Installation Guide

Oracle® Health Sciences Central Coding
Release 3.0.3
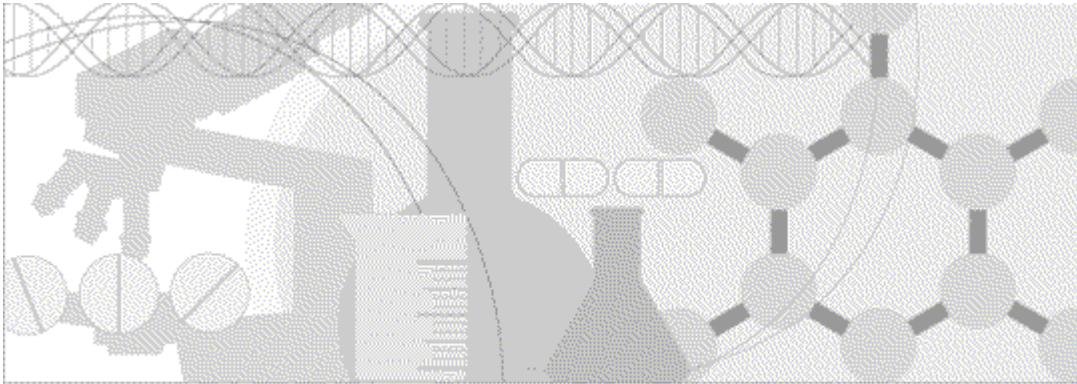
ORACLE®

Part Number: E48424-01

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About this guide

In this preface

Overview of this guide

This guide provides an architectural overview of the Central Coding application; step-by-step instructions for installing, upgrading, and uninstalling the Central Coding software; descriptions of system functions; and 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.

If you are integrating with the InForm application, the InForm Adapter software must also be installed. The Central Coding software uses the InForm Adapter software to control communication between Central Coding servers and InForm studies. For more information, see the InForm Adapter *Installation Guide*.

Audience

This guide is for IT administrators and others who are responsible for installing and uninstalling the Central Coding software and the coding dictionaries, and for users responsible for integrating the Central Coding application with the Clintrial or InForm applications.

Related information

Documentation

The Central Coding 3.0 .3 documentation includes the following items. All documentation is available from the Oracle Software Delivery Cloud (https://edelivery.oracle.com) and the Download Center (https://extranet.phaseforward.com).

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.
	Note: The most current list of known issues is available on the Phase Forward Extranet.
	To sign in to the Extranet, go to https://extranet.phaseforward.com and click **Customer Login**. Enter your email address and password, and navigate to the **Known Issues** section. Select a product, and then enter your search criteria.
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.
	This document is also available from the Documentation CD.
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.
	This document is also available from the Documentation CD and the Central Coding user interface.

Title	Description
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.
	This document is also available from the Documentation CD.
Page-level Help	The page-level Help describes the function(s) and fields for each page in the user interface.
	This document is also available from the Central Coding 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.

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.

C H A P T E R   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.

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.

Architectural overview

The Central Coding software is built on a Microsoft .NET and Oracle platform. It uses web services over a network for the transmission of coding requests and responses, and uses Internet Information Services (IIS) to provide its web-based user interface to the coding team, so they can provide coding services through the Internet.

The Central Coding software requires a database server and one or more application servers. This architecture provides for flexibility and scalability, allowing you to configure the web server, application server, and database server layers independently. You can add web and application servers to meet increased demand. In all configurations, you access the Central Coding software on the application server through HTTP sessions from Windows clients using Internet Explorer. Each Central Coding application server runs on a Windows server, which uses the Oracle client with the Oracle Data Provider for .NET interface with an Oracle database server.

- **Central Coding and Clintrial integration**—The two applications communicate through a web service that is configured using the Clintrial application. This integration does not require an adapter. For more information, see the Clintrial *Admin & Design* guide.

  The Clintrial application initiates all communication to and from the Central Coding application.

- **Central Coding and InForm integration**—The Central Coding software uses the InForm Adapter software to control communication between Central Coding servers and InForm studies.

  The Central Coding application initiates all communication to and from the InForm application.
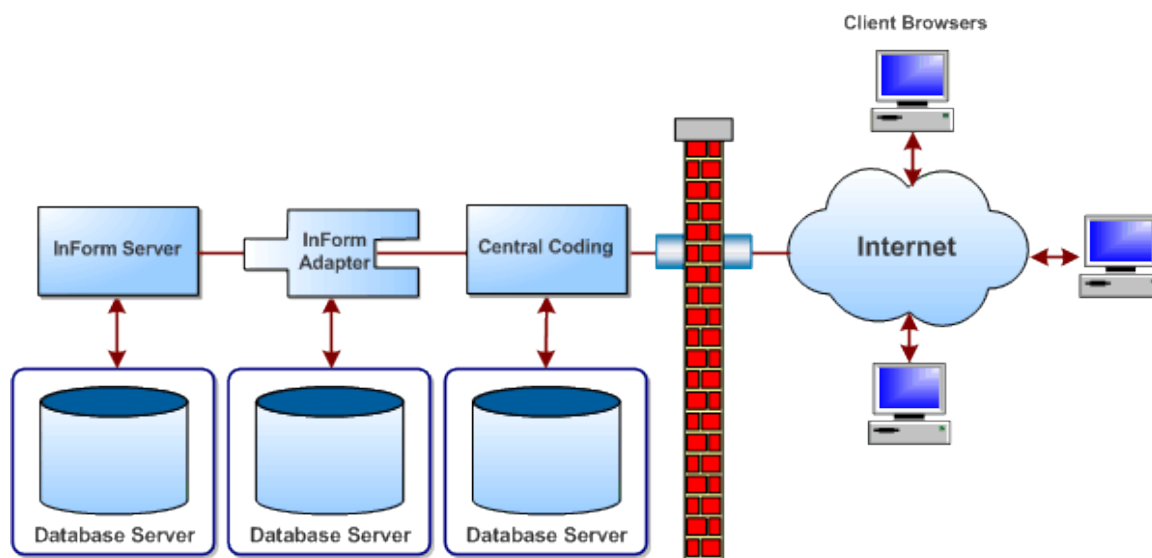
Physical configuration options

- **Central Coding and Clintrial integration**—The Clintrial software must be installed on a different machine than any of the Central Coding application servers.

- **Central Coding and InForm integration**—The InForm software and the InForm Adapter software must be installed on different machines than any of the Central Coding application servers. The InForm Adapter software can be installed on the same machine as the InForm software or on its own machine.

Single application server configurations

The single application server configurations are:

- The Central Coding application server and database server running on the same machine.

- The Central Coding application server running on one machine and the database server running on a separate machine.

  In a production environment, Oracle recommends running the Central Coding application server and database server on separate machines. This configuration allows more flexibility, scalability, and performance; is easier to manage and troubleshoot; and is easier to expand in the future by adding additional application servers.

Multiple application server configurations

The multiple application server configurations are:

- Multiple Central Coding application servers and the database server on the same machine.

- Multiple Central Coding application servers on one machine and the database server on a different machine.

- Multiple Central Coding application servers on different machines and the database server on a different machine.

  This configuration might be practical, for example, if you want to use the Central Coding application across different geographic regions.

You can configure application servers as logical entities, allowing multiple application servers to co-exist on the same machine. Application servers can map to either:

- Unique database instances, each of which has its own dictionaries.

- A single database instance that shares dictionaries.

In multiple application server environments, each application server has its own:

- URL

- Job scheduler

Deployment scenarios

About integrating with the Clintrial or InForm application

The Central Coding application supports integration with the InForm application and the Clintrial application at the same time under the following circumstances:

- One of the following is true:

    - The InForm application, Clintrial application, and Central Coding application are behind the same firewall.

    - The InForm application, Clintrial application, and Central Coding application are not behind the same firewall, but a VPN is used between the Central Coding application and the Clintrial application.

- The Clintrial software must be installed on a different machine than any of the Central Coding application servers.

- The InForm software and the InForm Adapter software must be installed on different machines than any of the Central Coding application servers. The InForm Adapter software can be installed on the same machine as the InForm software or on its own machine.

To determine the hardware and software requirements for using the Central Coding application with another application via the Services Interface (API), consult your Oracle Services representative.

Central Coding and Clintrial application components

The Central Coding and Clintrial applications must be hosted at the customer site behind the customer firewall. As a result, additional security features are not needed.

Central Coding and InForm application components

The Central Coding application components can be deployed with or without enabling security.

All InForm and Central Coding components behind a firewall

When integrating with the InForm application, the application servers for all the software components in the Central Coding environment can be behind a firewall. This is the typical scenario when Oracle hosts all the applications.
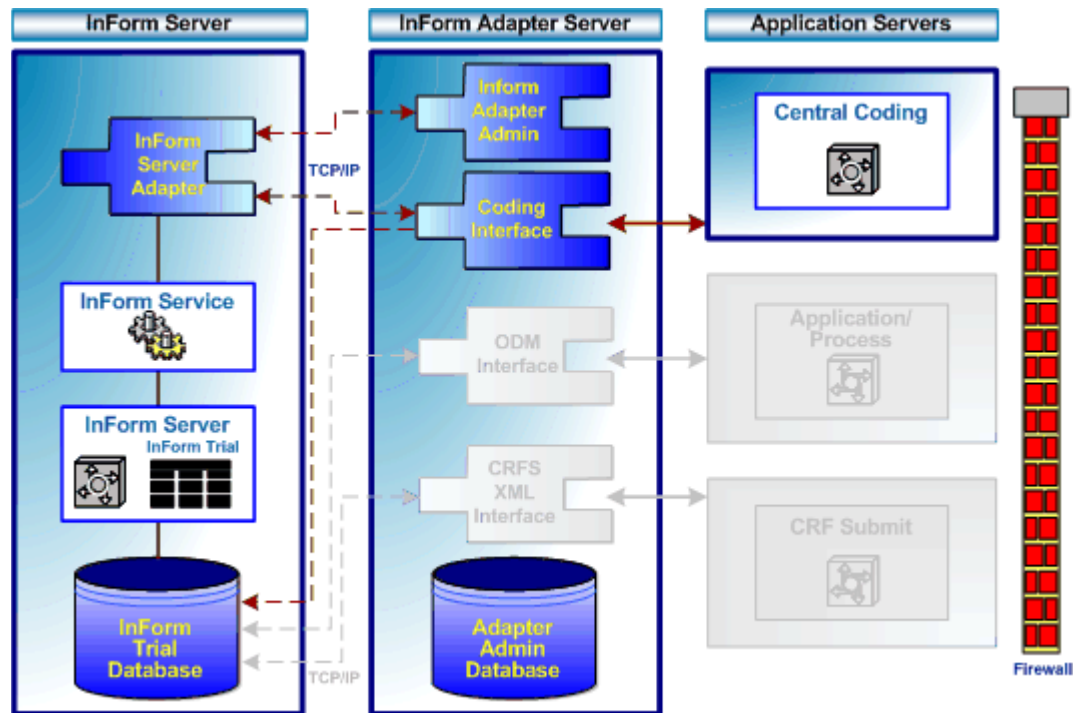
Central Coding server(s) outside a firewall

When integrating with the InForm application, the application servers for the InForm and InForm Adapter software components can be behind a firewall, while the Central Coding server(s) are outside the firewall. This is the typical scenario when Oracle hosts the InForm servers and a customer hosts its own Central Coding application server(s).
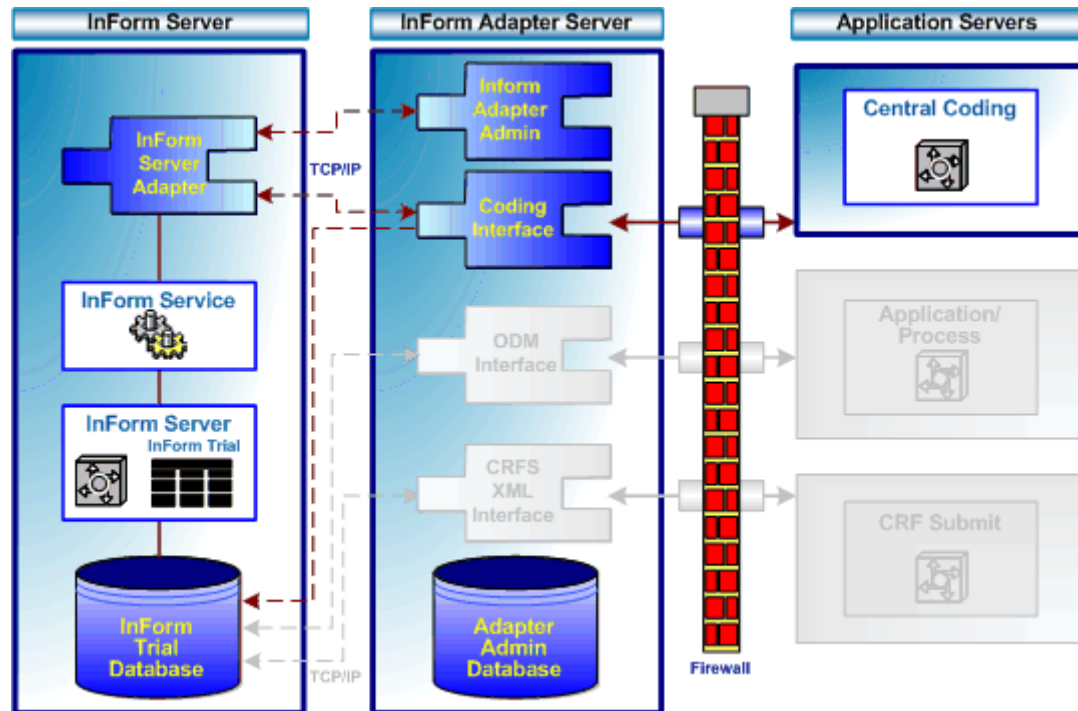
C H A P T E R 2

Planning your Central Coding installation

In this chapter

About the Central Coding 3.0.3 release

The Central Coding 3.0.3 release includes the following components:

- Central Coding 3.0.3 product.

- Central Coding 3.0.3 documentation.

- InForm Adapter product and documentation.

Before beginning the installation, check the Oracle Software Delivery Cloud (https://edelivery.oracle.com) for the latest patchsets and patches, as well as the accompanying *Release Notes* and *Known Issues* documents, and the latest versions of the documentation.

InForm Adapter product and documentation

To use the Central Coding software with the InForm application, the InForm Adapter software must also be installed and configured. For more information, see the InForm Adapter *Installation Guide*.

Prerequisites

Set the regional language option on the client and application servers—English operating systems only

You must set the regional language option on the client server(s) and the application server where you install the Central Coding software if you are going to perform a fresh installation on an English operating system and you want to support both English and Japanese verbatims.

1   Select **Start > Settings > Control Panel > Regional and Language options**.

The Regional and Language Options dialog box appears. The **Regional Options** tab appears by default.

2   Click the **Languages** tab.

3   In the **Supplemental language support** group box, select **Install files for East Asian languages**, and click **OK**.

Rename the dictionary file for the JDrug dictionary

The Dictionary Loader tool does not recognize Japanese file names. Therefore, you must rename the JDrug dictionary file so that the Dictionary Loader can recognize the file name and load the dictionary.

•   Rename, or copy and rename, the JDrug dictionary file (全件.txt) to **all_cases.txt**.

> **Note:** Make sure that this file is in a local directory with only English names in its path.

For instructions on loading the coding dictionaries, see *Loading and managing the coding dictionaries* (on page 55).

Checklist: Setup tasks for integrating the Central Coding and Clintrial applications

To integrate the Central Coding and Clintrial applications, perform the following tasks using the Clintrial application before you install the Central Coding 3.0.3 software.

Checklist: Setup tasks for integrating the Central Coding and Clintrial applications		
☑	Task	For details, see...
❑ 1	Install the Clintrial software.	Clintrial *Getting Started* guide.
		Note: The Clintrial software must be installed on a different machine than any of the Central Coding application servers.
❑ 2	Configure network or Internet access to the Central Coding application server.	Clintrial *Getting Started* guide.
❑ 3	Configure the CC_HOST parameter with the HTTP address of the Central Coding interface.	Clintrial *Admin & Design* guide.
		This may be set in the Clintrial Admin module as a System or Protocol parameter.
❑ 4	Set the USE_CENTRAL_CODING parameter to Yes for the target protocol.	Clintrial *Admin & Design* guide.
		This may be set in the Clintrial Admin module as a System or Protocol parameter.
❑ 5	Create a new dictionary definition.	Clintrial *Manage, Classify & Lab Loader* guide.
❑ 6	Define labels for the dictionary definition.	Clintrial *Manage, Classify & Lab Loader* guide.
❑ 7	Select a dictionary definition for an item in a panel.	Clintrial *Admin & Design* guide.
❑ 8	Create a Central Coding encoding target.	Clintrial *Manage, Classify & Lab Loader* guide.
❑ 9	Map the target items with the defined labels.	Clintrial *Manage, Classify & Lab Loader* guide.
❑ 10	Use the Clintrial Manage module to send coding requests (define the delivery schedule) to the Central Coding application.	Clintrial *Admin & Design* guide.

Checklist: Setup tasks for integrating the Central Coding and InForm applications

To integrate the Central Coding and InForm applications, perform the following tasks before you install the Central Coding 3.0.3 software.

Checklist: Setup tasks for integrating the Central Coding and InForm applications	
☑ Task	For details, see...
Install the applications	
❑ 1 Install the Central Designer software.	Central Designer *Installation Guide*.
❑ 2 Install the InForm software.	InForm *Installation Guide*. **Note:** Set up the InForm Adapter to accept data securely.
❑ 3 Install the InForm Adapter software.	InForm Adapter *Installation Guide*. **Note:** Set up the InForm Adapter to accept data securely.
Note: The InForm software and the InForm Adapter software must be installed on different machines than any of the Central Coding application servers.	
Perform this step on the InForm application server	
❑ 4 Install the InForm Server Adapter Interface (ISA).	InForm Adapter *Installation Guide*.
Perform these steps on the InForm Adapter server	
❑ 5 Install the Coding interface.	InForm Adapter *Installation Guide*.
❑ 6 Manually add studies.	InForm Adapter *Installation Guide*.
❑ 7 Set up one or more InForm studies.	Specify mappings and add InForm users for use with the Central Coding application. For integration with the InForm 5.0 release or later, see the *Study and Reporting Setup Guide*. For integration with releases prior to the InForm 5.0 release, see the *Installation and Configuration* guide. For more information, see ***About setting up InForm studies for use with the Central Coding application*** (on page 16) and ***About mapping data for coding with the Central Coding application*** (on page 17).

About setting up InForm studies for use with the Central Coding application

To set up one or more InForm studies for use with the Central Coding application, perform the steps listed in the following table.

Checklist: Setting up InForm studies for use with the Central Coding application	
☑ Task	Description
Perform these tasks using the InForm application	
❑ 1 Specify a valid InForm user whose credentials can be used by the Central Coding application to access the InForm application.	Enter a valid InForm user name and password on the System Configuration > Get/Put Job Options page. 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.
❑ 2 Create a rule in the InForm application to clear the coding targets (optional).	If the following key items are changed in the InForm application *after a verbatim is coded*, they will not be updated in the Central Coding application. **Note:** The key items *are* updated in the Central Coding application if the verbatim is *not coded* in the InForm application. • SubjectInitials • SubjectNumber • Visit • Site Name • Site • Study If you want the key items to be updated, you must create a rule in the InForm application to clear the coding targets.
Perform this task using the Central Designer application	

Checklist: Setting up InForm studies for use with the Central Coding application	
☑ Task	Description
❑ 3 Create the coding maps.	Specify mapping definitions for controls that hold verbatim text and controls that hold the coded values assigned by the InForm application.
	For more information, see the Central Designer *InForm Design Guide*.
	Note: Oracle recommends that you do not modify coding maps after coding begins for the study. Doing so can slow the coding process.

About mapping InForm data for coding with the Central Coding application

Use the Central Designer application to specify the InForm mapping definitions for controls that hold verbatim text and controls that hold the coded values. For more information, see the Central Designer *InForm Design Guide*.

1   For each form that contains data to be coded, design controls to hold data as entered (verbatims), controls to hold coded data (code targets), items to hold query data (query targets), and if supported by the dictionary, controls to hold additional context information (context items).

Verbatim, code target, query target, and context items must be:

- In the same visit if the visit is repeating.

- On the same form if the form is repeating.

- In the same itemset if the coded data appears in an itemset.

- Different from each other.

2   Create a mapping definition that specifies:

- Each verbatim to be coded.

- The dictionary used for coding.

- Each code target to which the Central Coding application returns a coded value.

- Each context item used to provide additional context data to the Central Coding application.

- Each applicable verbatim type.

- Each query target on which to place a query associated with the verbatim. The query target can be the verbatim item, or any other visible, editable item on the form.

3   In a production study, use the Central Coding application to:

a   Export the verbatim and context data from the InForm application to the Central Coding application.

b   Code the data.

c   Import the coded data from the Central Coding application to the InForm application.

Overview of the Central Coding installation process

The following table outlines the process for installing the Central Coding software, indicates the order in which you must perform the steps, and provides cross-references to instructions for completing the procedures.

> **Note:** Before performing the tasks in the table, be sure you have met the requirements listed in the *Prerequisites* (on page **13**).

Overview of the Central Coding installation process		
Step	**Task**	**For details, see...**
1	Prepare the database and application servers.	*Preparing the database and application servers* (on page 19).
2	Install the Central Coding software.	*Installing the Central Coding software* (on page 29).
3	Load the coding dictionaries.	*Loading and managing the coding dictionaries* (on page 55).
4	Configure the Central Coding application.	*User Guide.*

Oracle® Health Sciences Central Coding 3.0.3

C H A P T E R 3
Preparing the database and application servers

In this chapter

Overview: Preparing the database and application servers

Preparing the database and application servers is **step 1** in the installation process. This step is shaded in the table.

For the database server, you must:

- Install and configure the Oracle software on the database server.

- Create the database and tablespaces that are used by the Central Coding application.

For the application server, you must:

- Verify the version of ASP.Net.

Note: The Central Coding application supports only one version of a database on a machine.

Overview of the Central Coding Installation process		
Step	Task	For details, see...
1	Prepare the database and application servers.	• *Install the Oracle software on the database server* (on page 21). • *Create the database and tablespaces* (on page 22). • *Verify the version of ASP.Net on the application server* (on page 23). • *Set the ISAPI and CGI restriction settings—Windows 2008 operating systems only* (on page 24). • *Install a certificate to secure internal communication with the Job Scheduler service* (on page 25). • *Disable SSLv2 on the Central Coding application server* (on page 27).
2	Install the Central Coding software.	*Installing the Central Coding software* (on page 29).
3	Load the coding dictionaries.	*Loading and managing the coding dictionaries* (on page 55).
4	Configure the Central Coding application.	*User Guide.*

Install the Oracle software on the database server

When the database server requirements are met, you can install your Oracle database. Use the Oracle installation documentation as needed.

Mandatory database parameters

Most of the default Oracle configuration parameters can be used for the Central Coding database. However, the following parameters must be set to the specified values.

Mandatory database parameters	
Parameter	Value
Database Character Set	AL32UTF8 - Unicode UTF-8 Universal character set
National Character Set	AL16UTF16 - Unicode UTF-16 Universal character set
db_cache_size	80 MB
sga_max_size	1000 MB
sga_target	600 MB (dependent on how much memory is available for Oracle)
pga_aggregate_target	300 MB (dependent on how much memory is available for Oracle)
BLOCK_SIZE	Database: 16k Tablespace: 16k

Note: Your database administrator should dynamically adjust the sga_target and pga_aggregate_target values using Oracle Enterprise Manager Advisors as the system grows.

Note: Oracle recommends that the Oracle instance registry parameter ORA_*SID*_AUTOSTART be set to True. This ensures that Oracle is synchronized with the job scheduler, which is an auto-started service.

Create the database and tablespaces

After installing the Oracle software, create the database and tablespaces. The Central Coding application uses the *Coding application* and *Coding platform* tablespaces listed in the following table.

- Note the names of the tablespaces you create.

  You need the names when you enter values for the database users during the Central Coding software installation.

  Each tablespace has one or more associated database users, which the installation wizard creates when you install a Central Coding application server. For more information, see **Installing a Central Coding application server** (on page 32).

  > **Note:** For demonstration purposes in this guide, example names are provided for the recommended tablespaces, and for their associated database users and passwords. The same example name is used for both the user name and password.
  >
  > The **Central Coding Database User** name and the **Coding Platform Database User** name cannot be the same.
  >
  > The tablespace and user names are *not* case-sensitive. The passwords *are* case-sensitive.

- The Coding application tablespace contains the coding dictionary database, which is created by the Dictionary Loader tool. For more information, see **About the Dictionary Loader tool** (on page 59).

> **Note:** All entries used as Oracle database objects (such as user names, passwords, and tablespaces) should follow Oracle recommendations for naming conventions. In addition, Oracle recommends using strong passwords, as described in the *Secure Configuration Guide*.

Recommended tablespaces			
Tablespace	Size	Contains	Database user(s)
Coding application **Example name:** CODING	500 MB Auto extend enabled, 10 MB increments.	Central Coding application	- Central Coding Database User **Example name:** cca

Coding platform
 	
Example name: CCP
	100 MB
	
	Auto extend enabled,
	10 MB increments.
		Coding dictionaries	- Coding Platform Database User
			
			  Example name: codingplatform
			
			- Coding Dictionary Database User
			
			  Example name: codingdictionaries

Verify the version of ASP.Net on the application server

After completing the database installation, verify the version of ASP.Net on the application server. If the correct version of ASP.Net is not being used by the IIS Manager, you cannot view the login page for the Central Coding application.

1   Select **Start > Programs > Administrative Tools > Internet Information Services (IIS) Manager**.

The Internet Information Services (IIS) Manager dialog box appears.

2   Expand **Web Sites**.

3   Right click **Default Web Site** and select **Properties**.

The Default Web Site Properties dialog box appears.

4   Click the **ASP.NET** tab.

5   In the **ASP.NET version** field, select **4.0**.

6   Click **OK**.

Set the ISAPI and CGI restriction settings—Windows 2008 operating systems only

For environments that use the Windows 2008 operating system, after you complete the database installation and verify the version of ASP.Net on the application server, you must set the ISAPI and CGI Restrictions option to allow the use of ASP.Net 4.0 on the machine on which you are installing the Central Coding application.

1   Select **Start > Programs > Administrative Tools > Internet Information Services (IIS) Manager**.

The Internet Information Services (IIS) Manager dialog box appears.

2   In the Connections pane, select the local machine on which you are working.

The [Computer Name] Home pane appears.

3   In the IIS section, make sure ASP is installed.

4   In the IIS section, double-click **ISAPI and CGI Restrictions**.

The ISAPI and CGI Restrictions pane appears.

5   Double-click **ASP.NET v4.0.30319**.

The Edit ISAPI or CGI Restriction dialog box appears.

6   Select **Allow extension path to execute**.

7   Click **OK**.

Install a certificate to secure internal communication with the Job Scheduler service

On each Central Coding application server, an administrator must install the certificate that is used to secure communication with the Job Scheduler service.

- The certificate must be installed to the **LOCAL_MACHINE\MY** store directory and made usable by the user who runs the ASP.NET worker process (by default, the NETWORK_SERVICE user). You must also grant this user Full Control rights to the private key for the certificate.

- The certificate and each certificate in the certification path must be 1024 bytes. For information about converting an existing certificate, see the Microsoft support website.

To install the certificate:

1 Open the Microsoft Management console:

    a Open a Command Prompt window.

    b Type **mmc**.

2 Select **File > Add/Remove Snap-in**.

The Add or Remove Snap-ins dialog box appears.

3 In the list of available snap-ins, select **Certificates**.

4 Click **Add**.

The Add dialog box appears.

5 Click **Computer account**.

6 Click **Next**.

7 Click **Local Computer**.

8 Click **Finish**.

9 Click **OK**.

10 In the Microsoft Management console, in the Console Root tree, select **Certificates (Local Computer)**.

11 In the Logical Store Name field, right-click the **Personal** folder.

12 Select **All Tasks > Import**.

The Certificate Import Wizard appears.

13 Click **Next**.

14 Click **Browse**, and select the PFX file provided by the certificate vendor.

15 You are prompted for a password. Type the password for the PFX file.

16 Click **Next** to accept the default options for the remaining dialog boxes.

17 Click **Finish**.

The new certificate appears in the displayed list.

18 Give the user full control to the certificate.

a   Do one of the following:

- For Windows 2008 operating systems, right-click the certificate, and select **All Tasks > Manage Private Keys**.

- For Windows 2003 operating systems, open the certificate in the WSE 2.0 X.509 certificate tool.

For specific instructions, see the documentation for your operating system.

b   For the certificate, assign both **Read** and **Read and execute** rights to the user.

- By default, for Windows 2003, the user is NETWORK_SERVICE.

- By default, for Windows 2008 and Windows 7, the user is NETWORK_SERVICE or IIS AppPool\Central Coding New Pool. Please add both users.

19 Click **OK**.

Disable SSLv2 on the Central Coding application server

Oracle recommends that for improved security you disable SSLv2 on the Central Coding application server. For more information, see the Microsoft website (http://social.technet.microsoft.com).

C H A P T E R 4

Installing the Central Coding software

In this chapter

Overview: Installing the Central Coding software

Installing the Central Coding software is **step 2** in the installation process.

This chapter includes instructions for installing the software (manually or by performing a silent installation), modifying an existing installation, upgrading from a previous version of the software, repairing an installation, and uninstalling the software.

Overview of the Central Coding installation process		
Step	Task	For details, see…
1	Prepare the database and application servers.	*Preparing the database and application servers* (on page 19).
2	Install the Central Coding software.	• *Before you begin* (on page 31). • *Installing a Central Coding application server* (on page 32). • *Modifying an existing Central Coding application server* (on page 42). • *Performing an interactive upgrade to the Central Coding 3.0 .3 software* (on page 43). • *Performing a silent installation* (on page 46). • *Performing a silent upgrade* (on page 48). • *Verifying the installation* (on page 51).
3	Load the coding dictionaries.	*Loading and managing the coding dictionaries* (on page 55).
4	Configure the Central Coding application.	*User Guide*.

Before you begin

You can perform either a manual or a silent installation of the Central Coding software.

Before you run the installation, make sure that:

- The database instance is running.

- All clocks are synchronized on the machines where you are installing the Central Coding software and the database server.

  The installation program verifies that the clocks are synchronized. If they are not synchronized, an error message appears. Installation cannot continue until the clocks are synchronized.

- The ASP.NET state service is started.

- The job scheduler is turned off.

Interactive installation or upgrade

Installing a Central Coding application server

Use this procedure to install an instance of the Central Coding software. After you install one instance of the Central Coding software, you can run the installation program as many times as necessary to install additional instances.

Perform this procedure on each application server.

> **Note:** This installation procedure requires that you enter the names of the database tablespaces and their associated database users and passwords. For demonstration purposes in this guide, example names for the tablespaces, users, and passwords are provided in this procedure in the appropriate steps. For more information, see *Create the database and tablespaces* (on page 22).
>
> **Caution:** All entries used as Oracle database objects (such as user names, passwords, and tablespaces) should follow Oracle recommendations for naming conventions. In addition, Oracle recommends using strong passwords, as described in the *Secure Configuration Guide*.

1   Locate **setup.exe**.

2   Right-click and select **Run as administrator**.

   • If you are installing the Central Coding application for the first time, the Welcome page appears.

   • If you have already installed an instance of the Central Coding application, the Existing Installed Instances Detected page appears.

      • Select **Install a new instance of this application**, and click **Next**.

        The Welcome page appears.

3   Click **Next**.

   The page that appears depends on the operating system.

   • If you are performing a fresh installation on a Japanese operating system, the Required System Components page appears. Proceed to step 5.

   • If you are performing a fresh installation on an English operating system, the Determine Database Sort page appears.

     Use this page to specify the locale, which determines the correct linguistic sorting in the database. The choice affects the language of verbatims that can be supported, the default date format, and which report templates are installed.

4   Select the locale.

- **English**—Sets the default database sort group to English. The English option maps to the Binary Oracle sort value.

  Select this option to:

  - Support only English verbatims.

  - Set the default date format to DD/MON/YYYY HH24:MI:SS.

  - Load the English report templates. The reports can contain only English data.

- **European**—Sets the default database sort group to WesternEuropean. The European option supports more character sets than the English option. It maps to the Generic_M Oracle sort value, which generally handles the order of the Latin, Cyrillic, Greek, and other European characters.

  Select this option to:

  - Support only English verbatims.

  - Set the default date format to DD/MON/YYYY HH24:MI:SS.

  - Load the English report templates. The reports can contain only English data.

- **Global**—Sets the default database sort group to JapaneseWesternEuropean. The Global option maps to the Japanese_M Oracle sort value.

  Select this option:

  - If you are using an English operating system and you want to support both English and Japanese verbatims, or if you are using a Japanese operating system.

  - To set the default date format to YYYY/MON/DD HH24:MI:SS.

  - To load the Japanese report templates. The reports can contain both Japanese and English data.

  > **Note:** For the best performance, Oracle recommends that you select **Global** only if you are working with **Japanese studies.**

5   Click **Next**.

The Required System Components page appears. The installation wizard verifies that the server has all the necessary software components, including the operating system, IIS, and the Oracle client.

If required components are missing or are the wrong version, installation stops. The missing and invalid components are listed on the Required System Components page. You must install them before continuing the installation.

6   Click **Next**.

The License Agreement page appears. Review the license agreement.

- If you want to print a copy of the license agreement, click **Print**.

- You must accept the terms of the license agreement to continue the installation.

7 Click **Yes**.

The Company Information page appears.

8 Enter the following information:

- **Company name**—Name of the company licensed to use the software.

  The company name may include any characters. This is informational only.

- **Company URL**—URL that is unique to the company.

  This is used to define the security domain in inter-product communication. The Company URL:

  - Must be in English.

  - Must follow the proper URL convention and be in valid URL (ascii) narrow characters.

    The URL does not need to point to an actual running website or service.

  - Should not begin with a protocol designation such as **http://**.

  > Note: The Company URL you enter for the Central Coding software **must be the same as the Company URL you entered for the InForm Adapter software.**

9 Click **Next**.

The Select Features page appears.

10 Select the features to install. At least one feature must be selected in order to continue with the installation. If you select only the Dictionary Loader tool, the installation program skips to the end of the wizard.

- Central Coding Server.

- Dictionary Loader.

  The Dictionary Loader tool must be installed in order to load standard and custom dictionaries. However, the Dictionary Loader tool:

  - Does not need to be installed on every machine or on every application server.

  - Can be on a different machine from the Central Coding application server(s).

  - Can be installed without also installing the Central Coding Server.

  If you want to verify whether the Dictionary Loader tool is installed, from the **Start Menu**, select **Programs > Phase Forward > Central Coding**. If **Dictionary Loader** appears, it is already installed.

- Coding Service Interface for Clintrial.

  Select only if you plan to use the Central Coding application with the Clintrial application. By default, the Coding Service Interface for Clintrial is not installed.

11 Click **Next**.

The Application Instance Settings page appears. This page collects the instance name and job scheduler port number. From the instance name, the installer derives the virtual directories and job scheduler service name. The port must be numeric and should designate a port that is currently open and will be reserved for only this service. The installation program attempts to select a port that has not been used by a prior run of the installation.

12 Enter the following information:

- **Instance Name**—Unique string identifier for this instance. The Instance Name derives names for the various services.

  - Do not use special characters and make sure that there are no spaces in the name.

  - If you plan to have multiple application servers, consider using a naming convention for the names that allows you to easily identify each instance.

- **TCP port**—Port through which the job scheduler communicates on this Central Coding application server.

  The Central Coding software reserves the range 54000 through 54999 by convention, although it can be any open port. Each instance must be assigned its own port. The installation program defaults to a unique number for each instance being installed, starting in the conventional range, but not limited to it.

The following information is automatically populated:

- **Service name**—NT service name for the application server you are creating. By default, this is set to Central Coding Job Scheduler.

  This must be a unique name across multiple instances so that the services can be distinguished from one another. The installation appends the instance name to the service name.

- **Application URL**—URL for the application server.

- **Application Server**—Name of the virtual directory under which the application is published in IIS.

  The installation appends the instance name to the service name.

- **Coding Service Virtual Directory**—Unique name for the application server you are creating.

  The installation appends the instance name to the service name.

- **Platform Service Virtual Directory**—Unique name for the platform you are creating for this application server.

  The installation appends the instance name to the service name.

- **Job Service Host Name**—Machine name of the host. The default is localhost.

13 Click **Next**.

The Choose Destination Location page appears.

14 Specify where on the local file system to install the instance of the application.

By default, the installation wizard installs the Central Coding software in the C:\Program Files\Phase Forward\Central Coding Application folder. However, you can click **Change** and navigate to another location. The folder should not be the same as any other installed instance.

> **Note:** The instructions, paths, and Start Menu navigation in this guide assume you are installing to the default location. Oracle strongly recommends that you install the software to the default directory. If you select a different location, the uninstaller might not remove all related files during the uninstall process.

15 Click **Next**.

The Central Coding Database User page appears. This page collects the connection string and the password for the Oracle SYS user account; the database user and password; and the default tablespace for the Central Coding application

The installation program detects the Oracle home location, finds all currently configured connection strings, and presents them in a list. Instead of typing in the connection string, you pick it from the list.

> **Note:** If the connection string that you want to use is not in the list, it means the connection has not been set up.

16 Select or enter the following database information:

- **Connection string**—TNS name to use when connecting to the database.

  > Note: You can specify the same connection strings on the Central Coding Database
  > User, the Coding Platform Database User, and the Create Coding Dictionary Database
  > User pages. To receive the best performance, Oracle recommends that you specify
  > different connection strings for each user account.

- **Password for SYS user**—Password for the Oracle SYS account.

  The password must contain:

  - One or more alphabetical (A-Z, a-z) and numeric (0-9) characters.

  - At least one non-alphanumeric character.

  - One or more upper case (A-Z) and lower case (a-z) characters.

  - A minimum of 8 characters.

  For more information, see the *Secure Configuration Guide*.

- **Test Connection**—Click to attempt an actual database connection using the selected
  Connection string and **Password**. You can continue with the installation only after the
  connection test succeeds.

> **Note:** If the Oracle system has the authentication mode set to NTS (sqlnet.ora), the password supplied will be ignored by Oracle, and the connection test will succeed when the NT user has permission to access the SYS user.

17 If you choose to create a new user, you must also enter data for the default tablespace. If the Create/Recreate User option is selected and an existing user is supplied, that user will be dropped and re-created.

Alternatively, the option to reuse an existing user is available. In this case, the database is assumed to be present already, and the specified user is not dropped. You can test a connection with this user before proceeding.

Select or enter the following information for the **Central Coding Database User**:

> **Note:** All entries used as Oracle database objects (such as user names, passwords, and tablespaces) should follow Oracle recommendations for naming conventions. In addition, Oracle recommends using strong passwords, as described in the *Secure Configuration Guide*.

- **Create/Recreate User**—Select to create a new **Central Coding Database User**.

  - **User Name**—Oracle user account name.

    The **Central Coding Database User** name and the **Coding Platform Database User** name cannot be the same. You enter the **Coding Platform Database User** name in step 19.

  - **Password**—Password for the Oracle user account.

    The password must contain:

  - One or more alphabetical (A-Z, a-z) and numeric (0-9) characters.

  - At least one non-alphanumeric character.

  - One or more upper case (A-Z) and lower case (a-z) characters.

  - A minimum of 8 characters.

    For more information, see the *Secure Configuration Guide*.

  - **Retype Password**—Password for the Oracle user account.

> **Note:** Do not use Oracle reserved words for the user name or password.

- **Existing User**—Select to reuse an existing database user.

  - **User Name**—Oracle user account name. The list is populated with users from the database.

  - **Password**—Password for the Oracle user account.

  - **Test User**—Click to test the database connection with this user.

- **Default tablespace**—Select the name that was created for the Central Coding application.

  This list is populated from the database. For the example in this guide, that name is **CODING**. For more information, see *Create the database and tablespaces* (on page 22).

> **Note:** This field is not available if you select the **Existing User** option.

- **Create**—Click to create a new tablespace.

    The Create New Default Tablespace dialog box appears. In the **Name** field, enter a name for the tablespace, and click **Create**. The dialog box closes and the name of the newly created tablespace appears in the **Default tablespace** field on the **Central Coding Database User** page.

> **Note:** The tablespace that is created is the default size and in the default location. If you want the tablespace to be a different size or in a different location, you must create the tablespace from the database.

18 Click **Next**.

The Coding Platform Database User page appears. This page collects the database user, password, and default tablespace for the Central Coding Platform.

If you choose to create a new user, you must also enter data for the default tablespace. If the Create/Recreate User option is selected and an existing user is supplied, that user will be dropped and re-created. Alternatively, the option to reuse an existing user is available. In this case, the database is assumed to be present already, and the specified user is not dropped. You can test a connection with this user before proceeding.

19 Select or enter the following information for the **Coding Platform Database User**:

> **Note:** All entries used as Oracle database objects (such as user names, passwords, and tablespaces) should follow Oracle recommendations for naming conventions. In addition, Oracle recommends using strong passwords, as described in the *Secure Configuration Guide*.

- **Connection string**—The TNS name to use when connecting to the Platform database.

> **Note:** You can specify the same connection strings on the Central Coding Database User, the Coding Platform Database User, and the Create Coding Dictionary Database User pages. To receive the best performance, Oracle recommends that you specify different connection strings for each user account.

- **Password for SYS user**—The password for the Oracle SYS account.
- **Create/Recreate User**—Select to create a new **Coding Platform Database User**.
  - **User Name**—The Oracle user account *(Example name:* **codingplatform***)*.

    The **Central Coding Database User** name and the **Coding Platform Database User** name cannot be the same. You enter the **Central Coding Database User** name in step 17.
  - **Password**—The password for the Oracle user account.

  The password must contain:

  - One or more alphabetical (A-Z, a-z) and numeric (0-9) characters.
  - At least one non-alphanumeric character.
  - One or more upper case (A-Z) and lower case (a-z) characters.
  - A minimum of 8 characters.

  For more information, see the *Secure Configuration Guide*.

  - **Retype Password**—The password for the Oracle user account.
- **Existing User**—Select to reuse an existing database user.
  - **User Name**—The Oracle user account name. The list is populated with users from the database.
  - **Password**—The password for the Oracle user account
  - **Test User**—Click to test the database connection with this user.
- **Default tablespace**—Select the name that was created for the Central Coding application.

  This list is populated from the database. For the example in this guide, that name is **CCP**. For more information, see *Create the database and tablespaces* (on page 22).

> **Note:** This field is not available if you select the **Existing User** option.

  - **Create**—Click to create a new tablespace.

    The Create New Default Tablespace dialog box appears. In the **Name** field, enter a name for the tablespace and click **Create**. The dialog box closes and the name of the newly

created tablespace appears in the **Default tablespace** field.

> **Note:** The tablespace that is created is the default size and in the default location. If you want the tablespace to be a different size or in a different location, you must create the tablespace from the database.

20 Click **Next**.

The Create Coding Dictionary Database User page appears. This page collects the user and password that the Central Coding application will use to connect to the dictionary database. This user is not dropped or created, and does not have to exist at the time of the installation. You create the dictionary database using the Dictionary Loader tool. For more information, see ***Setting up the dictionary database*** (on page 61).

21 Enter the following information:

> **Note:** All entries used as Oracle database objects (such as user names, passwords, and tablespaces) should follow Oracle recommendations for naming conventions. In addition, Oracle recommends using strong passwords, as described in the *Secure Configuration Guide*.

- **Connection string**—TNS name to use when connecting to the dictionary database.

> **Note:** You can specify the same connection strings on the Central Coding Database User, the Coding Platform Database User, and the Create Coding Dictionary Database User pages. To receive the best performance, Oracle recommends that you specify different connection strings for each user account.

- **User**—Name of the user account for the dictionaries *(Example name:* **codingdictionaries***)*.

- **Password**—Password for the user account for the dictionaries.

    The password must contain:

    - One or more alphabetical (A-Z, a-z) and numeric (0-9) characters.

    - At least one non-alphanumeric character.

    - One or more upper case (A-Z) and lower case (a-z) characters.

    - A minimum of 8 characters.

    For more information, see the *Secure Configuration Guide*.

- **Retype password**—Retype the password for the user account for the dictionaries *(Example name:* **codingdictionaries***)*.

> **Note:** Make a note of these values. You must use them when you create the repository for the dictionaries and when you connect to the database. For more information, see ***Creating a dictionary repository*** (on page 61) and ***Creating a connection to the database*** (on page 62).

22 Click **Next**.

The Create Coding Administrator Account page appears.

23 Enter the following information, and click **Next**.

- **User**—Name of the initial user account for the Central Coding application.

- **Password**—Password for the initial user account.

  The password must contain:

  - One or more alphabetical (A-Z, a-z) and numeric (0-9) characters.

  - At least one non-alphanumeric character.

  - One or more upper case (A-Z) and lower case (a-z) characters.

  - A minimum of 8 characters.

  For more information, see the *Secure Configuration Guide.*

- **Retype password**—Retype the password for the initial user account.

The Create Job Service Account page appears.

24 Enter and retype a password for the Job Schedule service, and then click **Next**.

The Create Job Schedule Service Account page appears.

25 Click **Choose Certificate**.

A list of X.509 certificates on the machine appears in a new window.

> **Note:** The certificate is for internal communication only, and must already be installed. For more information, see *Install a certificate to secure internal communication with the Job Scheduler service* (on page 25).

26 Select the certificate to use, and click **OK**.

The certificate properties appear on the page.

27 Click **Next**.

The Ready to Install the Program page appears.

28 Click **Install**.

After the installation completes, the Central Coding Installation Wizard Complete page appears.

29 Click **Finish**.

Modifying an existing Central Coding application server installation of the same version

Use this procedure to change the feature(s) of the same version of the software that you installed on an application server. The combination of features includes:

- Central Coding Server.

- Dictionary Loader.

1 Locate **setup.exe**.

2   Right-click and select **Run as administrator**.

The Existing Installed Instances Detected page appears.

3   Select **Maintain or update the instance of this application selected below**.

4   Select the appropriate server, and click **Next**.

The Welcome page appears.

5   Select **Modify**, and click **Next**.

The Select Features page appears.

6   To modify an application server installation, select the feature(s) to change:

- Central Coding Server.

- Dictionary Loader.

    The Dictionary Loader tool must be installed in order to load standard and custom dictionaries. However, the Dictionary Loader tool:

    - Does not need to be installed on every machine or on every application server.

    - Can be on a different machine from the Central Coding application server(s).

    - Can be installed without also installing the Central Coding Server.

If you want to verify whether the Dictionary Loader tool is installed, from the **Start Menu**, select **Programs > Phase Forward > Central Coding**. If **Dictionary Loader** appears, it is already installed.

7   Select the feature(s) that you want to install, deselect the feature(s) that you want to uninstall, and click **Next**.

The files are updated and the Maintenance Complete page appears.

8   Click **Finish**.

Performing an interactive upgrade to the Central Coding 3.0.3 software

Use this procedure to update the Central Coding software to the current version. The installation program verifies the components that are currently installed on your system and prompts you to update the existing application instance.

> **Note:** You can upgrade to the current release from the Central Coding 3.0 SP0, 3.0 SP1, and 3.0.2 releases. If you are using an earlier version of the Central Coding software you must first upgrade to the 3.0 SP0 (or later) release on an English operating system. You cannot perform an upgrade to support the Japanese language. To accommodate multilingual studies, you must do a complete install of the Central Coding software.

1   Make sure that the Central Coding release 3.0 SP0, 3.0 SP1, or 3.0.2 software is installed.

2   Download the Central Coding 3.0.3 ZIP file.

3   Distribute the Central Coding 3.0.3 ZIP file to every machine where you installed the Central Coding software.

4   If the Central Coding job scheduler service is running, stop the service.

5   Reset IIS, and restart the World Wide Web Publishing Service.

6   Back up the coding database (all schema owners defined for the Central Coding application).

Oracle recommends that you run a full export of the Central Coding database.

7   Back up the Central Coding installation directory.

This creates backup copies of all CONFIG files and can provide information about the Central Coding configuration before the upgrade.

8   Right-click and select **Run as administrator**.

The Existing Installed Instances Detected page appears.

9   Select **Maintain or update the instance of this application selected below**.

When an existing instance is selected, the installation program automatically enters the upgrade mode. Details about the existing instance are read from the instance itself, so that you do not need to supply information again. The installation program:

- Verifies the updated software prerequisites.

- Copies over all assemblies and relevant files with the new versions, except for configuration files that have been modified since the previous installation.

- Automatically updates the configuration and database.

10   Select the application server to upgrade, and click **Next**.

The Welcome page appears.

11   Click **Next**.

The Required System Components page appears.

12   Click **Next**.

The Setup Status page appears. When the setup is complete, a command prompt window opens that displays the upgrade steps as they occur. When the upgrade is complete, the command prompt window closes and the Central Coding Update Wizard Complete page appears.

The Choose Certificate page appears.

13   Click **Choose Certificate**.

A list of X.509 certificates on the machine appears in a new window.

> **Note:** The certificate is for internal communication only, and must already be installed. For more information, see *Install a certificate to secure internal communication with the Job Scheduler service* (on page 25).

14   Select the certificate to use, and click **OK**.

The certificate properties appear on the page.

15   Click **Finish**.

> **Note:** The upgrade may delete the connections that were defined for the dictionary repository. After the upgrade is complete, you can restore the connections using the previous user information, and the dictionary repository objects will be available again. For more information, see *Creating a connection to the database (on page 62)*.

16 Clear the browser's cache on your local machine.

    a   Click **Tools > Internet Options**.

        The Internet Options dialog box appears.

    b   In the **Browsing history** section, click **Delete**.

        The Delete Browsing History dialog box appears.

    c   In the **Temporary Internet Files** section, click **Delete files**.

17 Optionally, before starting the job scheduler, specify the length of time that you want entries in the job log to remain in the Central Coding database.

The **PhaseForward.Platform.JobScheduler.exe.config** file includes a job entry that manages the size of the job log table in the database for scheduled jobs.

The job runs daily and by default deletes entries that are 45 days old. If you want to keep entries in the job log for a different amount of time you must edit the file. The file is in **...\CentralCodingServer\CodingWebUI\bin**.

Silent installation or upgrade

Performing a silent installation

After you install one instance of the Central Coding software, you can run the silent installation as many times as necessary to install additional instances. To perform a silent installation of the Central Coding software:

1   Modify the response file.

   For more information, see *Modifying the response file* (on page 46).

2   Run the installation from the command line.

   For more information, see *Running the installation* (on page 48).

Modifying the response file

Perform this procedure on each application server.

> **Note:** All entries used as Oracle database objects (such as user names, passwords, and tablespaces) should follow Oracle recommendations for naming conventions. In addition, Oracle recommends using strong passwords, as described in the *Secure Configuration Guide*.

1   Copy the Central Coding installation folder to your local machine.

2   Locate the **setup.iss** response file.

3   Save the **setup.iss** response file with a different name.

> **Note:** Oracle recommends saving the response file with a name that references the Central Coding instance with which it is associated.

4   Modify the response file with the following information:

Parameter	Description
svLanguage	Locale: • English • European • Global
szCompanyName	Company name.
szCompanyURL	Company URL.
szDir (First)	Base installation directory. This should match the information you specify in the parameter for the Central Coding instance directory.
instanceName	Instance name.

Parameter	Description
svPort	TNS port number.
	This must be an empty port that has not been used by any other software.
szDir	Directory for the Central Coding instance.
(Second)	This should match the information you specified in the installation directory parameter.
Central Coding Database user parameters	
svDBServer	Database server connection string for the Central Coding Database user.
svOracleSysPassword	Oracle system password.
svdbUID	Central Coding Database user ID.
svdbPID	Central Coding Database user password.
svDBTablespace	Name of the tablespace for the Central Coding database.
Platform Database user parameters	
svDBServer	Database server connection string for the Platform Database user.
svOracleSysPassword	Oracle system password.
svdbUID	Platform Database user ID.
svdbPID	Platform Database user password.
svDBTablespace	Name of the tablespace for the Platform database.
Dictionary Database user parameters	
svDBServer	Database server connection string for the Dictionary Database user.
svdbUID	Dictionary Database user ID.
svdbPID	Dictionary Database user password.
Job Scheduler user parameters	
svdbPID	Job Scheduler user password.
Certificate parameters	
svCertSubject	Certificate subject.
svCertIssuer	Certificate issuer.
svCertName	Certificate name.
svCertExpiration	Certificate expiration date, in the format MM/DD/YYYY H:MM:SS AM/PM.

Parameter	Description
svCertThumbprint	Certificate thumbprint.

Running the installation

1   Open a Command Prompt window and navigate to the installation folder on your local machine.

2   Run the following command:

...setup.exe -s -f1"[Location of response file]\[Response file name]" -f2"[Location of log file]\[Log file name]"

where:

- **Location of response file**—The directory where the response file you modified exists.

- **Response file name**—The name you gave the response file to use during the silent installation.

- **Location of log file**—The directory where you want the log file to be created.

- **Log file name**—The name to give the log file.

> **Note:** The log file is automatically created during the installation.

3   After you run the silent installation, Oracle recommends that you check the log file to ensure that the installation was successful. For more information, see *Checking the log file* (on page 50).

Performing a silent upgrade

Use this procedure to update the Central Coding software to the current version. The installation program verifies the components that are currently installed on your system and prompts you to update the existing application instance.

> **Note:** You can upgrade to the current release from the Central Coding 3.0 SP0, 3.0 SP1, and 3.0.2 releases. If you are using an earlier version of the Central Coding software you must first upgrade to the 3.0 SP0 (or later) release on an English operating system. You cannot perform an upgrade to support the Japanese language. To accommodate multilingual studies, you must do a complete install of the Central Coding software.

1   Make sure that the Central Coding release 3.0 SP0, 3.0 SP1, or 3.0.2 software is installed.

2   Download the Central Coding 3.0.3 ZIP file.

3   Distribute the Central Coding 3.0.3 ZIP file to every machine where you installed the Central Coding software.

4   If the Central Coding job scheduler service is running, stop the service.

5   Reset IIS, and restart the World Wide Web Publishing Service.

6   Back up the coding database (all schema owners defined for the Central Coding application).

Oracle recommends that you run a full export of the Central Coding database.

7   Back up the Central Coding installation directory.

This creates backup copies of all CONFIG files and can provide information about the Central Coding configuration before the upgrade.

8   Navigate to the installation folder.

9   Copy the installation folder to your local machine.

10 Locate the **upgrade.iss** response file.

11 In order to successfully run the silent upgrade, you need to know the GUID for the existing instance of the Central Coding application that you are upgrading. To find this information:

    a   Click **Start > Run**.

       The Run dialog box appears.

    b   Type **regedit**.

       The Registry Editor dialog box appears.

    c   Expand the HKEY_LOCAL_MACHINE_SOFTWARE_PHASEFORWARD node.

    d   Locate the instance of the Central Coding application that you are upgrading.

    e   Copy the GUID information into a text file so that you can easily copy and paste it into the command line during the upgrade.

12 Open a Command Prompt window and navigate to the installation folder on your local machine.

13 Run the following command:

...setup.exe -s -ig"[Central Coding instance GUID] -f1"[Location of upgrade response file]\[Response file name]" -f2"[Location of the log file]\[Log file name]"

where:

- **Central Coding instance GUID**—GUID for the Central Coding instance to upgrade.

- **Location of response file**—The directory where the upgrade response file you modified exists.

- **Response file name**—The name you gave the upgrade response file to use during the silent installation.

- **Location of log file**—The directory where you want the upgrade log file to be created.

> **Note:** The upgrade log file is automatically created during the installation.

- **Log file name**—The name to give the upgrade log file.

14 Clear the browser's cache on your local machine.

    a   Click **Tools > Internet Options**.

       The Internet Options dialog box appears.

    b   In the **Browsing history** section, click **Delete**.

       The Delete Browsing History dialog box appears.

    c   In the **Temporary Internet Files** section, click **Delete files**.

15 After you run the silent upgrade, Oracle recommends that you check the error log to ensure that the upgrade was successful. For more information, see *Checking the log file* (on page 50).

Checking the log file

1   Navigate to the directory in which the response file that you modified exists.

2   Open the log file with the name you specified during the installation.

- For successful installations, the log file includes **ResultCode=0**.

- For unsuccessful installations, the **ResultCode** field is populated with a number that specifies the type of error that occurred during the installation.

> **Note:** The error codes in the log file are created by InstallShield. If an error occurs during the installation, contact Oracle for details.

Verify the installation

After the application server is created, do the following to verify that the installation was successful:

- Review the **setup log**.

  This log contains messages the system generated during the installation. It is available at ...\Central Coding Application\CentralCodingServer\Setuplog.txt

  If the following message appears in **Setuplog.txt** it indicates that the block size of the tablespace for the Central Coding user is not large enough. For more information, see *Mandatory database parameters* (on page 21).

  ```
  create index CCA_FLAT_LEVELS_IDX1 on CCA_FLAT_LEVELS (*

  ERROR at line 1:
  ORA-01450: maximum key length (6398) exceeded
  ```

- In IIS, verify that **centralcoding<InstanceName>** exists; where <InstanceName> is the Instance Name you entered on the Application Instance Settings page during the Central Coding installation.

  1   To open IIS, select **Start > Settings > Control Panel > Administrative Tools > Internet Information Services (IIS)**.

  2   Double-click the **machine name**, expand **Web Sites > Default Web Sites**, and locate **centralcoding<InstanceName>**.

- Verify that the **Dictionary Loader** tool is installed.

  If you selected Dictionary Loader on the Select Features page when you installed the Central Coding software, the Dictionary Loader tool is available from the Start menu. Select **Program Files > Phase Forward > Central Coding > Dictionary Loader**.

> **Note:** For instructions on using the Dictionary Loader tool to load and manage the coding dictionaries, see *Loading and managing the coding dictionaries* (on page 55).

Repairing an installation

Use this procedure to re-copy all relevant installation files onto the target machine. This option is intended to help if the installation files were corrupted.

1   Locate **setup.exe**.

2   Right-click and select **Run as administrator**.

    The Existing Installed Instances Detected page appears.

3   Select **Maintain or update the instance of this application selected below**.

4   Select the appropriate server, and click **Next**.

    The Welcome page appears.

5   Select **Repair**, and click **Next**.

Uninstalling a Central Coding application server

Use this procedure to perform a complete uninstall of the Central Coding software.

> **Note:** The uninstall procedure does not remove the Central Coding folder from the Start menu. You must manually remove this folder.

1   Locate **setup.exe**.

2   Right-click and select **Run as administrator**.

   The Existing Installed Instances Detected page appears.

3   Select **Maintain or update the instance of this application selected below**.

4   Select the appropriate server, and click **Next**.

   The Welcome page appears.

5   Select **Remove**, and click **Next**.

   A confirmation dialog box appears.

6   Click **Yes**.

   Messages display as the system removes the Central Coding components. When the process is complete, the Uninstall Complete page appears.

7   Select whether to restart the computer now or later, and click **Finish**.

C H A P T E R 5

Loading and managing the coding dictionaries

In this chapter

About loading and managing the coding dictionaries

After you install the Central Coding software, you must load the coding dictionaries on the Central Coding application server.

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

About dictionary types and dictionary schemas

A dictionary type is a Central Coding concept that identifies a family of coding dictionaries.

Dictionary types are defined in XML files that contain the metadata for the dictionary levels and the SQL needed to set up the tables in the database. These files also contain the default element configuration settings that control which coding features and information are available to users in the Central Coding user interface.

Dictionary schemas are created from dictionary types. Each dictionary version is loaded into a separate Oracle database schema.

Standard dictionary type XML files

The Central Coding software includes XML files for the standard dictionary types in ...\Central Coding Application\DictionaryLoader\Setup.

Standard dictionary type XML files	
Dictionary type XML file	Description
MedDRA_DictionaryType.xml	All versions of MedDRA dictionaries have the dictionary type MedDRA.
MedDRAJ_DictionaryType.xml	All versions of MedDRA-J dictionaries have the dictionary type MedDRAJ.
MedDRAJ_ja-JP.xml	Used by the Dictionary Loader tool to install the language pack for the MedDRA-J dictionary. The language pack displays the dictionary level names and additional information labels in Japanese in the user interface.
WHO-DD_DictionaryType.xml	All versions of WHO-DD dictionaries have the dictionary type WHODD.
JDrug_DictionaryType.xml	All versions of JDrug dictionaries have the dictionary type JDrug. **Note:** You must rename the dictionary file so that the Dictionary Loader tool can recognize the file name. For more information, see *Renaming the dictionary type file for the JDrug dictionary* (on page 58).
JDrug_ja-JP.xml	Used by the Dictionary Loader tool to install the language pack for the JDrug dictionary. The language pack displays the dictionary level names and additional information labels in Japanese in the user interface.

Custom dictionary type XML files

For custom dictionaries, you must create the required XML file that defines the dictionary type. For more information, see the *User Guide*.

Renaming the dictionary file for the JDrug dictionary

The Dictionary Loader tool does not recognize Japanese file names. Therefore, you must rename the JDrug dictionary file so that the Dictionary Loader can recognize the file name and load the dictionary.

- Rename, or copy and rename, the JDrug dictionary file (全件.txt) to **all_cases.txt**.

  > **Note:** Make sure that this file is in a local directory with only English names in its path.

About the Dictionary Loader tool

The Central Coding software includes a stand-alone component, called the Dictionary Loader tool, that you use to manage all functions associated with loading and managing the coding dictionaries. The Dictionary Loader tool can be installed on a machine as part of the Central Coding software installation.

- The Dictionary Loader tool is installed into the Central Coding application directory and added to the Start menu for the Central Coding application.

  The Dictionary Loader tool is accessible only from the Central Coding server. You must have server-level access to run the Dictionary Loader tool; you cannot run it from the user interface.

- Dictionaries can be loaded on the same machine as the Central Coding application or on a different machine.

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

- All dictionaries can be loaded into a single tablespace, or you can create a separate tablespace for each dictionary.

  The instructions in this guide assume that all dictionaries are loaded into one tablespace.

- Dictionaries can be used by multiple application servers.

Launching the Dictionary Loader tool

Use the Dictionary Loader tool for all dictionary installation and maintenance tasks.

- Select **Start > Program Files > Phase Forward > Central Coding > Dictionary Loader**.

  The Dictionary Loader dialog box appears.
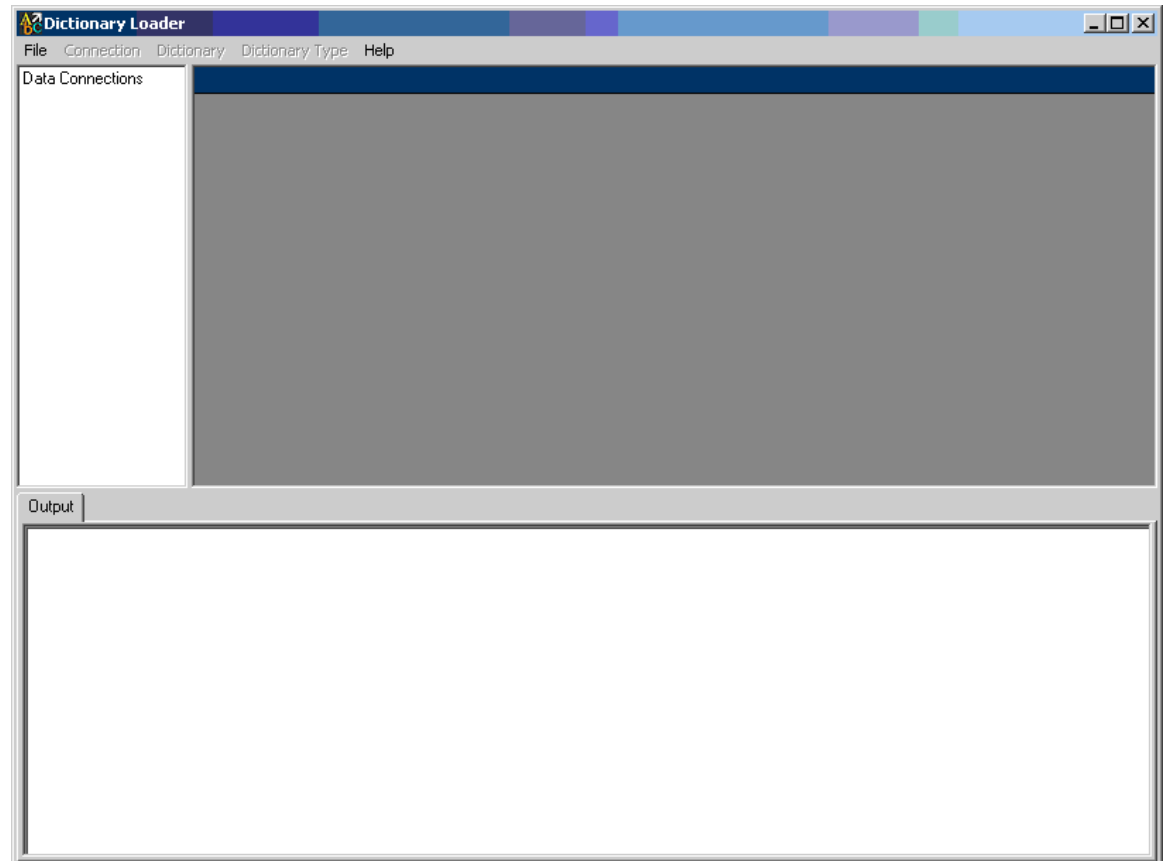
- This dialog box remains open when you use the Dictionary Loader tool.
- The first time you install the Central Coding software, the **Data Connections** tree in the top left pane is empty.

  Information appears in the tree after you create connections to the database.

  > **Note:** When you upgrade the Central Coding software, information about previously defined connections appears in the **Data Connections** tree. The upgrade may delete the connections that were defined for the dictionary repository. You can restore the connections using the previous user information so that the dictionary repository objects become available again. For more information, see *Creating a connection to the database* (on page 62).

- For each connection, information for the associated **Dictionaries** and **Types** appears in the top right pane of the dialog box.
- The **Output** pane at the bottom of the dialog box displays system messages.

Setting up the dictionary database

Overview of the steps to set up the dictionary database

> **Note:** Setting up the dictionary database is the same for both standard and custom dictionaries.

Steps to set up the dictionary database	
Step	Description
1 *Create a dictionary repository* (on page 61).	Use to create a repository in the database to hold the dictionaries associated with a connection. Although you can create multiple repositories, only one repository can be connected at a time.
2 *Create a connection to the database* (on page 62).	Use to create a connection to the database. Connections are created within repositories. Although you can create multiple connections, only one connection can be active at a time.
3 *Connect to the database* (on page 63).	Use to connect to an existing database connection.
4 *View the dictionaries available for a database connection* (on page 63).	Use to view information about the dictionary types that are available for a connection.
5 *Import the dictionary type XML file* (on page 64).	Use to import the dictionary type XML file for the dictionary that you want to load.

Creating a dictionary repository

Use this procedure to create a repository in the database to hold the dictionaries associated with a connection. Although you can create multiple repositories, only one repository can be connected at a time.

1 If not already started, launch the Dictionary Loader tool.

   For more information, see *Launching the Dictionary Loader tool* (on page 60).

2 Select **File > New > Dictionary Repository**.

   The New Repository dialog box appears.

3 Enter the following information:

   The values you enter here must match the values you specified during the Central Coding software installation.

   - **Oracle Server**—Oracle database server connection string.

   - **SYS Password**—Oracle password.

- **Schema Owner**—Name of the coding dictionary database user.

  - This must be the same name that was entered for the **Central Coding Dictionary User** during the Central Coding installation.

  - This name is also required when creating a connection to the database.

    For more information, see *Creating a connection to the database* (on page 62).

- **Schema Password** and **Confirm Schema Password**—Password for the coding dictionary database user.

  - This must be the same password that was entered for the **Central Coding Dictionary User** during the Central Coding installation.

  - This password is also required when connecting to the database.

    For more information, see *Connecting to the database* (on page 63).

- **Tablespace**—The tablespace for the coding dictionaries.

  The example used in this guide is **coding**.

  > **Note:** For more information about the Oracle fields, see *Create the database and tablespaces* (on page 22). For instructions on installing the Central Coding software, see *Installing the Central Coding software* (on page 29).

4 Click **OK**.

Messages appear in a window as the repository is created.

When repository creation is complete:

- A message appears in the Output pane in the Dictionary Loader tool.

- The log for the job is available at ...\Central Coding Application\DictionaryLoader\Setup\CreateRepository.log.

Creating a connection to the database

Use this procedure to create a connection to the database. Connections are created within repositories. Although you can create multiple connections, only one connection can be active at a time.

> **Note:** If a connection is already active, select **File > Disconnect** before beginning this procedure.

1 If not already started, launch the Dictionary Loader tool.

For more information, see *Launching the Dictionary Loader tool* (on page 60).

2 In the **Dictionary Loader** tool, select **File** > **New** > **Connection**.

The Connection Information dialog box appears.

3 Enter the following information:

- **Connection Name**—Unique name for the connection.

- **Server**—Oracle connection string for the database.

- **User Name**—Name of the coding dictionary database user that was created when the

repository was set up.

This is the name you entered in the **Schema Owner** field in the **New Repository** dialog box. For more information, see *Creating a dictionary repository* (on page 61).

> **Note:** For more information about the Oracle fields, see *Create the database and tablespaces* (on page 22). For instructions on installing the Central Coding software, see *Installing the Central Coding software* (on page 29).

4   Click **Save**.

The connection is created. It appears in the Data Connections tree view in the left pane of the Dictionary Loader tool dialog box.

> **Note:** If the connection does not appear in the tree, close the Dictionary Loader tool and open it again.

Connecting to the database

Use this procedure to connect to an existing database connection.

1   If not already started, launch the Dictionary Loader tool.

For more information, see *Launching the Dictionary Loader tool* (on page 60).

2   In the **Dictionary Loader** tool, select a connection from the **Data Connections** tree view in the left pane.

3   Select **File > Connect**.

The Connection Information dialog box appears.

4   Type the password that was created when the repository was set up.

This is the name you entered in the **Schema Password** field in the New Repository dialog box. For more information, see *Creating a dictionary repository* (on page 61).

5   Click **Connect**.

When the connection is established:

- A **Dictionaries** node is added to the Data Connections tree for this connection.

  Select this node for information about the installed dictionaries.

- A **Types** node is added to the Data Connections tree for this connection.

  Select this node for information about the installed dictionary types.

Viewing the dictionary types for a connection

Use this procedure to view information about the dictionary types that are available for a connection. When the dictionary types appear in the Dictionary Loader tool, the **Dictionary Types** menu options are active.

1   If not already started, launch the Dictionary Loader tool.

For more information, see *Launching the Dictionary Loader tool* (on page 60).

2   If not already connected, select a connection and connect to the database.

For more information, see *Connecting to the database* (on page 63).

3   In the **Data Connections** tree in the left pane, select the **Types** node for the active connection.

Information about the Dictionary Types for this connection appears in the top pane.

4   If the dictionary type file for the coding dictionary you want to load does not appear in the Dictionary Loader tool, you can import the dictionary type.

For more information, see *Importing the dictionary type file* (on page 64).

Importing the dictionary type XML file

Use this procedure to import the dictionary type XML file for the dictionary that you want to load.

1   If not already started, launch the Dictionary Loader tool.

For more information, see *Launching the Dictionary Loader tool* (on page 60).

2   If not already connected, select a connection and connect to the database.

For more information, see *Connecting to the database* (on page 63).

3   In the **Data Connections** tree in the left pane, select the **Types** node for the active connection.

Information about the Dictionary Types for this connection appears in the top pane.

4   Select **Dictionary Type > Import**.

The Locate Files dialog box appears.

5   Browse to the folder that contains the XML file to import.

The Central Coding software includes XML files for the standard dictionary types in ...\Central Coding Application\DictionaryLoader\Setup.

- MedDRA_DictionaryType.xml

- MedDRAJ_DictionaryType.xml

- WHODD_DictionaryType.xml

- JDrug_DictionaryType.xml

> **Note:** If you created a custom dictionary type, browse to the file you created. For more information, see *Creating a new dictionary type for a custom dictionary* (on page 70).

6   Select a file and click **Open**.

The full path to the XML file appears in the Location field.

7   Click **OK**.

When the import is complete, a message appears in the Output pane and information about the dictionary type appears at the top of the Dictionary Types pane.

Loading standard dictionaries

Overview of the steps to load a standard coding dictionary

Steps to load a standard coding dictionary	
Step	Description
1 If you are using a WHO-DD dictionary, determine whether you are using a pre-ICH or ICH format of the dictionary.	For more information, see: • *About pre-ICH and ICH formats of the WHO-DD dictionary* (on page 65). • *Loading a pre-ICH version of the WHO-DD dictionary* (on page 66).
2 Make sure that the dictionary type for the dictionary that you want to load has been imported.	For more information, see *Importing the dictionary type XML file* (on page 64).
3 Make sure that the dictionary connection is established.	For more information, see *Viewing the dictionaries available for a database connection* (on page 66).
4 *Generate the schema for a dictionary* (on page 67).	The Dictionary Loader tool uses dictionary types to create dictionary schemas.
5 *Load the dictionary data* (on page 68).	Use to load dictionary data into the database using the schema that was generated when you created a new dictionary schema. The dictionary schema must exist before you can load data into it.
6 *Activate the dictionary* (on page 68).	Dictionaries must be activated in order to be used for coding.

About pre-ICH and ICH formats of the WHO-DD dictionary

The format of the WHO-DD C dictionary files was changed for compliance with the ICH guidelines for drug dictionaries. The Central Coding application ships with the control files for both the pre-ICH and ICH dictionary formats. You can load either format of the WHO-DD dictionary for use in the Central Coding application.

• **ICH format**—An ICH version of the WHO-DD dictionary is one released in or after March 2006.

  The control files for the ICH version of the dictionary are stored in two locations:

  • ...\Central Coding Application\Dictionary Loader\bin\setup\control files\whodd

  • ...\Central Coding Application\Dictionary Loader\bin\setup\control files\whodd\ICH

  The Central Coding application is set up by default to use the ICH version of the WHO-DD dictionary. Therefore, if you want to use this dictionary format, no changes to the control files are required.

• **Pre-ICH format**—A pre-ICH version of the WHO-DD dictionary is one released prior to

March 2006.

The control files for the pre-ICH version of the dictionary are stored in:

* ...\Central Coding Application\Dictionary Loader\bin\setup\control files\whodd\Pre-ICH

If you want to use this dictionary format, you must copy the control files to a different directory.

For more information, see *Loading a pre-ICH version of the WHO-DD dictionary* (on page 66).

Loading a pre-ICH version of the WHO-DD dictionary

> **Note:** Use this procedure only if you plan to load a pre-ICH version of the WHO-DD dictionary. A pre-ICH version of the WHO-DD dictionary is one released prior to March 2006.

1   Navigate to **...\Central Coding Application\DictionaryLoader\bin\setup\control files\whodd**.

2   Delete the control files (CTRL) from the **whodd** directory.

    The control files for the ICH dictionary format are also stored in ...\Central Coding Application\Dictionary Loader\bin\setup\control files\whodd\ICH so that they are available if you decide to use the ICH dictionary format at a later time.

3   Navigate to **...\Central Coding Application\DictionaryLoader\bin\setup\control files\whodd\Pre-ICH** and copy the **CTRL** files into the **...\Central Coding Application\DictionaryLoader\bin\setup\control files\whodd** directory.

Viewing the dictionaries available for a database connection

> **Note:** When the **Dictionaries** node is selected, the **Dictionary** menu options are active.

1   If not already started, launch the Dictionary Loader tool.

    For more information, see *Launching the Dictionary Loader tool* (on page 60).

2   If not already connected, select a connection and connect to the database.

    For more information, see *Connecting to the database* (on page 63).

3   In the **Data Connections** tree in the left pane, select the **Dictionaries** node for the active connection.

    The Dictionaries pane displays one row of information for every dictionary associated with this connection.

Dictionary statuses

Dictionary statuses	
Status	Description
DEFINED	The type, version, culture, and schema that hold data for the dictionary are defined. Data is not loaded into the schema.
LOADED	Data is loaded into the schema for the defined dictionary.
ACTIVE	The dictionary is defined, data is loaded into the schema, and the dictionary is available for coding. Only dictionaries with an ACTIVE status are available for coding.
INACTIVE	The dictionary is defined and data is loaded into the schema, but the dictionary is not available for coding.
REMOVED	The schema and data associated with the dictionary are deleted.

Generating the schema for the dictionary data

> **Note:** The Dictionary Loader tool uses dictionary types to create dictionary schemas.

1 If not already started, launch the Dictionary Loader tool.

   For more information, see *Launching the Dictionary Loader tool* (on page 60).

2 If not already connected, select a connection and connect to the database.

   For more information, see *Connecting to the database* (on page 63).

3 Verify that the dictionary type for the dictionary that you want to create has been imported.

   If necessary, import the dictionary type. For more information, see *Importing the dictionary type file* (on page 64).

4 In the **Data Connections** tree in the left pane, select the **Dictionaries** node for the active connection.

   Information about the Dictionary Types for this connection appears in the top pane.

5 Select **File > New > Dictionary**.

   The New Dictionary dialog box appears.

6 Enter the following information:

   • **Type**—Dictionary type that exists for this connection. Standard dictionary types are WHO-DD and MedDRA. If you imported custom types, they appear in the drop-down list.

   • **Version**—The version of the dictionary. For example, 06Q4 identifies the 2006 Q4 version for WHO-DD; 9.1 identifies the 9.1 version for MedDRA. 30 characters maximum.

   • **Culture**—The culture setting for the dictionary data. For example, en-US. 10 characters maximum.

   • **Punctuation Filter**—The characters that are to be considered as punctuation by the coding algorithm in the step that removes punctuation. OPTIONAL. 100 characters maximum.

- **Description**—A brief description of the dictionary. OPTIONAL. 200 characters maximum.

- **Owner for Schema**—The unique name for the schema.

- **Schema Password**—The password for this dictionary schema.

- **Confirm Schema Password**—The password for this dictionary schema.

- **SYS Password**—The password for the Oracle user account.

- **Tablespace**—The name of the tablespace that was created for the dictionaries.

7   Click **OK**.

When the dictionary has been created, a message appears in the Output pane and information about the dictionary appears in the Dictionaries list in the top pane in the Dictionary Loader tool.

Loading dictionary data

Use this procedure to load dictionary data into the database using the schema that was generated when you created a new dictionary schema. The dictionary schema must exist before you can load data into it. For more information, see *Generating the schema for a dictionary* (on page 67).

1   If not already started, launch the Dictionary Loader tool.

For more information, see *Launching the Dictionary Loader tool* (on page 60).

2   If not already connected, select a connection and connect to the database.

For more information, see *Connecting to the database* (on page 63).

3   In the **Data Connections** tree in the left pane, select the **Dictionaries** node for the active connection.

Information about the Dictionaries for this connection appears in the top pane.

4   In the **Dictionaries** pane, select the dictionary into which you want to load data.

5   Select **Dictionary > Load**.

The Locate Files dialog box appears.

6   Enter the following information:

- **Location**—Browse to the folder that contains the file with the dictionary data to load.

  Select a directory and click **Open**. The full path to the files appears in the Location field.

- **Dictionary schema password**—Password for this dictionary schema, which was created when the dictionary was created.

7   Click **OK**.

The dictionary data loads. Messages appear in the Output pane in the Dictionary Loader tool. When the load is complete, you can check the log file to verify the status of the load operation. The log file is in ...\DictionaryLoader\Setup\gather_stats_[schemaowner].log.

Activating the dictionary

> **Note:** Dictionaries must have a status of ACTIVE in order to be available for coding.

1   If not already started, launch the Dictionary Loader tool.

For more information, see *Launching the Dictionary Loader tool* (on page 60).

2   If not already connected, select a connection and connect to the database.

For more information, see *Connecting to the database* (on page 63).

3   In the **Data Connections** pane, select a connection.

4   Select **Dictionary > Activate**.

The dictionary status changes to ACTIVE. The dictionary is defined, data is loaded into the schema, and the dictionary is available for coding. Only dictionaries with an ACTIVE status are available for coding.

Loading custom dictionaries

Overview of the steps to load a custom dictionary

Steps to load a custom coding dictionary	
Step	**Description**
1 *Create a custom dictionary definition XML file* (on page 70).	Use to create an XML file that contains the metadata for the dictionary levels and the SQL needed to set up the tables in the database.
2 Create a new dictionary type for a custom dictionary.	For more information, see *Creating a new dictionary type for a custom dictionary* (on page 70).
3 Import the dictionary type XML file.	For more information, see *Importing the dictionary type XML file* (on page 64).
4 View the dictionaries available for a database connection.	For more information, see *Viewing the dictionaries available for a database connection* (on page 63).
5 *Generate the schema for a dictionary* (on page 67).	The Dictionary Loader tool uses dictionary types to create dictionary schemas.
6 *Load dictionary data* (on page 68).	Use to load dictionary data into the database using the schema that was generated when you created a new dictionary schema. The dictionary schema must exist before you can load data into it.
7 *Activate the dictionary* (on page 68).	Dictionaries must be activated in order to be used for coding.
8 *Create custom icons for the coding browser* (on page 76).	Use to create custom dictionary icons for use in the coding browser Browse mode.

Creating a custom dictionary definition XML file

Use the standard XML files for the MedDRA, MedDRA-J, WHO-DD, and JDrug dictionaries as the basis for your custom XML files. These files are in
...Central Coding Application\DictionaryLoader\Setup.

For the **DictionaryType** element:

- **adaptertype** sub-element must be **Custom**.

- **numlevels** must be greater than 0 and must equal the number of **Level** elements.

Creating a new dictionary type for a custom dictionary

1   If not already started, launch the Dictionary Loader tool.

For more information, see ***Launching the Dictionary Loader tool*** (on page 60).

2   If not already connected, select a connection and connect to the database.

For more information, see ***Connecting to the database*** (on page 63).

3   Select the **Types** node for the active connection from the **Data Connections** tree in the left pane.

Information about the Dictionary Types for this connection appears in the top pane.

4   Select **File > New > New Dictionary Type**.

The New Type dialog box appears.

When working in the grid:

- Each row represents one level in the dictionary.

- Use the buttons to add and remove levels and to change the order of levels for the dictionary type.

- Create at least one level.

- Create the same number of terms (one or two) at each level.

5   Enter the following information:

- **Type**—The name for the new dictionary type.

- **Description**—A description of the dictionary type. OPTIONAL.

- **Supports Stopwords**—Select if you want to run the algorithm step(s) that remove stopwords from the text to be coded for dictionaries of this type.

- **Term**—A label for the first term of this level.

- **Additional Information**—A label for each additional level of the dictionary. Separate each additional information item with a pipe (**|**).

- **Abbreviation**—An abbreviated name to identify this level.

  The full name of this level is the label for the first term, concatenated with the label for the second term.

- **Tablename**—The name of the table to create in the schema of a dictionary of this type to hold data for this level.

- **Filename**—The name of the flat file that contains the data for this level.

- **Encoding**—The encoding type of the file specified in the Filename field. OPTIONAL.

  If not specified, the default encoding type is used.

- **Delimiter**—The field delimiter used in records in the file specified in the Filename field. OPTIONAL.

  If not specified, the default delimiter is used.

6   Click **OK**.

The custom dictionary type is added to the Dictionary Types pane in the Dictionary Loader tool.

Importing the dictionary type XML file

Use this procedure to import the dictionary type XML file for the dictionary that you want to load.

1   If not already started, launch the Dictionary Loader tool.

    For more information, see *Launching the Dictionary Loader tool* (on page 60).

2   If not already connected, select a connection and connect to the database.

    For more information, see *Connecting to the database* (on page 63).

3   In the **Data Connections** tree in the left pane, select the **Types** node for the active connection.

    Information about the Dictionary Types for this connection appears in the top pane.

4   Select **Dictionary Type > Import**.

    The Locate Files dialog box appears.

5   Browse to the folder that contains the XML file to import.

    The Central Coding software includes XML files for the standard dictionary types in
    ...\Central Coding Application\DictionaryLoader\Setup.

    - MedDRA_DictionaryType.xml

    - MedDRAJ_DictionaryType.xml

    - WHODD_DictionaryType.xml

    - JDrug_DictionaryType.xml

    > **Note:** If you created a custom dictionary type, browse to the file you created. For more
    > information, see *Creating a new dictionary type for a custom dictionary* (on page 70).

6   Select a file and click **Open**.

    The full path to the XML file appears in the Location field.

7   Click **OK**.

    When the import is complete, a message appears in the Output pane and information about the
    dictionary type appears at the top of the Dictionary Types pane.

Viewing the dictionary types for a connection

Use this procedure to view information about the dictionary types that are available for a connection.
When the dictionary types appear in the Dictionary Loader tool, the **Dictionary Types** menu options
are active.

1   If not already started, launch the Dictionary Loader tool.

    For more information, see *Launching the Dictionary Loader tool* (on page 60).

2   If not already connected, select a connection and connect to the database.

    For more information, see *Connecting to the database* (on page 63).

3   In the **Data Connections** tree in the left pane, select the **Types** node for the active connection.

Information about the Dictionary Types for this connection appears in the top pane.

4   If the dictionary type file for the coding dictionary you want to load does not appear in the Dictionary Loader tool, you can import the dictionary type.

For more information, see *Importing the dictionary type file* (on page 64).

Dictionary statuses

Dictionary statuses	
Status	Description
DEFINED	The type, version, culture, and schema that hold data for the dictionary are defined. Data is not loaded into the schema.
LOADED	Data is loaded into the schema for the defined dictionary.
ACTIVE	The dictionary is defined, data is loaded into the schema, and the dictionary is available for coding. Only dictionaries with an ACTIVE status are available for coding.
INACTIVE	The dictionary is defined and data is loaded into the schema, but the dictionary is not available for coding.
REMOVED	The schema and data associated with the dictionary are deleted.

Generating the schema for the dictionary data

> **Note:** The Dictionary Loader tool uses dictionary types to create dictionary schemas.

1   If not already started, launch the Dictionary Loader tool.

For more information, see *Launching the Dictionary Loader tool* (on page 60).

2   If not already connected, select a connection and connect to the database.

For more information, see *Connecting to the database* (on page 63).

3   Verify that the dictionary type for the dictionary that you want to create has been imported.

If necessary, import the dictionary type. For more information, see *Importing the dictionary type file* (on page 64).

4   In the **Data Connections** tree in the left pane, select the **Dictionaries** node for the active connection.

Information about the Dictionary Types for this connection appears in the top pane.

5   Select **File > New > Dictionary**.

The New Dictionary dialog box appears.

6   Enter the following information:

- **Type**—Dictionary type that exists for this connection. Standard dictionary types are WHO-DD and MedDRA. If you imported custom types, they appear in the drop-down list.

- **Version**—The version of the dictionary. For example, 06Q4 identifies the 2006 Q4 version

for WHO-DD; 9.1 identifies the 9.1 version for MedDRA. 30 characters maximum.

- **Culture**—The culture setting for the dictionary data. For example, en-US. 10 characters maximum.

- **Punctuation Filter**—The characters that are to be considered as punctuation by the coding algorithm in the step that removes punctuation. OPTIONAL. 100 characters maximum.

- **Description**—A brief description of the dictionary. OPTIONAL. 200 characters maximum.

- **Owner for Schema**—The unique name for the schema.

- **Schema Password**—The password for this dictionary schema.

- **Confirm Schema Password**—The password for this dictionary schema.

- **SYS Password**—The password for the Oracle user account.

- **Tablespace**—The name of the tablespace that was created for the dictionaries.

7   Click **OK**.

When the dictionary has been created, a message appears in the Output pane and information about the dictionary appears in the Dictionaries list in the top pane in the Dictionary Loader tool.

Loading dictionary data

Use this procedure to load dictionary data into the database using the schema that was generated when you created a new dictionary schema. The dictionary schema must exist before you can load data into it. For more information, see *Generating the schema for a dictionary* (on page 67).

1   If not already started, launch the Dictionary Loader tool.

For more information, see *Launching the Dictionary Loader tool* (on page 60).

2   If not already connected, select a connection and connect to the database.

For more information, see *Connecting to the database* (on page 63).

3   In the **Data Connections** tree in the left pane, select the **Dictionaries** node for the active connection.

Information about the Dictionaries for this connection appears in the top pane.

4   In the **Dictionaries** pane, select the dictionary into which you want to load data.

5   Select **Dictionary > Load**.

The Locate Files dialog box appears.

6   Enter the following information:

- **Location**—Browse to the folder that contains the file with the dictionary data to load.

  Select a directory and click **Open**. The full path to the files appears in the Location field.

- **Dictionary schema password**—Password for this dictionary schema, which was created when the dictionary was created.

7   Click **OK**.

The dictionary data loads. Messages appear in the Output pane in the Dictionary Loader tool. When the load is complete, you can check the log file to verify the status of the load operation.

The log file is in ...\DictionaryLoader\Setup\gather_stats_[schemaowner].log.

Activating the dictionary

> **Note:** Dictionaries must have a status of ACTIVE in order to be available for coding.

1   If not already started, launch the Dictionary Loader tool.

For more information, see *Launching the Dictionary Loader tool* (on page 60).

2   If not already connected, select a connection and connect to the database.

For more information, see *Connecting to the database* (on page 63).

3   In the **Data Connections** pane, select a connection.

4   Select **Dictionary > Activate**.

The dictionary status changes to ACTIVE. The dictionary is defined, data is loaded into the schema, and the dictionary is available for coding. Only dictionaries with an ACTIVE status are available for coding.

Using custom icons in the coding browser

The coding browser in the Central Coding application displays icons for the levels of the coding dictionary. When you create a custom dictionary, you must also provide the icons for the coding browser.

To identify the custom dictionary icons to use in the coding browser:

1   Copy the graphics for the icons to the Resources folder in the virtual directory where the Central Coding application is running.

2   Use the following naming convention for the custom icons:

```
<dictionary type>_<tablename for the level>.gif
```
where:

- **<dictionary type>** is the name of the XML file that defines the dictionary type.

  For more information, see *Creating a custom dictionary definition XML file* (on page 70).

- **<tablename for the level>** is the name of the Oracle table, where the data for that level is stored.

For example, if a custom dictionary type XML file is named **CustomTest.xml** and it has three levels named **soc**, **pt**, and **llt**, name the icons for the levels as follows:

- CustomTest_soc.gif

- CustomTest_pt.gif

- CustomTest_llt.gif

Installing the language packs for the Japanese dictionaries

Use this procedure to install the language pack for the MedDRA-J or JDrug dictionary. The language pack displays the dictionary level names and additional information labels in Japanese in the user interface.

1   If not already started, launch the Dictionary Loader tool.

    For more information, see *Launching the Dictionary Loader tool* (on page 60).

2   Make sure that the dictionary database is set up, that you are connected to the database, and that the dictionary or dictionaries are loaded.

    For more information, see *Setting up the dictionary database* (on page 61) and *Loading dictionaries* (on page 55).

3   In the **Data Connections** tree in the left pane, select the **Types** node for the active connection.

    Information about the Dictionary Types for this connection appears in the top pane.

4   Select the **Dictionary Type** for which you want to install the language pack.

5   Select **Dictionary Type > Localized Elements**.

    The Localized Elements dialog box appears.

6   Click **Import**.

    The Locate Files dialog box appears.

7   Browse to the **<LanguagePack>.xml** file that you want to install.

    The Central Coding software includes XML files for the standard dictionary types in ...\Central Coding Application\DictionaryLoader\Setup.

    •   MedDRA_ja-JP.xml

    •   JDrug_ja-JP.xml

8   Click **OK**.

Maintaining the coding dictionaries

Overview of the coding dictionary maintenance tasks

You can perform the following dictionary maintenance tasks:

- *Change the punctuation filter for a dictionary type* (on page 78).
- *Update a dictionary type* (on page 79).
- *Delete a dictionary type* (on page 80).
- *Inactivate a dictionary* (on page 81).
- *Delete a connection to the database* (on page 81).
- *Remove a dictionary schema* (on page 81).
- *Revive a dictionary schema* (on page 82).
- *Delete a dictionary* (on page 83).

Changing the punctuation filter for a dictionary type

Use this procedure to change the characters in the punctuation filter for a dictionary type. The punctuation filter identifies characters that you want the coding algorithm to consider as punctuation in the step that removes punctuation.

1   If not already started, launch the Dictionary Loader tool.

    For more information, see *Launching the Dictionary Loader tool* (on page 60).

2   If not already connected, select a connection and connect to the database.

    For more information, see *Connecting to the database* (on page 63).

3   Select the **Types** node for the active connection from the **Data Connections** tree in the left pane.

    Information about the Dictionary Types for this connection appears in the top pane.

4   Select a row to select the dictionary type that you want to modify.

    An arrow appears in the column to the left of the Type column.

5   Select **Dictionary > Change Punctuation Filter**.

    The Punctuation Filter dialog box appears.

6   Add or remove characters as necessary.

7   Click **OK**.

Updating a dictionary type and applying the changes to installed dictionaries

Use this procedure to apply changes from a <Dictionary_Type>.xml file to installed dictionaries. For more information, see **About dictionary types** (on page 57) and the *User Guide*.

> **Note:** The <Dictionary_Type>.xml file contains, among other things, the element configuration settings for each dictionary type (MedDRA, MedDRA-J, WHO-DD, JDrug, and custom). These settings control which coding features and information are available to users in the Central Coding user interface. For more information, see the *User Guide*.

1   If not already started, launch the Dictionary Loader tool.

    For more information, see **Launching the Dictionary Loader tool** (on page 60).

2   If not already connected, select a connection and connect to the database.

    For more information, see **Connecting to the database** (on page 63).

3   Select the **Types** node for the active connection.

4   Select a dictionary type.

5   Select **Dictionary Type > Update**.

    The Locate Files dialog box appears.

6   Browse to the **<Dictionary_Type>.xml** file that you want to use for the update.

    The Central Coding software includes XML files for the standard dictionary types in ...\Central Coding Application\DictionaryLoader\Setup.

    - MedDRA_DictionaryType.xml

    - MedDRAJ_DictionaryType.xml

    - WHODD_DictionaryType.xml

    - JDrug_DictionaryType.xml

    If you are using a custom dictionary type, browse to the file you created. For more information, see **Creating a new dictionary type for a custom dictionary** (on page 70).

7   Click **OK**.

    The Dictionary Selection Form dialog box appears.

8   Select one or more versions of the dictionary.

9   Click **OK**.

Converting the WHO-DD dictionary to C format

Using the Dictionary Loader to convert the WHO-DD dictionary to C format

Use this procedure to convert a WHO-DD dictionary in B format to C format.

1   If not already started, launch the Dictionary Loader tool.

    For more information, see **Launching the Dictionary Loader tool** (on page 60).

2   If not already connected, select a connection and connect to the database.

For more information, see *Connecting to the database* (on page 63).

3   In the **Data Connections** tree in the left pane, select the **Dictionaries** node for the active connection.

Information about the dictionaries for this connection appears in the top pane.

4   Select the WHO-DD B format dictionary.

5   Select **Dictionary > Convert WHODD B to C**.

The Locate File dialog box appears.

6   Click **Browse** and locate the folder that contains WHO-DD B format dictionary files.

7   Select the directory and click **Open**.

The full path to the files appears in the **Location** field.

Using the ConvertToC utility to convert the WHO-DD dictionary to C format

Use this procedure to convert a WHO-DD dictionary in B format to C format.

1   Open a Command Prompt window and type the name of the drive in which the executable file is installed.

> **Note:** By default, the executable file is installed in the same location as the Central Coding application.

2   Type the location of the executable file in the drive that you specified.

3   Type the following syntax for converting the WHO-DD B format dictionary to C format:

ConvertToC [File Path]

where

*   **File Path**—Path for the location of the WHO-DD B format dictionary files.

The ConvertToC utility creates a folder called **C** in the folder in which the WHO-DD B format dictionary files are installed.

Deleting a dictionary type

Use this procedure to delete a dictionary type. You can delete dictionary types that do not have schemas associated with them. If a dictionary schema that uses this dictionary type exists, you must delete the schema before you can delete the dictionary type. For more information, see *Removing a dictionary schema* (on page 81).

1   If not already started, launch the Dictionary Loader tool.

For more information, see *Launching the Dictionary Loader tool* (on page 60).

2   If not already connected, select a connection and connect to the database.

For more information, see *Connecting to the database* (on page 63).

3   In the **Data Connections** tree in the left pane, select the **Types** node for the active connection.

Information about the Dictionary Types for this connection appears in the top pane.

4   Select **Dictionary Type > Delete**.

A confirmation dialog box appears.

5   Click **Yes**.

Inactivating a dictionary

Use this procedure to inactivate a dictionary. Inactive dictionaries remain in the list of dictionaries for a connection and can be reactivated if necessary.

> **Note:** You must inactivate a dictionary before you can delete it.

1   If not already started, launch the Dictionary Loader tool.

For more information, see *Launching the Dictionary Loader tool* (on page 60).

2   If not already connected, select a connection and connect to the database.

For more information, see *Connecting to the database* (on page 63).

3   Select the **Dictionaries** node for the active connection.

4   Select a dictionary.

5   Select **Dictionary > Inactivate**.

The dictionary status changes to INACTIVE. The dictionary is defined and data is loaded into the schema, but the dictionary is not available for coding.

Deleting a connection to the database

Use this procedure to delete a connection to the database. Deleted connections remain visible in the Data Connections tree view in the left pane of the Dictionary Loader tool until you close the dialog box.

1   If not already started, launch the Dictionary Loader tool.

For more information, see *Launching the Dictionary Loader tool* (on page 60).

2   If not already connected, select a connection and connect to the database.

For more information, see *Connecting to the database* (on page 63).

3   Select **Connection > Delete**.

Removing a dictionary schema

Use this procedure to remove a dictionary, which removes the dictionary schema and all data. When you remove a dictionary schema, all synonym lists, coding definitions, assignment rules, and requests entered against the dictionary are lost and cannot be retrieved.

> **Caution:** Oracle recommends that you do not remove the dictionary schema or delete a dictionary that has been used for coding. Only delete dictionaries that you have set up but not coded against.

1   If not already started, launch the Dictionary Loader tool.

For more information, see *Launching the Dictionary Loader tool* (on page 60).

2   If not already connected, select a connection and connect to the database.

For more information, see *Connecting to the database* (on page 63).

3   Make sure that you have inactivated the dictionary whose dictionary schema you want to remove.

For more information, see *Inactivating a dictionary* (on page 81).

4   Select the **Dictionaries** node for the active connection.

5   Select a dictionary to remove.

6   Select **Dictionary > Remove**.

A confirmation dialog box appears.

7   Click **Yes**.

A dialog box appears and prompts you for the SYS user password.

8   Enter the password and click **OK**.

The dictionary remains in the list of Dictionaries. The dictionary status changes to REMOVED.

> **Note:** You must revive this dictionary type before you can use it again to load dictionaries.
> For more information, see *Reviving a dictionary schema* (on page 82).

Reviving a dictionary schema

Use this procedure to revive a dictionary schema, which recreates the schema of a previously removed dictionary. For more information, see *Removing a dictionary schema* (on page 81). After reviving a dictionary schema, you can load data into the dictionary.

1   If not already started, launch the Dictionary Loader tool.

For more information, see *Launching the Dictionary Loader tool* (on page 60).

2   If not already connected, select a connection and connect to the database.

For more information, see *Connecting to the database* (on page 63).

3   Select the **Dictionaries** node for the active connection.

4   Select a dictionary.

You can only revive dictionaries that have a status of REMOVED.

5   Select **Dictionary > Revive**.

The New Dictionary dialog box appears. The information in most fields is read-only because it already exists in the database.

6   Enter the following information, and click **OK**.

- **Schema Password**—The password for this dictionary schema.

- **Confirm Schema Password**—The password for this dictionary schema.

- **SYS Password**—The password for the Oracle user account.

- **Tablespace**—The name of the tablespace that was created for the dictionaries.

Deleting a dictionary

Use this procedure to permanently remove a dictionary from the Central Coding system. Deleted dictionaries cannot be revived or reactivated. When you delete a dictionary, all synonym lists, coding definitions, assignment rules, and requests entered against the dictionary become invalid and cannot be retrieved.

> **Caution:** Oracle recommends that you do not remove the dictionary schema or delete a dictionary that has been used for coding. Only delete dictionaries that you have set up but not coded against.

1   If not already started, launch the Dictionary Loader tool.

    For more information, see *Launching the Dictionary Loader tool* (on page 60).

2   If not already connected, select a connection and connect to the database.

    For more information, see *Connecting to the database* (on page 63).

3   Make sure that you have removed the schema for the dictionary that you want to delete.

    For more information, see *Removing a dictionary schema* (on page 81).

4   Select the **Dictionaries** node for the active connection.

5   Select a dictionary.

6   Select **Dictionary > Delete**.

    A confirmation dialog box appears.

7   Click **Yes**.

    A dialog box appears and prompts you for the SYS user password.

8   Enter the password and click **OK**.

C H A P T E R 6

Setting up coding metadata using the command line

In this chapter

Using the Data Installer

About the Data Installer

The Central Coding software includes a command line application, called the Data Installer, that you can use to import data instead of entering the data through the user interface, and to export the data.

The Data Installer is installed automatically as part of the Central Coding software installation in **...\Central Coding Application\CentralCodingServer\CodingWebUI\bin**.

You can use the Data Installer to:

- Export and import synonym lists, stopword lists, coding algorithms, and coding definitions.

  > **Note:** You cannot update coding definitions. You can replace or update a synonym list.

- Import assignment rules.

  > **Note:** You cannot update assignment rules.

- Export and import security data such as users, rights, roles, and workteams from an existing installation to another installation.

  > **Note:** Security data cannot be created manually. You must export it and then import it to the new instance.

- Export and import system settings such as the authentication options, application settings and lock management options, and impact analysis options from an existing installation to another installation.

> **Note:** Oracle recommends that you use the Data Installer to export data from a configured instance of the Central Coding application, and import the data file as is, or edit it and perform an update. Oracle does not recommend creating your own configuration file for import.

Data Installer modes

The Data Installer has three modes:

- **Download**—Used to export data from the Central Coding application.

  When you export data using the Download mode, an export configuration XML file is created. You can use this file with the Data Installer to import or update data in the Central Coding application.

- **Setup**—Used to import data into the Central Coding application.

  To import data in the Central Coding application, you can use the export configuration XML file that is created when you run the Data Installer in Download mode, a manually created XML configuration file, or the sample XML configuration file called **MasterConfig.xml**, which you can edit as needed.

- **Update**—Used to update existing data in the Central Coding application.

  To update data in the Central Coding application, you can use the export configuration XML file

that is created when you run the Data Installer in Download mode, a manually created XML configuration file, or the sample XML configuration file called **MasterConfig.xml**, which you can edit as needed.

> **Note:** The sample XML file is installed in the same location as the Data Installer.

Data Installer parameters

Parameter	Description
ApplicationName	Name of the Central Coding application. The application name is located in the PhaseForward.Platform.Config.xml file, which is installed in the same directory as the Data Installer. The default application name is CentralCodingApplication.
Mode	Type of action to perform. The available options are: • **Download**—Export data from the Central Coding application. • **Setup**—Import data to the Central Coding application. • **Update**—Update existing data in the Central Coding application. **Note:** When using the Data Installer in Update mode, make sure that the GUIDs for the data in the update configuration file do not already exist in the Central Coding application. If duplicate GUIDs exist, the Data Installer displays an error message and the update does not complete.
Type	Always **SysConfig**.
MasterFile	Path to the master configuration file, called MasterConfig.xml. The master configuration file is installed in the same directory as the Data Installer.
/DISABLESINGLETRANSACTION	Instructs the Data Installer to execute each transaction separately. By default, the Data Installer executes all commands in a single transaction.

Exporting data with the Data Installer

To export data from an instance of the Central Coding application, use the Data Installer in Download mode. You can export synonym lists, stopword lists, coding algorithms, coding definitions, and system settings.

1   Specify the data to export:

  • Edit an existing configuration file.

  • Create a configuration file.

  Make sure to specify the directory path in which to generate the export files.

  > **Note:** The directory must exist before you run the Data Installer.

2   Open a Command Prompt window and type the name of the drive in which the Data Installer is installed.

3   Type the location of the Data Installer in the drive you specified:

  ...\Central Coding Application\CentralCodingServer\CodingWebUI\bin

4   Run the utility in Download mode, using the following syntax:

  ```
  PhaseForward.Platform.Installation.DataInstaller.exe [ApplicationName]
  [Download] [SysConfig] [MasterFile]
  ```
    where:

  • **ApplicationName**—Name of the Central Coding application. The application name is located in the **PhaseForward.Platform.Config** config file, which is installed in the same directory as the Data Installer. The default application name is CentralCodingApplication.

  • **MasterFile**—Path to the master configuration file. The master configuration file is called **MasterConfig.xml**, and is located in the same directory as the Data Installer.

The Data Installer extracts the data and generates the XML files in the directory that you specified in the export configuration file.

Importing data with the Data Installer

To import data into an instance of the Central Coding application, use the Data Installer in Setup mode. You can import users, roles, workteams, assignment rules, synonym lists, stopword lists, coding algorithms, and coding definitions.

> **Note:** You cannot import an object if its GUID is already used in the database into which you are importing. If duplicate GUIDs exist, an error message appears, and the import stops.

1   Specify the data to import:

   • Edit an existing configuration file.

   • Create a configuration file.

   • Locate an existing export file.

     For more information about the export procedure, see *Exporting data with the Data Installer* (on page 87).

> **Note:** Oracle recommends that you use the Data Installer to export data from a configured instance of the Central Coding application, and import the data file as is, or edit it and perform an update. Oracle does not recommend creating your own configuration file for import.

   Make sure to specify the directory path of the file to import.

> **Note:** Data in XML files is case-sensitive.

2   Open a Command Prompt window and type the name of the drive in which the Data Installer is installed.

3   Type the location of the Data Installer in the drive you specified:

   ...\Central Coding Application\CentralCodingServer\CodingWebUI\bin

4   Run the utility in Setup mode, using the following syntax:

```
PhaseForward.Platform.Installation.DataInstaller.exe [ApplicationName]
[Setup] [SysConfig] [MasterFile]
where:
```

   • **ApplicationName**—Name of the Central Coding application. The application name is located in the **PhaseForward.Platform.Config** config file, which is installed in the same directory as the Data Installer. The default application name is CentralCodingApplication.

   • **MasterFile**—Path to the master configuration file. The master configuration file is called **MasterConfig.xml**, and is located in the same directory as the Data Installer.

   The Data Installer adds the data to the appropriate tables in the target Central Coding database, based on the import data type.

Updating data with the Data Installer

To update existing data in the Central Coding application using the Data Installer, run the utility in Update mode. You can update users, roles, workteams, synonym lists, stopword lists, coding algorithms, and system settings. You cannot update coding definitions or assignment rules.

> **Note:** You cannot import an object if its GUID is already used in the database into which you are importing. If duplicate GUIDs exist, an error message appears, and the import stops.

1   Specify the data to update:

- Edit an existing configuration file.

- Create a configuration file.

- Locate an existing export file.

  For more information about the export procedure, see ***Exporting data with the Data Installer*** (on page 87).

> **Note:** Oracle recommends that you use the Data Installer to export data from a configured instance of the Central Coding application, and import the data file as is, or edit it and perform an update. Oracle does not recommend creating your own configuration file for import.

Make sure to specify the directory path of the file to use in the update procedure.

> **Note:** Data in XML files is case-sensitive.

2   Open a Command Prompt window and type the name of the drive in which the Data Installer is installed.

3   Type the location of the Data Installer in the drive you specified:

...\Central Coding Application\CentralCodingServer\CodingWebUI\bin

4   Run the utility in Update mode, using the following syntax:

```
PhaseForward.Platform.Installation.DataInstaller.exe [ApplicationName]
[Update] [SysConfig] [MasterFile]
where:
```

- **ApplicationName**—Name of the Central Coding application. The application name is located in the **PhaseForward.Platform.Config** config file, which is installed in the same directory as the Data Installer. The default application name is CentralCodingApplication.

- **MasterFile**—Path to the master configuration file. The master configuration file is called **MasterConfig.xml**, and is located in the same directory as the Data Installer.

The Data Installer adds the data to the appropriate tables in your target Central Coding database, based on the update data type.

Adding adapters and studies using the command line

About adding adapters and studies using the command line

You can add adapters and studies from the user interface, and also through the command line. The following executable files are installed as part of the Central Coding software installation. Run the executable files to install adapters and studies into the Central Coding application.

- **PhaseForward.CentralCoding.SetAdapter.exe**—Installs an adapter to a Central Coding instance.

  When you install the adapter using the executable file, you use the available parameters to define Get Requests and Return Codes schedules for the adapter.

- **PhaseForward.CentralCoding.SetStudyGroup.exe**—Creates a study group in a Central Coding instance.

  When you create a study group, you use the available parameters to specify the study to add to the group, and the Get Requests and Return Codes schedules for the study.

- **PhaseForward.CentralCoding.SetStudy.exe**—Installs a study to a Central Coding instance.

  When you add the study, you use the available parameters to specify which adapter with which to associate the study, and you add the study to Get Requests and Return Codes schedules.

> **Note:** You can only add a study to a Get Requests or Return Codes schedule if the schedule is already defined for the adapter to which you are adding the study.

For a list of available parameters for use with the command line executable files, see *Available parameters* (on page 91).

The files are available in the following location:

```
Phase Forward\[ApplicationName]\CentralCodingServer\CodingWebUI\bin
where
ApplicationName—The name of your Central Coding application.
```

> **Note:** You must run the executable files in the location in which they were installed.

Available parameters

Parameter	Description
SetAdapter.exe	
AdapterName	Name of the adapter to add.
AdapterURL	URL of the adapter to add.
GetVerbatimsSchedule	Rate at which to run the get verbatims job schedule. This parameter corresponds to the Time span configuration setting on the Schedule GetRequests Job page in the user interface. • **0**—Indicates that you will run manual get verbatims jobs for the adapter, and the adapter should not be added to a Get Verbatims schedule. • **1**—Set a Get Verbatim job schedule to run every minute for the adapter. • **5**—Set a Get Verbatim job schedule to run every five minutes for the adapter. • **15**—Set a Get Verbatim job schedule to run every fifteen minutes for the adapter. • **30**—Set a Get Verbatim job schedule to run every thirty minutes for the adapter. **Note:** This parameter is optional. In the Central Coding application, the default value is 15.
ReturnCodesSchedule	Rate at which to run the return codes job schedule. This parameter corresponds to the Time span configuration setting on the Schedule ReturnCodes Job page in the user interface. • **0**—Indicates that you will run manual return codes jobs for the adapter, and the adapter should not be added to a Return Codes schedule. • **1**—Set a Return Codes job schedule to run every minute for the adapter. • **5**—Set a Return Codes job schedule to run every five minutes for the adapter. • **15**—Set a Return Codes job schedule to run every fifteen minutes for the adapter. • **30**—Set a Return Codes job schedule to run every thirty minutes for the adapter. **Note:** This parameter is optional. In the Central Coding application, the default value is 15.

Parameter	Description
SetStudyGroup.exe	
Source Application	The name of the application that is integrated with the Central Coding application. • **InForm** • **Clintrial** • **Other**—Any supported third-party application.
Study Group Name	Name of the study group to add.
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.
AllowAutoQuery	Specify whether to allow 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. • **Y**—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. • **N**—Instructs the Central Coding application not to apply a query to all matching verbatims in the study group.
AllowAutoClose	Specify whether to allow the Central Coding application to automatically close a query if the verbatim associated with the query is successfully coded and approved. • **Y**—Instructs the Central Coding application to automatically close a query if the verbatim associated with the query is successfully coded and approved. • **N**—Instructs the Central Coding application not to automatically close a query if the verbatim associated with the query is successfully coded and approved.
SetStudy.exe	
AdapterName	Name of the adapter to which to add the study.
StudyName	Name of the study to add.
StudyURL	URL for the study to add.
StudyGroupName	Name of the study group to which to add the study. **Note:** The study group must already exist in the Central Coding instance.

Parameter	Description
GetVerbatimsSchedule	Specify whether to add the study to the Get Verbatims schedule for the adapter you specified.
	• **Y**—Indicates that you want to add the study to the Get Verbatims schedule that is defined for the adapter you specified.
	Note: You can only specify **Y** if a Get Verbatims schedule is already defined for the adapter to which you are adding the study.
	• **N**—Indicates that you do not want to add the study to the Get Verbatims schedule that is defined for the adapter you specified.
ReturnCodesSchedule	Specify whether to add the study to the Return Codes schedule for the adapter you specified.
	• **Y**—Indicates that you want to add the study to the Return Codes schedule that is defined for the adapter you specified.
	Note: You can only specify **Y** if a Return Codes schedule is already defined for the adapter to which you are adding the study.
	• **N**—Indicates that you do not want to add the study to the Return Codes schedule that is defined for the adapter you specified.

Adding a study group using the command line

1 Open a Command Prompt window and type the name of the drive in which the executable file is installed.

> **Note:** By default, the executable file is installed in the same location as the Central Coding application.

2 Type the location of the executable file in the drive that you specified:

...\Central Coding Application\CentralCodingServer\CodingWebUI\bin

> **Note:** You must run the application from this directory.

3 Type the following syntax for adding a study group:

PhaseForward.CentralCoding.SetStudyGroup.exe [StudyGroupName] [AllowAutoQuery] [AllowAutoClose]

where

• **StudyGroupName**—Name of the study group to add.

• **AllowAutoQuery**—Specify whether to allow 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.

- **Y**—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.

- **N**—Instructs the Central Coding application not to apply a query to all matching verbatims in the study group.

- **AllowAutoClose**—Specify whether to allow the Central Coding application to automatically close a query if the verbatim associated with the query is successfully coded and approved.

  - **Y**—Instructs the Central Coding application to automatically close a query if the verbatim associated with the query is successfully coded and approved.

  - **N**—Instructs the Central Coding application not to automatically close a query if the verbatim associated with the query is successfully coded and approved.

Adding a study to an adapter and job schedules using the command line

1   Open a Command Prompt window and type the name of the drive in which the executable file is installed.

> **Note:** By default, the executable file is installed in the same location as the Central Coding application.

2   Type the location of the executable file in the drive that you specified:

...\Central Coding Application\CentralCodingServer\CodingWebUI\bin

> **Note:** You must run the application from this directory.

3   Type the following syntax for adding a study to an adapter and job schedules:

PhaseForward.CentralCoding.SetStudy.exe [SourceApplication] [AdapterName] [StudyName] [StudyURL] [StudyGroupName] [GetVerbatimsSchedule] [ReturnCodesSchedule]

where

- **SourceApplication**—The name of the application that is integrated with the Central Coding application.

  - **InForm**

  - **Clintrial**

  - **Other**—Any supported third-party application.

- **AdapterName**—Name of the adapter to which to add the study.

- **StudyName**—Name of the study to add.

- **StudyURL**—URL of the study to add.

- **ClientAuditUser**—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.

- **StudyGroupName**—Name of the study group with which to associate the study.

- **GetVerbatimsSchedule**—Specify whether to add the study to the Get Requests schedule for the adapter you specified.

  - **Y**—Indicates that you want to add the study to the Get Requests schedule that is defined for the adapter you specified.

    > **Note:** You can only specify **Y** if a Get Requests schedule is already defined for the adapter to which you are adding the study.

  - **N**—Indicates that you do not want to add the study to the Get Requests schedule that is defined for the adapter you specified.

- **ReturnCodesSchedule**—Specify whether to add the study to the ReturnCodes schedule for the adapter you specified.

  - **Y**—Indicates that you want to add the study to the Return Codes schedule that is defined for the adapter you specified.

    > **Note:** You can only specify **Y** if a Return Codes schedule is already defined for the adapter to which you are adding the study.

  - **N**—Indicates that you do not want to add the study to the Return Codes schedule that is defined for the adapter you specified.

Adding an adapter and defining its job schedules using the command line

1 Open a Command Prompt window and type the name of the drive in which the executable file is installed.

> **Note:** By default, the executable file is installed in the same location as the Central Coding application.

2 Type the location of the executable file in the drive that you specified:

...\Central Coding Application\CentralCodingServer\CodingWebUI\bin

> **Note:** You must run the application from this directory.

3 Type the following syntax for adding an adapter and defining its job schedules:

PhaseForward.CentralCoding.SetAdapter.exe [AdapterName] [AdapterURL] [GetVerbatimsSchedule] [ReturnCodesSchedule]

where

- **AdapterName**—Name of the adapter to add.

- **AdapterURL**—URL of the adapter to add.

- **GetVerbatimsSchedule**—Rate at which to run the Get Requests job schedule. This parameter corresponds to the Time span configuration setting on the Schedule GetRequests Job page in the user interface.

- **0**—Indicates that you will run manual Get Requests jobs for the adapter, and the adapter should not be added to a Get Requests schedule.

- **1**—Set a Get Requests job schedule to run every minute for the adapter.

- **5**—Set a Get Requests job schedule to run every five minutes for the adapter.

- **15**—Set a Get Requests job schedule to run every fifteen minutes for the adapter.

- **30**—Set a Get Requests job schedule to run every thirty minutes for the adapter.

> **Note:** This parameter is optional.

- **ReturnCodesSchedule**—Rate at which to run the Return Codes job schedule. This parameter corresponds to the Time span configuration setting on the Schedule ReturnCodes Job page in the user interface.

  - **0**—Indicates that you will run manual Return Codes jobs for the adapter, and the adapter should not be added to a Return Codes schedule.

  - **1**—Set a Return Codes job schedule to run every minute for the adapter.

  - **5**—Set a Return Codes job schedule to run every five minutes for the adapter.

  - **15**—Set a Return Codes job schedule to run every fifteen minutes for the adapter.

  - **30**—Set a Return Codes job schedule to run every thirty minutes for the adapter.

> **Note:** This parameter is optional.

Performance reports

In this chapter

About performance reports

The Central Coding software installation includes an executable file that gathers coding data, and a Microsoft Excel spreadsheet template that uses the data to create reports for analysis and troubleshooting assistance. You can produce data for a specified set of studies, for the entire system, or a combination of both options, according to the parameters you set when running the utility.

To produce the performance reports, you must have server-level access. If you do not have access to the Central Coding server for your studies, please contact Oracle for assistance.

Generating performance reports

To generate performance reports:

1   Run a script to gather study or system data, which is compiled into a CSV file.

    For more information, see *Gathering data for performance reports* (on page 101).

2   Create histograms from the data in a Microsoft Excel spreadsheet.

    For more information, see *Generating performance reports in Microsoft Excel* (on page 101).

Gathering data for performance reports

1   Open a Command Prompt window and type the name of the drive in which the executable file is installed.

2   Type the location of the executable file in the drive you specified:

    ...\Central Coding Application\CentralCodingServer\CodingWebUI\Utilities\UsageCharts

3   Run **PhaseForward.CentralCoding.CreateUsageCharts.exe**, using the following syntax:

    PhaseForward.CentralCoding.CreateUsageCharts.exe [dbUser] [dbPassword] [UsageType] [csvFileDirectory] [TrialList]

    where:

    - **dbUser**—Central Coding Database user ID.

    - **dbPassword**—Central Coding Database user password.

    - **UsageType**—The type of data to compile and display in Microsoft Excel.

        - **DAILYUSAGE**—Produce reports for data from one or more specified studies.

        - **SYSTEMSUMMARY**—Produce reports for data from the entire system.

        - **BOTH**—Produce separate reports for individual studies, and reports for the system as a whole.

    - **csvFileDirectory**—The directory in which you want to store the CSV data file.

    - **TrialList**—For **DAILYUSAGE** or **BOTH** usage type, the list of studies for which to produce the reports.

        - For one study, specify the study name.

        - For more than one study, list the study names in quotation marks, separated by commas (for example, "PFST50, PFSTCardio").

    The utility produces a CSV file that you open in Microsoft Excel.

Generating performance reports in Microsoft Excel

1   Navigate to the Central Coding installation folder.

2   Open the **UsageCharts.xlsm** file.

    A Microsoft Excel spreadsheet opens.

3   Click the **Data** tab.

4   In the **Get External Data** section of the ribbon, click **From Text**.

    The Import Text File dialog box appears.

5   Navigate to the directory you specified for the **csvFileDirectory** parameter.

6   Click **Import**.

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

7   Click **Next**.

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

8   Select the **Tab** and **Comma** delimiters.

9   Click **Next**.

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

10 Click **Finish**.

    The Import Data dialog box appears.

11 Select **Existing worksheet** and specify that you want to put the data in cell A1.

12 Click **OK**.

    The worksheet is populated with the data from the CSV file.

13 Click the **Process Usage Data** button.

    > Note: You may need to scroll to the right in order to see the button.

    It may take several minutes to process the data.

Performance report descriptions

Tab Name	Report Name	Description
Daily usage reports		
<StudyName>	Daily Tally of *<StudyName>*'s Verbatim Traffic	For the specified study, the number of verbatims that were received, delivered, undelivered, or deleted each day, from the beginning of the study.
<StudyName>	Total Number of Verbatims in *<StudyName>* Measured Daily	For the specified study, the total number of verbatims that existed and the total number of verbatims that were delivered each day, from the beginning of the study.
System summary reports		
Days of Activity	Days of Activity	For each study in the system, the number of days during which preprocessing occurred, verbatims were received, and verbatims were returned to the source application.
Trial Running Days	Trial Running Days	The duration of each study in the system, in days.
Verbatim and Transaction Counts	Verbatim and Transaction Counts	For each study in the system, the number of verbatims that exist, the number of deletions that occurred, the number of times a verbatim was received by the Central Coding application, and the largest number of times a single verbatim was received by the Central Coding application.
Percentage of Activity	Percentage of Activity During Trial Up-Time	For each study in the system, the percentage of time taken for preprocessing, receiving verbatims, and returning verbatims to the source application. **Note:** Each percentage is calculated based on a 20-hour day, allowing for 4 hours of system inactivity. The number of hours per day is a configurable setting in Microsoft Excel.
Verbatim Throughput	Number of Verbatims Processed per Hour over a Day	The maximum number of verbatims processed in one hour, and the average number of verbatims processed in one hour. This data is calculated based on a 20-hour day and normalized to one hour. **Note:** This data is displayed in two graphs. The first graph is organized by system, and the second graph displays the data for each study in the system.

Tab Name	Report Name	Description
Percentage Autocoded	Percentage of Verbatims Autocoded	For each study in the system, the percentage of verbatims that were autocoded.
Active Trials	Active Trials shown with Median Verbatims Received per Day	The number of studies in the system on any given day, and the corresponding median number of verbatims received on that day.
Verbatim Trial Size	Size of Trial by # of Verbatims	The number of verbatims in each study, and the percent of total verbatims in the system to which it corresponds.
Histograms	Preprocess Median/Active Day	The median number of verbatims that were preprocessed in a day, and the number of studies that fall into each category.
	Preprocess Average/All Days	The average number of verbatims that were preprocessed in a day, and the number of studies that fall into each category.
	Return Median/Active Day	The median number of verbatims that were returned to the source application in a day, and the number of studies that fall into each category.
	Return Average/All Days	The average number of verbatims that were returned to the source application in a day, and the number of studies that fall into each category.
	Receive Median/Active Day	The median number of verbatims that were received in the Central Coding application in a day, and the number of studies that fall into each category.
	Receive Average/All Days	The average number of verbatims that were received in the Central Coding application in a day, and the number of studies that fall into each category
	Verbatim Trial Size	The number of verbatims in the system, and the number of studies that fall into each category.

C H A P T E R 8
Troubleshooting

In this chapter

Analyzing tables and indexes for performance

Oracle recommends analyzing all tables and indexes for better performance. You should perform this analysis whenever a significant amount of coding data is entered. To help analyze tables and indexes, Oracle recommends that you run the following Oracle database utilities:

- **dbms_utility.analyze_schema**—Run this utility using the Central Coding application schema owner.

  This utility updates the Oracle system tables that are used to perform analysis on a schema.

- **dbms_utility.analyze_schema**—Run this utility to update the Oracle system tables for the Central Coding database.

Changing the execution timeout value

The execution timeout value determines the number of seconds the Central Coding application waits to receive information from the InForm application. The Central Coding installation program sets the default value to 900 seconds.

If you consistently receive the **Request timed out** error message, you can change the value for **executionTimeout** in the **machine.config** file. The following shows a sample **machine.config** file.

```
<globalization requestEncoding="utf-8" responseEncoding="utf-8" /> <!--
httpRuntime Attributes:
        executionTimeout=[seconds] - time in seconds before request is
automatically timed out
        maxRequestLength=[KBytes] - KBytes size of maximum request length to
accept
        useFullyQualifiedRedirectUrl="[true|false]" - Fully qualify the URL for
client redirects
        minFreeThreads="[count]" - minimum number of free thread to allow
execution of new requests
        minLocalRequestFreeThreads="[count]" - minimum number of free thread to
allow execution of new local requests
        appRequestQueueLimit="[count]" - maximum number of requests queued for
the application
        enableKernelOutputCache="[true|false]" - enable the http.sys cache on
IIS6 and higher - default is true
        enableVersionHeader="[true|false]" - outputs X-AspNet-Version header with
each request
-->
<httpRuntime executionTimeout="900" maxRequestLength="4096"
useFullyQualifiedRedirectUrl="false"
minFreeThreads="8" minLocalRequestFreeThreads="4" appRequestQueueLimit="100"
enableVersionHeader="true" /> <!-- compilation Attributes:
tempDirectory="directory"
```

To change the **executionTimeout** value:

1   Open **machine.config**.

    This file is usually located in the **\windows\Microsoft.NET\Framework\version\CONFIG** folder.

2   Locate **<httpRuntime executionTimeout="900" maxRequestLength="4096"** in the file.

3   Change the value to meet your requirements.

4   Save **machine.config**.

Changing the transaction timeout value

If an error occurs when you are importing a large synonym file or when running the Code and Propagate action, increase the transaction timeout value for the Microsoft Distributed Transaction Coordinator (MS DTC).

1   On the application server, open **Microsoft Component Services**.

2   Select **Start > Programs > Administrative Tools > Component Services**.

3   Expand **Component Services**.

4   Expand **Computers**.

5   Right-click **My Computer** and select **Properties**.

6   Click the **Options** tab.

7   Set the **Transaction timeout** (seconds) to 300 or more, and click **Apply**.

8   Click the **MSDTC** tab, and under **Service Control Status for DTC**, click the **Stop** button to stop the DTC.

9   Click the **Start** button to apply the new transaction timeout setting.

10 Click **OK**.

Changing the number of matched terms that display in the coding browser

In the Coding Browser dialog box—Search mode, the Return All Matches checkbox indicates whether you want all the matched terms found to display in the browser. By default, the coding browser displays 200 matches. This number, and whether this option is available, is set by your administrator.

The CodingPlatform.config file contains the following section (these are the default values the Central Coding application ships with):

```
<CodingBrowserSettings>
    <QuickRowLimit>200</QuickRowLimit>
    <AllowReturnAllMatches>true</AllowReturnAllMatches>
    <HardRowLimit>500</HardRowLimit>
</CodingBrowserSettings>
```

where:

- **QuickRowLimit**—The number of matched terms to display in the browser.

  The browser displays only the number of terms specified in this setting. It does not allow you to page through the terms in lists.

- **AllowReturnAllMatches**—Determines whether the **Return All Matches** option appears in the browser.

  If you change this setting to false, the **Return All Matches** checkbox does not appear in the coding browser, and the number of terms specified in the HardRowLimit display in the browser.

- **HardRowLimit**—The number of matched terms to display in the browser when the **Return All Matches** option does not appear in the browser or if the option is not selected.

  If the QuickRowLimit is set to -1, or the **Return All Matches** checkbox is selected, the HardRowLimit determines the maximum number of matches that can be returned.

  If HardRowLimit is set to -1, **all** matches will be returned if the QuickRowLimit is -1 or the **Return All Matches** checkbox is selected. Oracle does not recommend setting the HardRowLimit to -1, as there could be thousands of possible returns.

About running statistics on the Central Coding application

Oracle recommends that a database administrator run statistics on a Central Coding application if:

- The performance of the Central Coding application is slow.

- A timeout exception error occurs when running a large get verbatims job.

  If the job was running for a long time and a timeout exception error occurred, the **ExceptionMap.xml** file contains an entry that instructs you to ask a database administrator to gather statistics on the Central Coding account.

  Oracle recommends that the database administrator monitor the statistics for the account during the day and gather statistics if the statistics start to be out of date and the performance of the application slows down.

Cross-product issues

Extra audit records in the Central Coding application

Issue	Additional audit records in the Central Coding application.
Possible cause	If you change a verbatim in the InForm application that has already been coded, and then change it back to what it was originally, the next time the InForm Adapter Coding interface delivers coding data to the Central Coding application, you will see additional audit records in the Audit History Report in the Central Coding application. This is because although the verbatim is unchanged, it is newer than its targets.
Solution	If you use the InForm Adapter software with the Central Coding application, you must: - Create a rule in the InForm software that is applied to every verbatim that clears the verbatim targets whenever the verbatim is changed. - Make sure the rule is case-sensitive. The rule ensures that the verbatim is treated as uncoded when it is delivered to the Central Coding application.

Code map not found—Undeliverable requests

Issue	Codes are not returned to the InForm application and the **Code map not found** error appears in the Central Coding application for undeliverable requests when: - The mappings for the Central Coding application have been updated in the InForm application. - Data that is in the Central Coding application was not delivered prior to the mapping change.
Possible cause	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. The **Code map not found** error appears when you view the hover help for a request with a delivery status of **Undeliverable** (✖) on the Coding Requests, Approvals, or All Requests page in the Central Coding application. For more information, see the *User Guide*.
Solution	Contact Oracle CAG.

Key items not updated

If the following key items are changed in the InForm application *after a verbatim is coded*, they will not be updated in the Central Coding application.

> **Note:** The key items *are* updated in the Central Coding application if the verbatim is *not coded* in the InForm application.

- Subject Initials
- Subject Number
- Visit
- Site Name
- Site
- Study

If you want the key items to be updated, you must create a rule in the InForm application to clear the coding targets.