator can configure the definition. By default, the red coding flag icon is defined as (I)nForm Query, and the green coding flag icon is defined as (C)oding Query.
Definition	The configurable meaning for each coding flag.
Action	Select Enable or Disable for each coding flag.

Buttons

Coding Flags—View mode		
Button	**Shortcut**	**Description**
Edit	Ctrl+Shift+E	Puts the Coding Flags page into Edit mode, from which you can edit the definitions of each coding flag, and enable or disable the flags.
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

Coding Flags—Edit mode

Use the Coding Flags—Edit mode page to edit the definitions associated with each coding flag.

Fields

Coding Flags—Edit mode	
Field	**Field**
Icon	The coding flag icon for which a Central Coding administrator can configure the definition. By default, the red coding flag icon is defined as (I)nForm Query, and the green coding flag icon is defined as (C)oding Query.
Definition	The configurable meaning for each coding flag.
Action	Select Enable or Disable for each coding flag.

Buttons

Coding Flags—Edit mode	
Button	**Description**
Save	Saves the changes.
Cancel	Returns the page to the view mode without saving any changes.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

System Configuration

System Configuration page—View mode

Use the System Configuration page to view the authentication, application, lock management, and impact analysis configuration options.

Fields

- Authentication options.

System Configuration page	
Field	**Description**
Authentication Options	
Authentication inactivity timeout	The period of inactivity after which a user session times out. The default is 20 minutes. Enter the time in hh:mm:ss format. For example, 23:59:30. REQUIRED. **Note:** After the session times out, access to the application requires the user to log in again. Upon successful re-authentication, the user is redirected to the page that was displayed before the session timed out. Any unsaved data is preserved on the screen.
Authentication expiration	The length of time after which a user session times out. The default is 4 hours (240 minutes). Enter the time in hh:mm:ss format. For example, 23:59:30. REQUIRED. **Note:** After the session times out, access to the application requires the user to log in again. Upon successful re-authentication, the user is redirected to the page that was displayed before the session timed out. Any unsaved data is preserved on the screen.
Failed logon limit	The number of times a user can try to log in before being locked out of the application, causing the user's account to become Inactive. The default value is 3. REQUIRED. **Note:** If the retry attempts exceed this value, the user account is automatically marked as Inactive, the user is not allowed to access the application, and a record of the failed login attempt is recorded in an audit log.
Authentication token duration	The length of time the user login is valid. The default is 10 hours. Enter the time in hh:mm:ss format. For example, 23:59:30. REQUIRED. **Note:** This value is used in the communication between the Central Coding and InForm Adapter applications. It does not affect the user interface. This field specifies the duration for which a security token (issued when a user successfully enters their user name and password) is valid. After the duration has passed, the security token is considered to have expired.

System Configuration page	
Field	Description
Authentication Options	
Authentication token renew duration	Specifies how long the password is valid until it needs to be changed. The default is one week. Enter the time in hh:mm:ss format. For example, 23:59:30. REQUIRED. **Note:** This value is used in the communication between the Central Coding and InForm Adapter applications. It does not affect the user interface. This field specifies the duration that a previously created security token can be renewed for without requiring a user to re-enter the user name and password. When a security token expires (that is, the duration specified in the **Authentication token duration** field has elapsed), it will automatically be renewed for this duration.
Authentication token clock slush	The number of minutes the server clocks for the Central Coding and InForm Adapter application servers can be out of sync. The default is 5 minutes (meaning that a token will be accepted if the server clock is within 5 minutes of the server that issued the token). Enter the time in hh:mm:ss format. For example, 23:59:30. REQUIRED. **Note:** This value is used in the communication between the Central Coding and InForm Adapter applications. It does not affect the user interface. Each security token contains the time it was issued and the time it will expire. The system subtracts and adds (respectively) the duration specified by this setting to allow server clocks to be out of sync by the specified number of minutes.
Password expiration	The length of time that a password is valid. The default is 30 days. Enter the value in ddd:hh:mm:ss format. For example, 02:23:59:30. REQUIRED. **Note:** Password expiration checking is performed when the user session is established. If the password has expired, the user is denied access to the system, notified of the expiration, and prompted to enter the existing password, a new password, and confirmation of the new password.
Minimum length of password	The minimum number of characters for a password. The default is 6 alphanumeric characters. REQUIRED.
Super user lockout timeout	Amount of consecutive inactive time before a session timeout occurs for a super user.
Non-Super user lockout timeout	Amount of consecutive inactive time before a session timeout occurs for a non-super user.

System Configuration page	
Field	**Description**
Authentication Options	
Password complexity requirement	Number of the following additional requirements a password must meet. • A mix of one or more of both alphabetical (A-Z , a-z) and numeric (0-9) characters. • At least one non-alphanumeric character (` ~ ! @ # $ % ^ & * ( ) _ + - = { } | [ ] \ : " ; ' < > ? , . /). • A mix of at least one or more characters of both alphabetical upper case [A-Z] and lower case [a-z]. **Note:** All passwords must conform to the specified minimum length requirement.
Password reuse limit	Number of previous passwords that cannot be reused. Default is 3. For example, when users change their password, they cannot set it to any of the last 3 passwords they used.

- Application settings.

System Configuration page	
Field	**Description**
Application Settings	
Date Format	The date format to use for data entry fields in the user interface. The format you select is also used in the Audit History Report. The default setting depends on the operating system. • **English OS**—DD/MON/YYYY HH24:MI:SS • **Japanese OS**—YYYY/MON/DD HH24:MI:SS
Display Context Items on Coding Requests and Approvals pages	Indicates whether to display the first 25 characters of the context items (Indication and Route of Administration) associated with a verbatim on the Coding Requests page, Approvals page, Unassigned Requests page, and the All Requests page. The full Route of Administration or Indication text appears on the Requests Details page. **Note:** By default, this option is **not** selected.

System Configuration page	
Field	**Description**
Application Settings	
Request List View Column Length	Sets the width of some columns on the list view pages to prevent a forced break between Japanese characters. This setting increases the width of the columns that appear to the right of the Code column on the Coding Requests, Approvals, and All Requests pages when viewing the requests for a particular coding definition. That is, when you are using the View filter. **Note:** This setting affects the list views only when you are using a Japanese operating system or an English operating system with a Global locale (the system accepts both English and Japanese verbatims).
Show Non Current Terms During Browser Search	Indicates whether to display non-current terms in the coding browser during a search. **Note:** By default, this option is selected.
Delete Study Mask	Specifies the set of characters that appears in the name of the studies that can be completely deleted. The default is **UAT**. This setting limits the type of study that you can delete using the **Delete Study and All Data** option on the Study Information page.
Show Delete Request After Delivery Option	Indicates whether to display the **Delete request after delivery** option on the [Assignment Rule Name] page. **Note:** By default, this option is **not** selected.
Delete Request Audit Information	Indicates whether to delete the audit information from the database tables for delivered requests that were deleted using the **Delete request after delivery** option on the [Assignment Rule Name] page. **Note:** By default, this option is **not** selected.
Lock expiration	The length of time after which a system lock expires. Enter the time in hh:mm:ss format. For example, 23:59:30. **Note:** After a user is done with an object, the Central Coding application automatically releases it. However, if an operation is not completed (if, for example, a user closes the browser or walks away, or an error occurs) the system automatically releases the lock at the lock expiration time.

- Impact analysis options.

<table>
<tr><th colspan="2">System Configuration page</th></tr>
<tr><th>Field</th><th>Description</th></tr>
<tr><th colspan="2">Impact Analysis Options</th></tr>
<tr><td>Reassociate Synonym</td><td>Indicates whether you want synonyms to be automatically or manually reassociated with current terms in the new dictionary. The choice affects which synonyms are available to manually reconcile (reassociate) on the Reconcile Synonyms page. This setting is only valid for MedDRA LLT terms.

• Selected—If you select this option, all synonyms associated with LLTs that have become non-current in the new version of the dictionary are automatically reassociated to a current LLT in the new dictionary version where possible.

The Central Coding application reassociates the synonyms according to MSSO policy:
▪ Every LLT is associated with a PT.
▪ Every PT has an associated LLT that has the same code and term as the PT.

The synonyms that are automatically reassociated do not appear on the Reconcile Synonyms page. However, they are included in the Synonym Reconciliation Report.

• Not selected—If you do not select this option (default), you must manually reconcile (reassociate) the synonyms with current terms in the new dictionary, or delete the synonyms.

The synonyms that require reconciliation appear on the Reconcile Synonyms page and are included in the Synonym Reconciliation Report.</td></tr>
</table>

<table>
<tr><th colspan="2">System Configuration page</th></tr>
<tr><th>Field</th><th>Description</th></tr>
<tr><th colspan="2">Impact Analysis Options</th></tr>
<tr><td>Set Delete Synonym as Default</td><td>Indicates whether you want unused synonyms to be automatically marked for deletion. The choice may save a step during the reconciling synonyms step on the Reconcile Synonyms page.
Selected—If you select this option, the Delete option in the Action column on the Reconcile Synonyms page is selected by default for all deleted terms.

Users can edit the selections as needed. The synonyms are deleted when the changes are approved.
Not selected—If you do not select this option (default), the Delete option in the Action column on the Reconcile Synonyms page is not selected by default.

The deleted terms on the Reconcile Synonyms page are not automatically marked for deletion. Users can interactively code the synonym to find a new term.
Note: When a user performs the Approve All action, a message appears to remind the user that one or more synonyms will be deleted. You must perform an action on each synonym to continue.</td></tr>
<tr><td>Allow Uncode</td><td>Allows users to have the option to not accept the code and term value from either the original or the new coding dictionary, and to return the verbatim to the coder's queue. The choice affects whether an option is available during the reconciling verbatims step on the Reconcile Verbatims page.
Selected—If you select this option, the Accept Uncode column appears on the Reconcile Verbatims page.

During the verbatim reconciliation process users can select the original code and term, select the new code and term, manually recode the verbatim, or choose the Uncode option. If they choose the Uncode option the verbatim is returned to the coder's queue.
Not selected—If you do not select this option (default), the Accept Uncode column does not appear on the Reconcile Verbatims page.

During the verbatim reconciliation process users can select the original code and term, select the new code and term, or manually recode the verbatim.

Note: When a user performs the Approve All action, a message appears if any verbatims are not coded, and the approval does not proceed.</td></tr>
</table>

System Configuration page	
Field	**Description**
Impact Analysis Options	
Skip Auto Suggestion Step	Indicates whether you want impact analysis to skip the **Auto Suggestion** step in the coding algorithm, which allows it to search for a possible better choice even if there is an auto-suggestion for a verbatim. • **Selected**—If you select this option (default), impact analysis skips the **Auto Suggestion** step in the coding algorithm. As a result, impact analysis can continue to look for a possible better choice regardless of whether there is an auto-suggestion for the verbatim. • **Not selected**—If you do not select this option, the Central Coding application uses the auto-suggestion for a verbatim (if any) as the coding and impact analysis cannot continue to search for a possible better choice.

- Query Management options.

System Configuration page	
Field	**Description**
Query Management Options	
Maximum Query Reason Length	The maximum number of characters a user can enter in the **Reason** field in the Create Query dialog box. By default, this option is set to 255 characters. Oracle recommends configuring this setting to match the maximum number of characters allowed in the version of the InForm application with which you are integrating the Central Coding application. **Note:** This setting also applies to the standard query reasons an administrator sets on the Query Default Reason List page.

System Configuration page	
Field	**Description**
Query Management Options	
Query Create User in Client	The account name for a user in the InForm application that has rights to create queries and indicates to sites and sponsors that the query was opened by a coder. The account name is case-sensitive. • For single sign-on InForm studies, the account name has two parts: Trial Company/Short Org ID.user ID. • For all other studies, the account name is the user ID only. Specify the InForm account name to use during the ExchangeQueryUpdate job. This account name is used to create and update queries in the InForm application, and the user name appears in the InForm application as the user who created each Central Coding query. You do not need to specify a password for the user. **Note:** Create User in Client is blank by default. You must enter an account name that matches an InForm user with query rights in the InForm application in order to transfer query data between the InForm and Central Coding applications.
Allow Multiple Query Reissue	Select this option if you want to allow a query to be reissued multiple times.

- Get/Put Job Options.

System Configuration page	
Field	**Description**
Get/Put Job Options	
GetRequests Job Chunk Size	Number of requests to retrieve from the source application in each web service call to the InForm Adapter application. The chunks run sequentially, and each job continues to process until all requests have been retrieved from the source application.
ReturnCodes Job Chunk Size	Number of requests to return to the source application in each web service call to the InForm Adapter application. The chunks run sequentially, and each job continues to process until all requests have been delivered to the source application.
Web Service Client Timeout	The amount of time (in milliseconds) to wait for the web service response before the web service client times out.

System Configuration page	
Field	**Description**
Get/Put Job Options	
InForm Authentication User Name and InForm Authentication User Password	A valid InForm user name and password. **Note:** This field is required for communication with the InForm application if you are using user name/password authentication. In addition, when you create a new InForm adapter, you must also select the option to Call InForm Adapter Web Services with User Name/Password Authentication on the ***[Adapter Name] page*** (on page 504). This InForm user created for the authentication of web services should not have any additional privileges in InForm. This authentication user should be different from transaction users specified in **PutCodes client audit user** or **Query Create User in Client** fields, which have additional rights in InForm and are used for returning codes or creating queries in InForm.
Authentication Certificate Name	Read-only field that contains the name of the authentication certificate used for signing InForm Adapter web service messages when certificate authentication is specified on the Adapter configuration page. **Note:** To change, update or remove the certificate, see *Installation Guide*.

Actions

System Configuration page—View mode		
Action	**Shortcut**	**Description**
Edit	Ctrl+Shift+E	Puts the System Configuration page into the Edit mode, from which you can edit the authentication, application, lock management, impact analysis query management, and job schedule configuration options.

Buttons

System Configuration page—View mode		
Button	**Shortcut**	**Description**
Edit	Ctrl+Shift+E	Puts the System Configuration page into the Edit mode, from which you can edit the authentication, application, lock management, impact analysis query management, and job schedule configuration options.

System Configuration page—View mode		
Button	**Shortcut**	**Description**
Refresh ( )		Updates the information on the page.
Help ( )		Opens online page-level help that describes the page function(s) and fields.

System Configuration page—Edit mode

Use System Configuration page to edit the authentication, application, lock management, impact analysis query management, and job schedule configuration options.

Fields

- Authentication options.

System Configuration page	
Field	**Description**
Authentication Options	
Authentication inactivity timeout	The period of inactivity after which a user session times out. The default is 20 minutes. Enter the time in hh:mm:ss format. For example, 23:59:30. REQUIRED. **Note:** After the session times out, access to the application requires the user to log in again. Upon successful re-authentication, the user is redirected to the page that was displayed before the session timed out. Any unsaved data is preserved on the screen.
Authentication expiration	The length of time after which a user session times out. The default is 4 hours (240 minutes). Enter the time in hh:mm:ss format. For example, 23:59:30. REQUIRED. **Note:** After the session times out, access to the application requires the user to log in again. Upon successful re-authentication, the user is redirected to the page that was displayed before the session timed out. Any unsaved data is preserved on the screen.
Failed logon limit	The number of times a user can try to log in before being locked out of the application, causing the user's account to become Inactive. The default value is 3. REQUIRED. **Note:** If the retry attempts exceed this value, the user account is automatically marked as Inactive, the user is not allowed to access the application, and a record of the failed login attempt is recorded in an audit log.

System Configuration page	
Field	**Description**
Authentication Options	
Authentication token duration	The length of time the user login is valid. The default is 10 hours. Enter the time in hh:mm:ss format. For example, 23:59:30. REQUIRED. **Note:** This value is used in the communication between the Central Coding and InForm Adapter applications. It does not affect the user interface. This field specifies the duration for which a security token (issued when a user successfully enters their user name and password) is valid. After the duration has passed, the security token is considered to have expired.
Authentication token renew duration	Specifies how long the password is valid until it needs to be changed. The default is one week. Enter the time in hh:mm:ss format. For example, 23:59:30. REQUIRED. **Note:** This value is used in the communication between the Central Coding and InForm Adapter applications. It does not affect the user interface. This field specifies the duration that a previously created security token can be renewed for without requiring a user to re-enter the user name and password. When a security token expires (that is, the duration specified in the **Authentication token duration** field has elapsed), it will automatically be renewed for this duration.
Authentication token clock slush	The number of minutes the server clocks for the Central Coding and InForm Adapter application servers can be out of sync. The default is 5 minutes (meaning that a token will be accepted if the server clock is within 5 minutes of the server that issued the token). Enter the time in hh:mm:ss format. For example, 23:59:30. REQUIRED. **Note:** This value is used in the communication between the Central Coding and InForm Adapter applications. It does not affect the user interface. Each security token contains the time it was issued and the time it will expire. The system subtracts and adds (respectively) the duration specified by this setting to allow server clocks to be out of sync by the specified number of minutes.
Password expiration	The length of time that a password is valid. The default is 30 days. Enter the value in ddd:hh:mm:ss format. For example, 02:23:59:30. REQUIRED. **Note:** Password expiration checking is performed when the user session is established. If the password has expired, the user is denied access to the system, notified of the expiration, and prompted to enter the existing password, a new password, and confirmation of the new password.

System Configuration page	
Field	**Description**
Authentication Options	
Minimum length of password	The minimum number of characters for a password. The default is 6 alphanumeric characters. REQUIRED.
Super user lockout timeout	Amount of consecutive inactive time before a session timeout occurs for a super user.
Non-Super user lockout timeout	Amount of consecutive inactive time before a session timeout occurs for a non-super user.
Password complexity requirement	Number of the following additional requirements a password must meet. • A mix of one or more of both alphabetical (A-Z , a-z) and numeric (0-9) characters. • At least one non-alphanumeric character (` ~ ! @ # $ % ^ & * ( ) _ + - = { } | [ ] \ : " ; ' < > ? , . /). • A mix of at least one or more characters of both alphabetical upper case [A-Z] and lower case [a-z]. **Note:** All passwords must conform to the specified minimum length requirement.
Password reuse limit	Number of previous passwords that cannot be reused. Default is 3. For example, when users change their password, they cannot set it to any of the last 3 passwords they used.

- Application settings.

System Configuration page	
Field	**Description**
Application Settings	
Date Format	The date format to use for data entry fields in the user interface. The format you select is also used in the Audit History Report. The default setting depends on the operating system. • **English OS**—DD/MON/YYYY HH24:MI:SS • **Japanese OS**—YYYY/MON/DD HH24:MI:SS
Display Context Items on Coding Requests and Approvals pages	Indicates whether to display the first 25 characters of the context items (Indication and Route of Administration) associated with a verbatim on the Coding Requests page, Approvals page, Unassigned Requests page, and the All Requests page. The full Route of Administration or Indication text appears on the Requests Details page. **Note:** By default, this option is **not** selected.

System Configuration page	
Field	**Description**
Application Settings	
Request List View Column Length	Sets the width of some columns on the list view pages to prevent a forced break between Japanese characters. This setting increases the width of the columns that appear to the right of the Code column on the Coding Requests, Approvals, and All Requests pages when viewing the requests for a particular coding definition. That is, when you are using the View filter. **Note:** This setting affects the list views only when you are using a Japanese operating system or an English operating system with a Global locale (the system accepts both English and Japanese verbatims).
Show Non Current Terms During Browser Search	Indicates whether to display non-current terms in the coding browser during a search. **Note:** By default, this option is selected.
Delete Study Mask	Specifies the set of characters that appears in the name of the studies that can be completely deleted. The default is **UAT**. This setting limits the type of study that you can delete using the **Delete Study and All Data** option on the Study Information page.
Show Delete Request After Delivery Option	Indicates whether to display the **Delete request after delivery** option on the [Assignment Rule Name] page. **Note:** By default, this option is **not** selected.
Delete Request Audit Information	Indicates whether to delete the audit information from the database tables for delivered requests that were deleted using the **Delete request after delivery** option on the [Assignment Rule Name] page. **Note:** By default, this option is **not** selected.
Lock expiration	The length of time after which a system lock expires. Enter the time in hh:mm:ss format. For example, 23:59:30. **Note:** After a user is done with an object, the Central Coding application automatically releases it. However, if an operation is not completed (if, for example, a user closes the browser or walks away, or an error occurs) the system automatically releases the lock at the lock expiration time.

- Impact analysis options.

System Configuration page	
Field	**Description**
Impact Analysis Options	

<table>
<tr><th colspan="2">System Configuration page</th></tr>
<tr><th>Field</th><th>Description</th></tr>
<tr><th colspan="2">Impact Analysis Options</th></tr>
<tr><td>Reassociate Synonym</td><td>Indicates whether you want synonyms to be automatically or manually reassociated with current terms in the new dictionary. The choice affects which synonyms are available to manually reconcile (reassociate) on the Reconcile Synonyms page. This setting is only valid for MedDRA LLT terms.

Selected—If you select this option, all synonyms associated with LLTs that have become non-current in the new version of the dictionary are automatically reassociated to a current LLT in the new dictionary version where possible.
The Central Coding application reassociates the synonyms according to MSSO policy:

Every LLT is associated with a PT.
Every PT has an associated LLT that has the same code and term as the PT.

The synonyms that are automatically reassociated do not appear on the Reconcile Synonyms page. However, they are included in the Synonym Reconciliation Report.
Not selected—If you do not select this option (default), you must manually reconcile (reassociate) the synonyms with current terms in the new dictionary, or delete the synonyms.
The synonyms that require reconciliation appear on the Reconcile Synonyms page and are included in the Synonym Reconciliation Report.
</td></tr>
<tr><td>Set Delete Synonym as Default</td><td>Indicates whether you want unused synonyms to be automatically marked for deletion. The choice may save a step during the reconciling synonyms step on the Reconcile Synonyms page.

Selected—If you select this option, the Delete option in the Action column on the Reconcile Synonyms page is selected by default for all deleted terms.
Users can edit the selections as needed. The synonyms are deleted when the changes are approved.
Not selected—If you do not select this option (default), the Delete option in the Action column on the Reconcile Synonyms page is not selected by default.
The deleted terms on the Reconcile Synonyms page are not automatically marked for deletion. Users can interactively code the synonym to find a new term.

Note: When a user performs the Approve All action, a message appears to remind the user that one or more synonyms will be deleted. You must perform an action on each synonym to continue.</td></tr>
</table>

<table>
<tr><th colspan="2">System Configuration page</th></tr>
<tr><th>Field</th><th>Description</th></tr>
<tr><th colspan="2">Impact Analysis Options</th></tr>
<tr><td>Allow Uncode</td><td>Allows users to have the option to not accept the code and term value from either the original or the new coding dictionary, and to return the verbatim to the coder's queue. The choice affects whether an option is available during the reconciling verbatims step on the Reconcile Verbatims page.
Selected—If you select this option, the Accept Uncode column appears on the Reconcile Verbatims page.

During the verbatim reconciliation process users can select the original code and term, select the new code and term, manually recode the verbatim, or choose the Uncode option. If they choose the Uncode option the verbatim is returned to the coder's queue.
Not selected—If you do not select this option (default), the Accept Uncode column does not appear on the Reconcile Verbatims page.

During the verbatim reconciliation process users can select the original code and term, select the new code and term, or manually recode the verbatim.

Note: When a user performs the Approve All action, a message appears if any verbatims are not coded, and the approval does not proceed.</td></tr>
<tr><td>Skip Auto Suggestion Step</td><td>Indicates whether you want impact analysis to skip the Auto Suggestion step in the coding algorithm, which allows it to search for a possible better choice even if there is an auto-suggestion for a verbatim.
Selected—If you select this option (default), impact analysis skips the Auto Suggestion step in the coding algorithm. As a result, impact analysis can continue to look for a possible better choice regardless of whether there is an auto-suggestion for the verbatim.
Not selected—If you do not select this option, the Central Coding application uses the auto-suggestion for a verbatim (if any) as the coding and impact analysis cannot continue to search for a possible better choice.</td></tr>
</table>

- Query Management Options.

System Configuration page	
Field	**Description**
Query Management Options	
Maximum Query Reason Length	The maximum number of characters a user can enter in the **Reason** field in the Create Query dialog box. By default, this option is set to 255 characters. Oracle recommends configuring this setting to match the maximum number of characters allowed in the version of the InForm application with which you are integrating the Central Coding application. **Note:** This setting also applies to the standard query reasons an administrator sets on the Query Default Reason List page.
Query Create User in Client	The account name for a user in the InForm application that has rights to create queries and indicates to sites and sponsors that the query was opened by a coder. The account name is case-sensitive. • For single sign-on InForm studies, the account name has two parts: Trial Company/Short Org ID.user ID. • For all other studies, the account name is the user ID only. Specify the InForm account name to use during the ExchangeQueryUpdate job. This account name is used to create and update queries in the InForm application, and the user name appears in the InForm application as the user who created each Central Coding query. You do not need to specify a password for the user. **Note:** Create User in Client is blank by default. You must enter an account name that matches an InForm user with query rights in the InForm application in order to transfer query data between the InForm and Central Coding applications.
Allow Multiple Query Reissue	Select this option if you want to allow a query to be reissued multiple times.

- Get/Put Job Options.

System Configuration page	
Field	**Description**
Get/Put Job Options	
GetRequests Job Chunk Size	Number of requests to retrieve from the source application in each web service call to the InForm Adapter application. The chunks run sequentially, and each job continues to process until all requests have been retrieved from the source application.
ReturnCodes Job Chunk Size	Number of requests to return to the source application in each web service call to the InForm Adapter application. The chunks run sequentially, and each job continues to process until all requests have been delivered to the source application.
Web Service Client Timeout	The amount of time (in milliseconds) to wait for the web service response before the web service client times out.
InForm Authentication User Name and InForm Authentication User Password	A valid InForm user name and password. **Note:** This field is required for communication with the InForm application if you are using user name/password authentication. In addition, when you create a new InForm adapter, you must also select the option to Call InForm Adapter Web Services with User Name/Password Authentication on the ***[Adapter Name] page*** (on page 504). This InForm user created for the authentication of web services should not have any additional privileges in InForm. This authentication user should be different from transaction users specified in **PutCodes client audit user** or **Query Create User in Client** fields, which have additional rights in InForm and are used for returning codes or creating queries in InForm.
Authentication Certificate Name	Read-only field that contains the name of the authentication certificate used for signing InForm Adapter web service messages when certificate authentication is specified on the Adapter configuration page. **Note:** To change, update or remove the certificate, see *Installation Guide*.

Actions

System Configuration page—Edit mode	
Action	**Description**
Save	Saves the changes.

Buttons

System Configuration page—Edit mode	
Button	**Description**
Save	Saves the changes.
Cancel	Returns the page to the view mode without saving any changes.
Refresh ( )	Updates the information on the page.
Help ( )	Opens online page-level help that describes the page function(s) and fields.

System Information

System Information page

Use the System Information page to view version information for the Central Coding product, the Oracle database, and Windows. You can also view copyright information for the software products used with the Central Coding application.

APPENDIX B

Default users, rights, and roles

In this appendix

Default users

The Central Coding application creates one initial user based on input during installation. You can use that user to create new users. For more information, see the *Installation Guide*.

Note: The **Basic Application User** and **Coding Interface Full Access** roles are system roles that you cannot modify or delete.

Default user		
Display name	Roles	Work Teams
Based on user input	Basic Application User User Manager User Administrator	None

Default roles and rights

The Central Coding application provides a default set of roles that are organized by job function. Each role has a set of rights associated with it. Rights control the pages that appear in the user interface and the actions available on each page. Rights are assigned to roles, and roles are assigned to users. Users can have multiple roles assigned to them.

The following rights are not included by default in any of the default roles:

- View Job Queues.
- Issue Candidate Query.
- Force Close Query.

Note: For details on the rights required for impact analysis, see Required rights and their associated impact analysis tasks. For details on the rights required for managing queries, see ***Required rights for working with queries*** (on page 230).

Note: The **Basic Application User** and **Coding Interface Full Access** roles are system roles that you cannot modify or delete.

	DEFAULT ROLES						
DEFAULT RIGHTS	Approver	Coder	Dictionary Manager	Reporter	System Admin	User Admin	User Manager
Approval							
Approve Coding	X						
Force Close Query							
Manage Auto Queries	X						
Manage Query Standard Reasons	X						
Reconcile Synonyms	X						
Reconcile Verbatims	X						
Reissue Query	X						
View Approval Request	X						
Coding							
Add Auto Queries		X					

	DEFAULT ROLES						
DEFAULT RIGHTS	Approver	Coder	Dictionary Manager	Reporter	System Admin	User Admin	User Manager
Clear Code		X					
Code Approved Request	X	X					
Code Delivered Request	X	X					
Code Request		X					
Code Single	X	X					
Issue Candidate Query							
Issue Open Query	X	X					
Propose Synonyms		X					
Retry Delivery	X	X					
Review Query Listing	X	X					
Submit Auto Suggestion		X					
View Coding Request		X					
Reporting							
Produce Report				X			
View Report				X			
Request Setup							
Accept Synonyms	X		X				
Activate Algorithms			X				
Activate StopwordLists			X				
Activate Stopwords	X		X				

	DEFAULT ROLES						
DEFAULT RIGHTS	Approver	Coder	Dictionary Manager	Reporter	System Admin	User Admin	User Manager
Activate SynonymLists			X				
Activate Synonyms	X		X				
Edit Algorithms			X				
Edit Assignment Rules					X		
Edit CodingDef Element Config			X				
Edit CodingDefs			X				
Edit DictVersion Element Config			X				
Edit StopwordLists	X		X				
Edit Stopwords	X		X				
Edit SynonymLists	X		X				
Edit Synonyms	X		X				
Manage Auto Suggestions	X		X				
Reset Element Config			X				
Run Impact Analysis			X				
View Algorithms			X				
View CodingDefs			X				
View Dictionaries	X		X				

	DEFAULT ROLES						
DEFAULT RIGHTS	Approver	Coder	Dictionary Manager	Reporter	System Admin	User Admin	User Manager
View Request Setup	X				X		
View Stopwords	X		X				
View Synonyms	X		X				
System Administration							
Cancel Request		X					
Edit Request Workteam Assignment					X		
Edit System Configuration					X		
Manage Job Queues					X		
Manage Object Lock					X		
Manage Study Lock					X		
View Administration					X	X	X
View All Requests					X		
View Audit History					X		
View Job Queues	X						
View Object Lock					X		
View Study Lock					X		
View System Configuration					X		
View System Information					X		
User Administration							

	DEFAULT ROLES						
DEFAULT RIGHTS	Approver	Coder	Dictionary Manager	Reporter	System Admin	User Admin	User Manager
Activate User							X
Create Role						X	
Create User						X	
Create Work Team						X	
Deactivate User							X
Delete Role						X	
Delete Work Team						X	
Manage Users					X	X	X
Terminate User							X
Update Role						X	X
Update User						X	X
Update Work Team						X	X

Default rights

Default rights	Description
Approval	
Approve Coding	Mark a coded verbatim Approved.
Force Close Query	Mark a query in any state Closed. **Note:** A query should only be forced closed when there is an irresolvable conflict between the Central Coding application and the InForm application. The query closes only in the Central Coding application. Oracle recommends that you assign this right to a limited number of users, and that you use it as infrequently as possible.
Manage Auto Queries	View the Auto Query List page, from which you can manage the verbatims for which a query is automatically created in the Central Coding application.
Manage Query Standard Reasons	Create and modify the default reasons that appear in the Reason drop-down list in the Create Query, Close Query, Reissue Query, and Cancel Query dialog boxes.
Reconcile Synonyms	View the Reconcile Synonyms page, from which you can reconcile the synonym differences between dictionary versions after you run impact analysis.
Reconcile Verbatims	View the Reconcile Verbatims page, from which you can reconcile the verbatim differences between dictionary versions after you run impact analysis.
View Approval Request	View the Approvals page, from which you can manually approve the code and term assignments for verbatims.
Coding	
Add Auto Queries	View the **Add to auto query list** checkbox in the Create Query dialog box, which allows you to add a verbatim query entry to the auto query list. For more information, see ***Auto query and auto close settings*** (on page 233).
Clear Code	Remove the code and term assigned to a verbatim in the Central Coding application. **Note:** Clearing the code value(s) in the Central Coding application clears the corresponding code value(s) in the source application.
Code Approved Request	Recode a verbatim that has been coded, but not yet delivered to the InForm application.
Code Delivered Request	Recode a verbatim that has been coded and delivered to the InForm application.
Code Request	Open the coding browser, assign a code and term to a verbatim, and propagate the coding to all matching verbatims.

Default rights	Description
Code Single	Open the coding browser and assign a code and term to a single verbatim.
Issue Candidate Query	Create a query in the Candidate state, which a Central Coding user with the appropriate rights will assign to the Open or Deleted state.
Issue Open Query	Create a query in the Open state, which will be propagated to matching verbatims in the coding request list.
Propose Synonyms	Use the Suggest Synonyms link in the coding browser to recommend a term and code that the Central Coding application should assign to all instances of the verbatim for which you suggest the synonym. For more information, see ***Synonyms and synonym lists*** (on page 22).
Retry Delivery	Select verbatims that are marked **Undeliverable** to retry the delivery of the codes and terms to the source application.
Review Query Listing	View the Queries page.
Submit Auto Suggestion	Enable the auto-suggestion feature in the coding browser.
View Coding Request	View the Coding Requests page, from which you can view the list of coding requests assigned to your work teams.
Reporting	
Produce Report	Produce reports and exports.
View Report	View report outputs.
Request Setup	
Accept Synonyms	Approve proposed synonyms.
Activate Algorithms	Activate algorithms that have been modified or added.
Activate StopwordLists	Activate stopword lists that have been modified or added.
Activate Stopwords	Activate stopwords that have been modified or added.
Activate SynonymLists	Activate synonym lists that have been modified or added.
Activate Synonyms	Activate synonyms that have been modified or added.
Edit Algorithms	Edit coding algorithms. To view algorithms, you must have both the Edit Algorithms right and the View Algorithms right.
Edit Assignment Rules	Modify existing assignment rules, which are used to filter coding requests among defined coding definitions.
Edit CodingDef Element Config	Edit the element configuration settings at the coding definition level.
Edit CodingDefs	Edit coding definitions by selecting the dictionary, synonym list, stopword list, and algorithm for the coding definition.
Edit DictVersion Element Config	Edit the element configuration settings at the dictionary level.
Edit StopwordLists	Modify existing stopword lists.

Default rights	Description
Edit Stopwords	Modify existing stopwords.
Edit SynonymLists	Modify existing synonym lists.
Edit Synonyms	Modify existing synonyms.
Manage Auto Suggestions	Allow users to review and remove autocoding suggestions from the list for a specific coding dictionary.
Reset Element Config	Reset the element configuration settings back to the default selections only at the coding definition level.
Run Impact Analysis	Run impact analysis to evaluate existing terms and code assignments against a new dictionary version, reconcile any differences, and report the differences between dictionary versions.
View Algorithms	View coding algorithms. To view algorithms, you must have both the Edit Algorithms right and the View Algorithms right.
View CodingDefs	View the list of coding definitions. To view the element configuration at the coding definition level, you must also have the Edit CodingDef Element Config right.
View Dictionaries	View the list of installed dictionaries. To view the element configuration at the dictionary level, you must also have the Edit DictVersion Element Config right.
View Stopwords	View the stopwords in a stopword list.
View Synonyms	View the synonyms in a synonym list.
System Administration	
Edit Request Workteam Assignment	Modify the work team assignment for a request.
Edit System Configuration	Edit preferences that affect the system. For example, password expiration, date format, maximum query length, etc.
Manage Job Queues	Stop jobs, delete jobs, and review job status.
Manage Object Lock	View objects that are locked and revoke a lock if required.
Manage Study Lock	View studies that are locked and revoke lock if required.
View Administration	Access the Admin tab and view administrative settings. To view the individual pages within this tab, you must have the additional rights that apply to viewing each page.
View All Requests	Access the All Requests page to view all coding request regardless of assignment rules.
View Audit History	View the audit history on the All Requests page.
View Job Queues	View the status of jobs.
View Object Lock	View object lock information.
View Study Lock	View study lock information.

Default rights	Description
View System Configuration	View the System Configuration page, from which you can view the authentication, application, lock management, and impact analysis configuration options.
View System Information	View the System Information page, from which you can view version information for the Central Coding product, the Oracle database, and the Windows system. You can also view copyright information for the software products used with the Central Coding application.
User Administration	
Activate User	Activate a user in the Central Coding application. To activate the user you create, you must have the Activate User right.
Create Role	Create a new role.
Create User	Create a new user.
Create Work Team	Create a work team.
Deactivate User	Deactivate a user.
Delete Role	Delete a role.
Delete Work Team	Delete a work team.
Manage Users	Access the User List page, from which you can perform actions on users such as activating and terminating user accounts, assigning rights and roles to users, and assigning users to work teams. To create users, you must have the create user right. To update user information, you must have the Update user right. To activate the user you create, you must have the Activate User right.
Terminate User	Permanently terminate a user's access to the Central Coding application.
Update Role	Add new rights to a role. You must also have the Create Role right.
Update User	Update user information. To activate the user, you must have the Activate User right.
Update Work Team	Update the name of a work team and modify work team assignments.

APPENDIX C

Impact analysis reference

In this appendix

Impact analysis concepts

About impact analysis, coding, dictionary terms, and dictionary paths

Coding is the process of mapping a standardized term and code from a given level of a standard coding dictionary to a verbatim. In the Central Coding application, that given level is the primary autocode target. It may be the Low Level Term (LLT) or Preferred Term (PT) in the MedDRA or MedDRA-J dictionary; the Trade Name or Medicinal Product in the WHO-DD dictionary; or the Generic Name, Trade Name, or Case Name in the JDrug dictionary.

In certain dictionaries, multiple paths may exist for a given term. One of those paths may be designated as the "primary path."

If multiple paths exist for a term and a primary path is designated, that designation may be used to support autocoding of verbatims that "code" to that term. If there is no primary path designation, the autocode algorithm cannot pick between the alternative paths until a coder creates an auto-suggestion for the verbatim. A verbatim for which a term is found but for which multiple paths exist, none of which can be chosen by the autocoder, is deemed to be "Partially Coded." Auto-suggestions utilize a secondary autocode target, which designates an item as a differentiator between paths—the auto-suggestion stores the code that appears in the specified item of the proper path.

When a new version of a given dictionary type is released, it may contain changes to terms, paths, and/or primary path designations.

Use impact analysis to identify those changes, and to adjust coding requests in response to those changes.

How impact analysis works

For each verbatim, the Central Coding application attempts to autocode the request data (verbatim and any context items). If autocoding finds a new result, it is compared to the original result for the verbatim.

In doing this comparison, the Central Coding application makes sure that every code, every term, and every piece of additional information on every level that is in the result (plus the primary path indicator for MedDRA), is exactly the same in the new result as in the original result. The comparison is case-insensitive.

The information in the result might not be everything that was in the dictionary for that coding, just those configuration elements that are selected in the Return column on the Element Configuration page. For more information, see ***Element Configuration page*** (on page 397).

The source application does not necessarily accept all the information that is returned in the result. The InForm or Clintrial coding map determines what is actually stored in the source product database.

Any differences found by this comparison are evaluated.

1. The Central Coding application makes a first comparison of the code and term of the primary autocode target level.
2. If the code and term match, the Central Coding application makes a second comparison of the rest of the hierarchy from the dictionary that is included in the result.

This is the path through the hierarchy, from the least selective to the most selective level, which you would have to traverse to find the autocode code and term.

3 Because the autocode code and term are the anchor of the path, if one or both of them have changed the original path no longer exists.

4 For differences in coding that the application cannot resolve automatically, the original results and the new results appear on the Reconcile Verbatim page, from which the user can perform an action.

An administrator or coding manager can configure which actions occur automatically and which options you want to make available in the user interface.

About autoreconciling data

You can configure the Central Coding application to automatically use a new coding result if it is the same as the original result in the details that matter to you.

This concept of "the same as the original result in the details that matter to you" is explained as follows. For these examples, we are using a MedDRA-like coding with five levels of hierarchy.

The original result for the example is:

	Code	Term
SOC	90	MNO
HLGT	78	JKL
HLT	56	GHI
PT	34	DEF
LLT	12	ABC

If the dictionary supports the concept of a primary path and the primary path indicator changes, the results are considered different for autoreconciliation purposes and the verbatim target will *not* be autoreconciled.

Autoreconciliation is only applied if the autocoder finds one, and only one, result.

Assuming the primary indicator is the same, and the autocoder found a unique result, the following five results can be seen to be variations of the original result:

	Code	Term	Code	Term	Code	Term	Code	Term	Code	Term
SOC	90	ONM	90	MNO	90	MNO	90	MNO	90	MNO
HLGT	78	LKJ	78	JKL	78	JKL	78	JKL	78	LKJ
HLT	56	IHG	65	GHI	56	IHG	65	IHG	65	IHG
PT	34	FED	34	DEF	34	DEF	34	DEF	34	DEF
LLT	12	CBA	12	ABC	12	ABC	12	ABC	12	ABC
		1		2		3		4		5

The five results are different from the original result as follows:

1 All terms are different.

2 Code of one level is different.

3 Term of one level is different.

4 Code and term of one level are different.

5 Code and term of one level, and term of another, are different.

Autoreconciliation allows you to configure impact analysis to consider each of the different coding results as the same as the original result where it matters to you.

To do this, you can configure the application to use only a subset of the configuration elements for a dictionary to be used when making the second comparison. If the second comparison finds that the values of the configured elements in the subset are the same in both the original and new results, then the two results are considered to be "the same in the details that matter to you" and the application marks the verbatim target as AutoReconciled.

The AutoReconciled and AutoAssign statuses

During impact analysis, the Central Coding application can assign different statuses to the verbatims.

- **AutoReconciled**—The new result is the same as the original result in the details that matter to the user.

  The Requires Reconciliation options (on the Element Configuration page) and optionally, the Auto Reconcile Terms option (on the Choose Source And Target Coding Definition dialog box) are selected for the dictionary levels, codes, and terms of interest.

- **AutoAssign**—The new result is not the same as the original result in the details that matter to the user.

  When the autocoder finds a unique new result and there would be only one action available to the user on the Reconcile Verbatims page (other than recode or leave the verbatim target uncoded), impact analysis automatically assigns the unique result to the verbatim request. When this happens, the verbatim target is given a status of AutoAssign.

Verbatims with either the AutoReconciled or AutoAssign status do not (with a few exceptions) appear on the Reconcile Verbatims page. Both, however, are listed in detail in the Impact Analysis Report so that the user can see what actions the application performed automatically.

Example: Autoreconcile the LLT code only

If all that matters to a user in a MedDRA coding is the LLT code, an administrator or coding manager can set the configuration parameters as follows:

- Deselect the **Requires Reconciliation** checkboxes for all levels other than the LLT level on the **Element Configuration** page for the *target* coding definition.

  For more information, see ***Element Configuration page*** (on page 397).

- Select the **Auto Reconcile Terms** checkbox in the **Choose Source And Target Coding Definitions** dialog box when initiating the impact analysis run.

  For more information, see ***Choose Source And Target Coding Definitions dialog box*** (on page 446) and ***Running impact analysis*** (on page 305).

As a result, the following new result is considered to be “the same in the details that matter to the user” and the application marks the verbatim target as AutoReconciled:

Original result

	Code	Term
SOC	90	MNO
HLGT	78	JKL
HLT	56	GHI
PT	34	DEF
LLT	12	ABC

New Result

	Code	Term
SOC	09	ONM
HLGT	87	LKJ
HLT	65	IHG
PT	43	FED
LLT	12	CBA

The LLT code is the same. The new result is different from the original result as follows:

- All terms are different.
- The codes of four levels are different.

When the autocoder returns a unique result

There is a situation that can occur if the user configures the system to consider something other than the complete result to be what matters.

The autocoder can find a unique result that is neither the original result nor a result that is the same as the original result where it matters, that the original result no longer exists in the new version of the dictionary, and that there is a new coding in the new version of the dictionary that is the same as the original result where it matters.

In this case, there are three codings that you might find useful:

- The original result.
- The new result found by the autocoder.
- The new coding that is the same as the original result where it matters.

The Reconcile Verbatims page has only two columns for showing results. Therefore, when this situation occurs (which should be rare), a red asterisk (*) appears next to the original result in the **Original Code and Term** column on the **Reconcile Verbatims** page.

About comparing dictionary versions

Dictionary changes include term changes at each dictionary level and path changes. You can view the dictionary changes through the user interface and export them to the Microsoft Excel spreadsheet software. Comparing the dictionary versions is optional.

The Central Coding application supports the comparison of dictionary versions for the MedDRA, MedDRA-J, WHO-DD, and JDrug dictionaries. Make sure that the two versions of the dictionary are installed and that the new dictionary has the same culture as the original dictionary. The application does not support impact analysis for custom dictionaries.

> **Note:** A dictionary manager typically performs these tasks.

About upgrading a synonym list to a new dictionary version

When upgrading a synonym list, the Central Coding application copies a synonym list and changes its dictionary version. If the synonym list has a parent synonym list, both child and parent synonym lists are upgraded at the same time.

It is possible for a given dictionary term to be associated with multiple synonyms, both within a single synonym list and within the parent list as well. If a change to a term in the new version of the dictionary invalidates that term, the synonyms for all synonyms that are associated with it are treated as a single collection—a synonym set.

When upgrading a synonym list, the Central Coding application tracks:

- The number of synonyms for which the associated term and code still exist that are active in the new version of the dictionary and map to the same primary SOC (if the dictionary supports the concept of primary path).

  These synonyms are copied into the new synonym list with a status of **Active**.

- Each synonym for which the associated term and code still exist and are active in the new version of the dictionary, but which map to a different primary SOC.

  These synonyms are copied into the new synonym list with a status of **Active**.

- Each automatically reassociated synonym.

  Reassociated synonyms are those synonyms for which the term and code that they are associated with are no longer active in the new dictionary version but, for dictionaries that support it, the application uses known relationships between levels to automatically reassign a synonym to a term.

  An administrator can configure whether to automatically reassociate synonyms. For more information, see *Central Coding system configuration settings for impact analysis* (on page 291). If the option is not selected, synonyms that are associated with terms that are no longer current in the new dictionary version are treated as if the term were deleted.

- Each synonym that has become a term in the new version of the dictionary.

  These synonyms are not copied into the new synonym list.

- Each synonym for which the associated term and code no longer exist, or are no longer current in the new version of the dictionary.

  These synonyms appear on the Reconcile Synonyms page. Depending on the selection you make, they are either copied to the new synonym list or, if you selected Delete, are not copied to the new synonym list. As each of these synonyms is reconciled, the resolution is added to the Synonym Reconciliation Report.

> **Note:** The term and code are viewed as a unit in this analysis. That is, a combination such as "headache / 10019211" is what a synonym is associated with, not either the term or the code separately. If the term headache were to be given a different code in a future version, or a different term was assigned to code 10019211, it would be viewed as the old term and code being deleted and a new term and code combination being inserted rather than either an existing term or code being modified.

About reconciling synonyms

You reconcile synonyms to create synonyms for the new dictionary version by reconciling synonyms from the previous dictionary version.

The process of reconciling synonyms consists of:

- Selecting a synonym list to upgrade.
- Upgrading the synonym list to compare the terms the synonyms are associated with to make sure they are still in the new dictionary.
- Reconciling any synonym differences between the two dictionary versions.
- Saving the upgrade and any synonym changes to the database.

About upgrading a coding definition for impact analysis

Verbatims to be coded in the Central Coding application are contained within requests—one verbatim per request. A request in the Central Coding application is coded to a specific dictionary type and version, which is specified by the coding definition assigned to the request. To change the version of a dictionary that a request is coded with when a new version of a particular dictionary type becomes available, a new coding definition for the new version of the dictionary should be created and the assignment of the request should then be changed to that new coding definition.

Because a coding definition incorporates a synonym list, stopword list, and coding algorithm in addition to a dictionary type and version, it is possible that recoding a verbatim that was coded with one coding definition will result in a different response when the coding definition assignment for the request changes for reasons other than just changes to the dictionary terms or paths. For this reason, whenever the coding definition assignment for requests is to be changed, an analysis of the impact that change will have on existing coding responses should be made.

About a coding definition upgrade and auto-suggestions

Each auto-suggestion is a coding response and, therefore, each maps to a path. Auto-suggestions are unique by verbatim and context items. If the path that an auto-suggestion maps to no longer exists in the new dictionary, the auto-suggestion entry is not copied to the new coding definition. Because auto-suggestions can be automatically rebuilt as part of interactive coding, you do not need to reconcile auto-suggestions.

About reconciling verbatims

You reconcile clinical data to identify a subset of coding requests that were originally coded with one coding definition, and verify and reconcile their coded verbatims against a new dictionary version. If the codes are no longer valid in the new dictionary, the Central Coding application provides options to reconcile the codes.

Note: The selection of requests on which to run impact analysis is by original coding definition, and not by study or any other criteria. The requests that you include in impact analysis may be determined by study, but the requests that the application considers are dependent on the coding definition.

The process of reconciling your clinical data consists of:

- Creating a coding definition for the new dictionary version, including a synonym list for that dictionary version.
- Running impact analysis to compare the coded verbatims.
- Reconciling the verbatims as needed.

Note: If you create a coding definition for a new dictionary version and then modify or create assignment rule(s) in order to code data from an existing study with the new coding definition, you might want to run impact analysis and then reconcile the verbatims for the existing requests from that study that were coded with coding definitions for the earlier version of the dictionary. If you do not do this, part of your study may contain data from an older version of the dictionary, and part may contain data from the new dictionary version. If you change your assignment rule(s) to use a new dictionary for a trial, you must run impact analysis and then reconcile the verbatims so that all your trial data contains current data. If you do not do this, part of your trial may contain data from an older version of a dictionary, and part may contain data from the new dictionary version.

Scenarios for using impact analysis

This section provides scenarios for using impact analysis. The scenarios depict tasks only; they do not provide the role(s) of the user (coder or administrator).

Note: The new dictionary version must be loaded before using impact analysis.

Scenario 1—Upgrading to a new dictionary version

This scenario describes the steps to upgrade verbatims coded with one version of a dictionary to a new dictionary version, including how to upgrade synonyms.

- Step 1: Manage your synonyms.
  - Option 1—Upgrade your synonyms as part of the dictionary upgrade.
  - Option 2—Create a new synonym list for the loaded dictionary.
- Step 2: Decide what set of verbatims to upgrade.
  - Option 1—Update the complete set of verbatims for a coding definition.
  - Option 2—Create or copy a new set of assignment rules.
- Step 3: Run impact analysis.
- Step 4: Reconcile verbatims.

Scenario 1—Upgrading to a new dictionary version		
Step / Option	Tasks / Hints	See topic(s)
STEP 1: Manage your synonyms		
Option 1—Upgrade your synonyms as part of the dictionary upgrade.	**To upgrade synonyms:** 1 Upgrade a synonym list. ▪ In the Upgrade Synonym List dialog box make sure that you select the dictionary you are upgrading to. ▪ Reconcile the synonyms, as needed. ▪ Optionally, generate the Synonym Reconciliation Report. 2 Update the changes.	• ***Upgrading a synonym list for impact analysis*** (on page 298). • ***Reconciling synonyms*** (on page 301). • ***Running the Synonym Reconciliation Report*** (on page 299). • ***Updating a synonym list*** (on page 303).
Option 2—Create a new synonym list for the loaded dictionary.	**To create a new synonym list:** • Create a new synonym list and add synonyms.	• Creating a synonym list and add synonyms to it.
STEP 2: Decide what set of verbatims to upgrade		

Scenario 1—Upgrading to a new dictionary version		
Step / Option	Tasks / Hints	See topic(s)
Option 1—Update the complete set of verbatims for a coding definition.	**To update the complete set of verbatims:** • Upgrade a coding definition. ▪ Select a coding definition that is related to the dictionary to upgrade. ▪ Complete all the "new" fields in the Upgrade Coding Definition dialog box. Make sure that you select the dictionary version you are upgrading to. ▪ If you upgraded a synonym list, make sure you select that one; otherwise, select the one you created. ▪ Select the **Update assignment rules with new coding definition** option in the Upgrade Coding Definition dialog box.	• Upgrading a coding definition for impact analysis.

Scenario 1—Upgrading to a new dictionary version		
Step / Option	Tasks / Hints	See topic(s)
Option 2—Create or copy a new set of assignment rules.	**To create a new set of assignment rules:** 1 Upgrade a coding definition. ▪ Select a coding definition that is related to the dictionary to upgrade. ▪ Complete all the "new" fields in the Upgrade Coding Definition dialog box. Make sure that you select the dictionary version you are upgrading to. ▪ If you upgraded a synonym list, make sure you select that one; otherwise, select the one you created. ▪ Select the **No Changes to Assignment Rules** option. 2 Create new assignment rules and make sure that they have the correct priorities. 3 Edit the existing assignment rules and their priorities, if needed.	• Upgrading a coding definition for impact analysis. • ***Adding an assignment rule*** (on page 190). • ***Viewing or editing the details of an assignment rule*** (on page 193). • ***Changing the order in which assignment rules are run*** (on page 194).
	To copy existing assignment rules: 1 Upgrade a coding definition. ▪ Select the **Copy assignment rules and use new coding definition** option in the Upgrade Coding Definition dialog box. 2 Edit the copy of assignment rules based on the set of verbatims you want coded with the new dictionary. 3 Make sure the assignment rules have the correct priorities. 4 Edit the original set of assignment rules, if needed.	• Upgrading a coding definition for impact analysis. • ***Viewing or editing the details of an assignment rule*** (on page 193). • ***Changing the order in which assignment rules are run*** (on page 194).

Scenario 1—Upgrading to a new dictionary version		
Step / Option	Tasks / Hints	See topic(s)
STEP 3: Run impact analysis		
Run impact analysis.	**To run impact analysis:** 1 In the Choose Source And Target Coding Definitions dialog box, enter the source and target coding definitions based on your entries in the Upgrade Coding Definitions dialog box. **Note:** Do not reverse the coding definitions. 2 In the Choose Source And Target Coding Definitions dialog box, select **Auto Reconcile Terms** if you do not want to consider any changes in terms on any level. You want the Central Coding application to autoreconcile the terms only and to require manual reconciliation of the codes only. The application autoreconciles the term, even if the **Requires Reconciliation** option is selected for an element on the Element Configuration page.	• *Running impact analysis* (on page 305).
STEP 4: Reconcile verbatims		
Reconcile verbatims.	**To reconcile the differences in the verbatims:** 1 On the In Process page, if there are items to be reconciled, the **Step** column displays **Reconcile** and the **Status** column displays **Not Started**. 2 Optionally, generate the Impact Analysis Report. 3 Update the changes.	• *Reconciling verbatims* (on page 310). • *Running the Impact Analysis Report* (on page 309). • *Saving the verbatim changes to the database* (on page 312).

Scenario 2—Previewing the results of impact analysis for a study

This scenario describes the steps to preview the results of impact analysis for a study.

Note: Perform these steps for each study for which you want to evaluate the impact of upgrading a dictionary.

- Step 1: Manage your synonyms.
  - Option 1—Upgrade your synonyms as part of the dictionary upgrade.
  - Option 2—Create a new synonym list for the loaded dictionary.
- Step 2: Decide what set of verbatims to upgrade.
  - Option 1—Update the complete set of verbatims for a coding definition.
  - Option 2—Create or copy a new set of assignment rules.
- Step 3: Run impact analysis.
- Step 4: Determine the impact to the study.

Scenario 2—Previewing the results of impact analysis		
Step / Option	Tasks / Hints	See topic(s)
STEP 1: Manage your synonyms		
Option 1—Upgrade your synonyms as part of the dictionary upgrade.	**To upgrade synonyms:** 1 Upgrade a synonym list. ▪ In the Upgrade Synonym List dialog box make sure that you select the dictionary you are upgrading to. ▪ Reconcile the synonyms, as needed. ▪ Optionally, generate the Synonym Reconciliation Report. 2 Update the changes.	• ***Upgrading a synonym list for impact analysis*** (on page 298). • ***Reconciling synonyms*** (on page 301). • ***Running the Synonym Reconciliation Report*** (on page 299). • ***Updating a synonym list*** (on page 303).
Option 2—Create a new synonym list for the loaded dictionary.	**To create a new synonym list:** • Create a new synonym list and add synonyms.	• Creating a synonym list and add synonyms to it.

Scenario 2—Previewing the results of impact analysis		
Step / Option	Tasks / Hints	See topic(s)
STEP 2: Decide what set of verbatims to upgrade		
Option 1—Update the complete set of verbatims for a coding definition.	**To update the complete set of verbatims:** • Upgrade a coding definition. ▪ Select a coding definition that is related to the dictionary to upgrade. ▪ Complete all the "new" fields in the Upgrade Coding Definition dialog box. Make sure that you select the dictionary version you are upgrading to. ▪ If you upgraded a synonym list, make sure you select that one; otherwise, select the one you created. ▪ Select the **Update assignment rules with new coding definition** option in the Upgrade Coding Definition dialog box.	• Upgrading a coding definition for impact analysis.

Scenario 2—Previewing the results of impact analysis		
Step / Option	**Tasks / Hints**	**See topic(s)**
Option 2—Create or copy a new set of assignment rules.	**To create a new set of assignment rules:** 1 Upgrade a coding definition. ▪ Select a coding definition that is related to the dictionary to upgrade. ▪ Complete all the "new" fields in the Upgrade Coding Definition dialog box. Make sure that you select the dictionary version you are upgrading to. ▪ If you upgraded a synonym list, make sure you select that one; otherwise, select the one you created. ▪ Select the **No Changes to Assignment Rules** option. 2 Create new assignment rules and make sure that they have the correct priorities. **Note:** In the assignment rules, include only the study that you want to see the impact on. 3 Edit the existing assignment rules and their priorities, if needed.	• Upgrading a coding definition for impact analysis. • ***Adding an assignment rule*** (on page 190). • ***Viewing or editing the details of an assignment rule*** (on page 193). • ***Changing the order in which assignment rules are run*** (on page 194).

<table>
<tr><th colspan="3">Scenario 2—Previewing the results of impact analysis</th></tr>
<tr><th>Step / Option</th><th>Tasks / Hints</th><th>See topic(s)</th></tr>
<tr><td></td><td>To copy existing assignment rules:
1 Upgrade a coding definition.
▪ Select the Copy assignment rules and use new coding definition option in the Upgrade Coding Definition dialog box.
2 Edit the copy of assignment rules based on the set of verbatims you want coded with the new dictionary.
Note: In the assignment rules, include only the study that you want to see the impact on.
3 Make sure the assignment rules have the correct priorities.
4 Edit the original set of assignment rules, if needed.</td><td>• Upgrading a coding definition for impact analysis.
• Viewing or editing the details of an assignment rule (on page 193).
• Changing the order in which assignment rules are run (on page 194).</td></tr>
<tr><th colspan="3">STEP 3: Run impact analysis</th></tr>
<tr><td>Run impact analysis.</td><td>To run impact analysis:
1 In the Choose Source And Target Coding Definitions dialog box, enter the source and target coding definitions based on your entries in the Upgrade Coding Definitions dialog box.
Note: Do not reverse the coding definitions.
2 In the Choose Source And Target Coding Definitions dialog box, select Auto Reconcile Terms if you do not want to consider any changes in terms on any level. You want the Central Coding application to autoreconcile the terms only and to require manual reconciliation of the codes only. The application autoreconciles the term, even if the Requires Reconciliation option is selected for an element on the Element Configuration page.</td><td>• Running impact analysis (on page 305).</td></tr>
</table>

Scenario 2—Previewing the results of impact analysis		
Step / Option	**Tasks / Hints**	**See topic(s)**
STEP 4: Determine the impact to the study		
Determine the impact on the study.	**To determine the impact on a study:** 1 On the In Process page, if there are items to be reconciled, the **Step** column displays **Reconcile** and the **Status** column displays **Not Started**. 2 Generate the Impact Analysis Report. 3 Save, view, print, or export the Impact Analysis report data. 4 If you do not want to apply the changes to the study at this time, on the In Process page, select the coding definition set and then select the **Cancel** action from the **Actions** menu. **Note:** This deletes the report from the database. 5 Repeat as needed for each study.	• *Running the Impact Analysis Report* (on page 309). • *Exporting impact analysis data* (on page 306).

Scenario 3—Reassigning verbatims for the same version of the dictionary

This scenario describes the steps to reassign the verbatims assigned to work teams. For example, use these steps if you want to assign a particular site to a different work team.

- Step 1: Manage your assignment rules (an administrator makes this decision).
  - Option 1—Create a new set of assignment rules.
  - Option 2—Copy and edit existing assignment rules.
- Step 2: Run impact analysis.
- Step 3: Reassign the requests.

> **Note:** **In this case, you will still be coding verbatims with the same version of the dictionary and the same synonym list, stopword list, and algorithm.**

Scenario 3—Reassigning verbatims		
Step	Tasks / Hints	See topic(s)
STEP 1: Manage your assignment rules		
Option 1—Create a new set of assignment rules.	**To create new assignment rules:** 1 Upgrade a coding definition. ▪ Select the coding definition that was used to code the verbatims that you want to reassign. ▪ Complete all fields in the Upgrade Coding Definition dialog box. ▪ All values should remain the same except for the Coding Definition Name. ▪ Select the **No changes to assignment rules** option in the Upgrade Coding Definition dialog box. 2 Create new assignment rules and make sure that they have the correct priorities. 3 Edit the existing assignment rules and their priorities, if needed.	• Upgrading a coding definition for impact analysis. • ***Adding an assignment rule*** (on page 190). • ***Changing the order in which assignment rules are run*** (on page 194). • ***Viewing or editing the details of an assignment rule*** (on page 193).

Scenario 3—Reassigning verbatims		
Step	**Tasks / Hints**	**See topic(s)**
Option 2—Copy and edit existing assignment rules.	**To copy existing assignment rules:** 1 Upgrade a coding definition. ▪ Select the **Copy existing assignment rules to new coding definition** option in the Upgrade Coding Definition dialog box. 2 Edit the copy of assignment rules based on how you want to reassign the verbatims. 3 Change the priority of the assignment rules so that they run before the original set so that they become active. 4 Edit the original set of assignment rules, if needed.	• Upgrading a coding definition for impact analysis. • *Viewing or editing the details of an assignment rule* (on page 193). • *Changing the order in which assignment rules are run* (on page 194).
STEP 2: Run impact analysis		
Run impact analysis.	**To run impact analysis:** • In the Choose Source And Target Coding Definitions dialog box, enter the source and target coding definitions based on your entries in the Upgrade Coding Definitions dialog box. **Note:** Do not reverse the coding definitions.	• *Running impact analysis* (on page 305).
STEP 3: Reassign the requests		
Reassign the requests.	**To update the changes and reassign the requests**: • On the In Process page, the **Step** column displays **Update** and the **Status** column displays **Not Started**. **Note:** Typically, because the upgrade was to the same dictionary, there is nothing to reconcile. However, there may be items to reconcile depending on the reconciliation options.	• *Reconciling verbatims* (on page 310). • *Saving the verbatim changes to the database* (on page 312).

Scenario 4—Changing a coding definition for a set of verbatims for the same version of the dictionary

This scenario describes the steps to change the synonym list, stopword list, or coding algorithm for a set of verbatims in a coding definition for the same version of the dictionary.

- Step 1: Create a new coding definition.
- Step 2: Run impact analysis.
- Step 3: Reconcile the verbatims.

Note: In this case, you will still be coding verbatims with the same version of the dictionary.

Scenario 4—Changing a coding definition for a set of verbatims		
Step	Tasks / Hints	See topic(s)
STEP 1: Create a new coding definition		
Create a new coding definition.	**To create a new coding definition:** 1 Create a new coding definition with the synonym list, stopword list, and algorithm that you want to use for the verbatim set. **Note:** The dictionary type, version, and culture must be the same as the one where the verbatims originate from. 2 Create new assignment rules and make sure that they have the correct priorities. 3 Edit the existing assignment rules and their priorities, if needed.	• *Adding a coding definition* (on page 182). • *Adding an assignment rule* (on page 190). • *Changing the order in which assignment rules are run* (on page 194). • *Viewing or editing the details of an assignment rule* (on page 193).
STEP 2: Run impact analysis		
Run impact analysis.	**To run impact analysis:** • In the Choose Source And Target Coding Definition dialog box, enter the source and target coding definitions.	• *Running impact analysis* (on page 305).

Scenario 4—Changing a coding definition for a set of verbatims		
Step	Tasks / Hints	See topic(s)
STEP 3: Reconcile the verbatims		
Reconcile the verbatims.	**To reconcile the verbatims and approve the changes:** • On the In Process page, if there are items to be reconciled, the **Step** column displays **Reconcile** and the **Status** column displays **Not Started**. If there are no items to reconcile, the **Step** column displays **Update** and the **Status** column displays **Not Started**. • Optionally, generate the Impact Analysis Report. • Update the changes (save the changes to the database).	• *Reconciling verbatims* (on page 310). • *Running the Impact Analysis Report* (on page 309). • *Saving the verbatim changes to the database* (on page 312).

Dictionary versions

Viewing the list of source and target dictionaries

Use this procedure to view the complete list of source and target dictionary versions that have been compared. This list includes the dictionary type, the source and target dictionary versions, the dictionary culture, and the status of the comparison.

> **Note:** The *source* dictionary is the dictionary the study has been coded to. The *target* dictionary is the dictionary you want to upgrade the study to.

1 Select **Coding Setup > Dictionaries**.

The Dictionaries page appears.

2 Select **Actions > View Dictionary Changes**.

The Dictionary Changes page appears. For a description of the fields on this page, see ***Dictionary Changes page*** (on page 400).

Selecting two dictionary versions to compare

> **Note:** Make sure that the two versions of the dictionary are installed and that the new dictionary has the same culture as the original dictionary.

1 Select **Coding Setup > Dictionaries**.

The Dictionaries page appears.

2 Select **Actions > View Dictionary Changes**.

The Dictionary Changes page appears. For a description of the fields on this page, see ***Dictionary Changes page*** (on page 400).

3 Select **Actions > New**.

or

Click **New**.

The Dictionary Selection dialog box appears. For a description of the fields on this page, see ***Dictionary Selection dialog box*** (on page 401).

4 In the **Old Dictionary** field, select the dictionary and version of the source (original) dictionary that you want to compare against a target (new) dictionary.

5 In the **New Dictionary** field, select the dictionary and version of the target (new) dictionary that you want to compare to the original version.

6 Click **OK**.

The Dictionary Changes page appears.

A job runs and the Central Coding application starts comparing the dictionary versions. This may take several minutes.

> **Note:** The job must complete before you can view the changes.

Viewing the term changes between two dictionary versions

There are three types of term changes: Add, Delete or non-current, and Update (the term itself can have changed, but the associated code remains the same in both versions). You can filter the list of changes to view each type of change.

1. Select **Coding Setup > Dictionaries**.

   The Dictionaries page appears.

2. Select **Actions > View Dictionary Changes**.

   The Dictionary Changes page appears.

3. Select a dictionary version set.

4. Select **Actions > View Term Changes**.

   or

   Click the **View Term Changes** button.

   The Term Changes page appears. For a description of the fields on this page, see ***Term Changes page*** (on page 402).

5. Optionally, filter the list of term changes to identify the items that you want to view.

   You can do any or all of the following:

   - In the **Level** filter field, select the dictionary level for which you want to view the changes.

     For MedDRA or MedDRA-J, the options are:

     - **No selection**—No filter; displays all options.
     - System Organ Class
     - High Level Group Term
     - High Level Term
     - Preferred Term
     - Low Level Term

     For WHO-DD, the options are:

- **No selection**—No filter; displays all options.
- ATC1
- ATC2
- ATC3
- ATC4
- Preferred Name
- Trade Name
- Medicinal Product

For JDrug, the options are:

- **No selection**—No filter; displays all options.
- TC1
- TC2
- TC3
- TC4
- Generic Name
- Trade Name
- Case Name

- In the **Change** filter field, select the type of term change that you want to view.

  For MedDRA or MedDRA-J, the options are:

  - **No selection**—No filter; displays all options.
  - **Add**—Displays only the terms that have been added to the dictionary.
  - **Delete or Non-current**—Displays only the terms that have been deleted from the dictionary or displays only the terms that are non-current (valid for LLT only).
  - **Update**—Displays only the terms that have been changed in the dictionary but use the same code.

  For WHO-DD or JDrug, the options are:

  - **No selection**—No filter; displays all options.
  - **Add**—Displays only the terms that have been added to the dictionary.
  - **Delete**—Displays only the terms that have been deleted from the dictionary.
  - **Update**—Displays only the terms that have been changed in the dictionary but use the same code.

Exporting the dictionary term changes

Use this procedure to export the term changes to a comma separated value (CSV) file so that you can view it as a Microsoft Excel spreadsheet software file within the browser, or so that you can save it.

1 Select **Coding Setup > Dictionaries**.

The Dictionaries page appears.

2 Select **Actions > View Dictionary Changes**.

The Dictionary Changes page appears.

3 Select a dictionary set.

4 Select **Actions > View Term Changes**.

or

Click the **View Term Changes** button.

The Term Changes page appears. For a description of the fields on this page, see ***Term Changes page*** (on page 402).

5 Select **Actions** > **Export**.

The Export Result Viewer—Term changes page appears with a Windows File Download dialog box. For a description of the fields on this page, see ***Export Result Viewer—Term changes page*** (on page 405).

6 Click **Open**.

The Microsoft Excel spreadsheet software opens and the term changes display; the file is in CSV format.

or

Click **Save.**

The Windows Save As dialog box appears, from which you can save the file in CSV format.

Viewing the path changes between two dictionary versions

There are two major types of path changes. For any primary autocode target term, a path that exists in the old dictionary version can be deleted in the new version. A path can be added to the new version.

In the MedDRA dictionaries, a term can have a new primary path, or the term hierarchy can change but the primary paths remains the same. For a selected term that has a path change, the Central Coding application displays three different sections of paths for old, new, and unchanged paths. For the MedDRA dictionaries there is an additional notation to mark the primary path.

1 Select **Coding Setup > Dictionaries**.

The Dictionaries page appears.

2 Select **Actions > View Dictionary Changes**.

The Dictionary Changes page appears.

3 Select a dictionary set.

4 Select **Actions > View Path Changes**.

or

Click the **View Path Changes** button.

The Path Changes page appears. For a description of the fields on this page, see ***Path Changes page*** (on page 406).

5 Optionally, filter the list of path changes to identify the items that you want to view.

- In the **Level** filter field, select the dictionary level for which you want to view the changes.

  > **Note:** The filter options are the primary autocode target levels set for the dictionary.

  For MedDRA or MedDRA-J, the options are:

  - **No selection**—No filter; displays all options.
  - Preferred Term
  - Low Level Term

  For WHO-DD, the options are:

  - **No selection**—No filter; displays all options.
  - Trade Name
  - Medicinal Product

  For JDrug, the options are:

  - **No selection**—No filter; displays all options.
  - Generic Name
  - Trade Name
  - Case Name

6 Optionally, view the details of the path changes.

- Click the **View Path Changes** link in the **Path Changes** column.

  or

  Click the **View Path Changes Details** button.

  The View Path Changes Details dialog box appears. For a description of the fields on this page, see ***View Path Changes Details dialog box*** (on page 407).

Exporting the dictionary path changes

Use this procedure to export the path changes to a comma separated value (CSV) file so that you can view it as a Microsoft Excel spreadsheet software file within the browser, or so that you can save it.

1 Select **Coding Setup > Dictionaries**.

The Dictionaries page appears.

2 Select **Actions > View Dictionary Changes**.

The Dictionary Changes page appears.

3 Select a dictionary set.

4 Select **Actions > View Path Changes**.

or

Click the **View Path Changes** button.

The Path Changes page appears. For a description of the fields on this page, see ***Path Changes page*** (on page 406).

5 Select **Actions** > **Export**.

The **Export Result Viewer—Path changes** page appears with a Windows File Download dialog box. For a description of the fields on this page, see ***Export Result Viewer—Path changes page*** (on page 407).

6 Click **Open**.

The Microsoft Excel spreadsheet software opens and the path changes display; the file is in CSV format.

or

Click **Save.**

The Windows **Save As** dialog box appears, from which you can save the file in CSV format.

Rerunning a dictionary comparison

Note: You can rerun a dictionary comparison only when the Status on the Dictionary Changes page is Failed.

1 Select **Coding Setup > Dictionaries**.

The Dictionaries page appears.

2 Select **Actions > View Dictionary Changes**.

The Dictionary Changes page appears.

3 Select a dictionary set.

4 Select **Actions > Rerun**.

Deleting a source and target dictionary set

1. Select **Coding Setup > Dictionaries**.

   The Dictionaries page appears.

2. Select **Actions > View Dictionary Changes**.

   The Dictionary Changes page appears.

3. Select a dictionary set.

4. Select **Actions > Delete**.

   A confirmation dialog box appears.

APPENDIX D

Verifying and updating codes

In this appendix

Verifying and updating codes after changing a dictionary

Use this procedure to verify and update the codes for all coded requests against a new dictionary. An administrator typically performs this task, which requires the EditCodingDefs right.

> **Note:** This action updates the codes for both undelivered coding requests and for coding requests that have been delivered to the InForm application.
>
> **Caution:** This action affects all coding requests for every study associated with the selected coding definition(s).

1 Unlock any studies marked as locked in the Central Coding application.

For more information, see ***Locking a study in the Central Coding application*** (on page 211).

> **Caution:** The Verify and Update Codes action affects all coding requests regardless of whether they are associated with studies marked as locked or unlocked in the Central Coding application. You must unlock all studies in the Central Coding application so that any items whose coding cannot be automatically updated can be manually recoded. Only requests associated with studies that are marked as unlocked in the Central Coding application are visible to coders and approvers on the Coding Requests and Approvals pages, and therefore available to be recoded.

2 Select **Coding Setup > Coding Definitions**.

The Coding Definitions page appears.

3 Select one or more coding definitions.

4 Select **Actions > Verify and Update Codes**.

The Central Coding application reviews the codings for all coded requests against the new dictionary.

- If the code, term, and path are current in the new dictionary, the coding request remains coded and its coding status does not change.
- If the code, term, and path are not current in the new dictionary, the Central Coding application attempts to autocode the request to find a new code match.
    - If the autocode succeeds, the system updates the request with the new coding. The request remains coded and its coding status does not change.
    - If the autocode fails, the system changes the coding status of the request to **Uncoded ( )** and returns it to the coder's queue.

> **Note:** Changes are tracked in the audit history.

Generating the Verify Codes Report for viewing

Use this procedure to generate the Verify Codes Report so that you can view the results of updating the codes for all coded requests against a new dictionary. For more information, see *Verifying and updating codes after changing a dictionary* (on page 582).

The report provides the verbatim; study name (host); subject ID; item type; previous and updated dictionary levels, codes, and terms; and count of the total number of updated requests.

> **Note:** The Central Coding application automatically generates the data for the Verify Codes Report when it updates the codes for all coded requests against a new dictionary. For more information, see *Verifying and updating codes after changing a dictionary* (on page 582).

1 Select **Coding Setup > Coding Definitions**.

The Coding Definitions page appears.

2 Select one or more coding definitions.

3 Make sure that you have run the **Verify and Update Codes** action.

> **Note:** If you have not run the verify and update codes action, data is not available to generate the report. For more information, see *Verifying and updating codes after changing a dictionary* (on page 582).

4 Select **Actions > View Verify and Update Job Log**.

- The View Job Log page appears.

  For a description of the fields on this page, see *View Job Log page* (on page 499).

- The system generates the Verify Codes Report.

  To view the report in PDF format, see *Viewing the Verify Codes Report* (on page 583).

Viewing the Verify Codes Report

> **Note:** The Central Coding application automatically generates the data for the Verify Codes Report when it updates the codes for all coded requests against a new dictionary. For more information, see *Verifying and updating codes after changing a dictionary* (on page 582).

1 Select **Reports**.

The Report Requests page appears. For a description of the fields on this page, see *Report Requests page* (on page 369).

2 Optionally, filter the list of requests to identify the items that you want to view, and click **Apply**.

You can do any or all of the following:

- In the **Report Type** filter field, select **Verify Codes Report**.
- In the **Status** filter field, select **Produced**.

3 Select a report.

4 Select **Actions > View Results**.

or

Click **View Results**.

or

Click the **Results Exist** ( ) icon.

The Verify Codes Report appears in PDF format in the Document Viewer page. The report provides the verbatim; study name (host); subject ID; item type; previous and updated dictionary levels, codes, and terms; and count of the total number of updated requests.

Glossary

A

adapter

A web services interface that supports the secure transfer of data between the InForm application and the Central Coding application.

administrator

A user with rights to perform system setup and maintenance tasks.

approver

An end user with rights to examine coded requests and to approve or disapprove the code, or mark a request as needing further action.

ASAP job queue

A job queue that includes the get verbatims jobs or return codes jobs for studies that are not included in the Get Verbatims or Return Codes job schedules. There is one ASAP job queue for each get verbatims or return codes job that you manually run for a study.

assignment rule

A set of criteria that defines how incoming coding requests are routed in the Central Coding application. Assignment rules are used in conjunction with coding definitions and work teams to provide a high level of control over the Central Coding request-processing workflow.

ATC (Anatomical Therapeutic Chemical)

A classification level in the WHO-DD dictionary.

autocode target

See ***primary autocode target*** (on page 587), ***secondary autocode target*** (on page 587).

autocoding

A type of coding that uses an algorithm to select an appropriate code value for a term. Also called *automatic coding*.

See also ***interactive coding*** (on page 586).

automatic coding

See ***autocoding*** (on page 585).

auto-suggestion

A manually selected unique coding response for requests with the same verbatim, coding definition, and context information that maps to a dictionary path. Auto-suggestions are shared among all verbatims using the same coding definition and context information. Auto-suggestions are not shared across multiple coding definitions.

B

browse method

A type of interactive coding that allows you to examine the target coding dictionary, from level to level, and select relevant terms. When you find an appropriate term, you can apply the term and code to the verbatim.

See also ***search method*** (on page 587).

C

Central Coding query

A query that you manually generate from the Central Coding application to mark that a coding request requires additional information before it can be coded. A Central Coding query is not sent to the InForm application.

See also ***InForm query*** (on page 586), ***query*** (on page 587).

code

A unique numerical value that identifies a term in a coding dictionary. The format is dependent on the coding dictionary.

coder

An end user with rights to perform coding tasks.

coding

The process of mapping a standardized term and code from a given level of a standard coding dictionary to a verbatim.

See also ***autocoding*** (on page 585), ***interactive coding*** (on page 586).

coding algorithm

The sequence of steps the Central Coding application performs to determine the most appropriate match for a term during autocoding. A coding algorithm is one of the items in a coding definition.

coding browser

A system component that allows you to code events, diseases, drugs, and other items by matching entered terms against the terminology in industry-standard or custom coding dictionaries.

coding definition

A set of information that is used in conjunction with assignment rules to control the Central Coding application request-processing workflow, and to make sure that requests are coded correctly. A coding definition is associated with a coding dictionary and consists of a synonym list, stopword list, and coding algorithm.

coding dictionary

A standardized collection of terms and the codes that correspond to those terms. The Central Coding application supports the following standard coding dictionaries: MedDRA, MedDRA-J, WHO-DD, and JDrug.

coding request

A data item from the source application that requires coding.

context information

Information from the source application such as the indication and route of administration for drugs. Context information is a type of key item, and is an element in the dictionary type XML file.

See also ***key item*** (on page 587).

G

Get Verbatims job queue

A job queue that includes the get verbatims jobs for all studies included in the Get Verbatims job schedule when the schedule runs. There is one Get Verbatims job queue for each adapter and its associated studies.

I

InForm query

A query that you manually generate from the Central Coding application to the InForm application to request additional information or clarification about a request.

See also ***Central Coding query*** (on page 585), ***query*** (on page 587).

interactive coding

A type of coding that you perform manually using the coding browser to select a code value for a term.

See also ***autocoding*** (on page 585).

internationalization

The ability to support Japanese dictionaries, Japanese operating systems, and multi-lingual studies.

J

JDrug

Data File for Ethical Drugs (Coding Table) from Iyaku-Joho-Kenkyujo, Inc. A comprehensive dictionary of medicinal product information that is used for identifying drug names, their active ingredients, and therapeutic uses.

job queue

A container for all the requests associated with running scheduled or non-scheduled (manual) jobs. There are three types of job queues: Get Verbatims, Return Codes, and ASAP.

job schedule

A user-defined timetable that specifies when the Central Coding application gets data from, and returns data to, the InForm application.

K

key item

A piece of data from the source application that is not a verbatim.

See also ***context information*** (on page 586).

M

MedDRA (Medical Dictionary for Regulatory Activities)

A standardized dictionary of medical terminology used to support the classification and communication of medical information throughout the medical product regulatory cycle. MedDRA-J is the Japanese version of MedDRA.

P

partially coded

When coding to a primary autocode target and a secondary autocode target, the application found a single match for the primary target and multiple matches for the secondary target. You must manually select the code you want to use.

There are no secondary autocode targets for the JDrug dictionary. Therefore, verbatims being coded against the JDrug dictionary cannot be partially coded.

primary autocode target

The term level in the coding dictionary to autocode the verbatim against, such as the MedDRA preferred term level or ATC level 2. Also called *autocode target*.

primary path

The main path for terms that are represented in the MedDRA dictionary in more than one SOC. The concept of a primary path is supported only by MedDRA; it is not supported by WHO-DD, JDrug, or custom dictionaries.

Q

query

An indicator in the Central Coding user interface that is associated with a coding request for which more information is required to code the request. There are two types of queries: Central Coding and InForm.

R

Return Codes job queue

A queue that includes the return codes jobs for all studies included in the Return Codes job schedule when the schedule runs. There is one Return Codes job queue for each adapter and its associated studies.

right

A privilege that identifies a feature to which a user has access. Rights control the pages that appear in the user interface and the actions available on each page.

role

A named collection of rights.

S

search method

A type of interactive coding that allows you to search selected fields in a coding dictionary for text that begins with or contains the verbatim text.

secondary autocode target

The term level in the coding dictionary that is higher than the primary autocode target. The Central Coding application uses the secondary target to find all the secondary nodes that the primary autocode node connects to. Also called *secondary target*.

stopword

A word in verbatim text that can be discarded during autocoding because it does not add significant meaning to the description of a term. Using stopwords increases the chance that the autocoding algorithm will find a code match for a verbatim.

stopword list

A group of stopwords. Stopwords can exist only within a stopword list. A stopword list is one of the items in a coding definition.

synonym

A word or phrase that is equivalent to the classification-level term associated with a code in a coding dictionary. Using synonyms increases the chance that the autocoding algorithm will find a code match for a verbatim.

synonym list

A group of synonyms. Synonyms can only exist within a synonym list. A synonym list is one of the items in a coding definition.

T

term

The word or phrase in a coding dictionary that is associated with a code.

U

user

A person who works with the Central Coding application through the user interface.

V

verbatim

The original reported text that describes the adverse event, disease, drug, or other item to be coded.

W

WHO-DD (World Health Organization Drug Dictionary)

A comprehensive dictionary of medicinal product information that is used for identifying drug names, their active ingredients, and therapeutic uses.

work team

A set of users that you organize and group by function for the purpose of performing tasks.

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