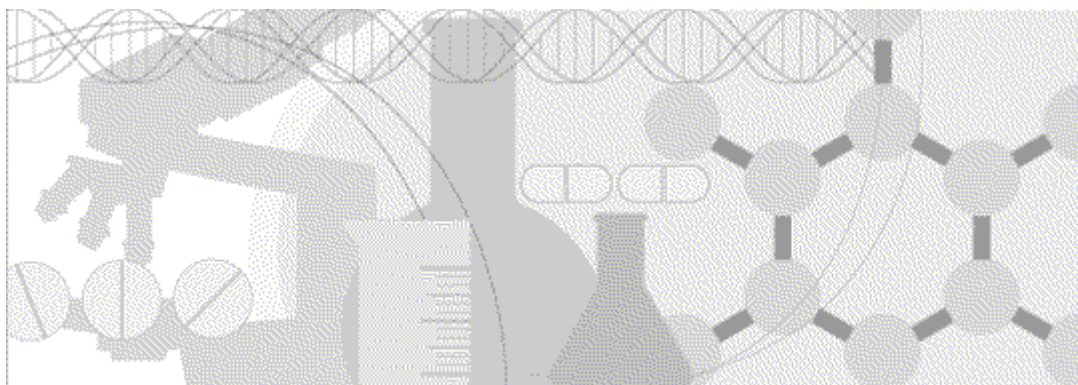


Getting Started

Clintrial
Release 4.7.1



ORACLE®

Part Number: E27574-01

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About this guide

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Overview of this guide

This guide provides a brief overview of the Clintrial software, a description of system requirements, step-by-step instructions for installing and uninstalling the software, setting security options, and troubleshooting information.

Audience

This guide is for IT administrators and others who are responsible for installing and integrating the Clintrial application with other applications, including Oracle-provided products, third-party products, and custom client processes.

Related information

Clintrial 4.7.1 documentation

The Clintrial 4.7.1 documentation includes the documents in the following table. All documentation is available from the Oracle Software Delivery Cloud (<https://edelivery.oracle.com>) and the Download Center (<https://extranet.phaseforward.com>).

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

Title	Description	Last updated
<i>Release Notes</i>	The <i>Release Notes</i> document describes enhancements introduced and problems fixed in the current release, upgrade considerations, release history, and other late-breaking information.	4.7.1
<i>Known Issues</i>	The <i>Known Issues</i> document provides detailed information about the known issues in this release, along with workarounds, if available. Note: The most current list of known issues is available on the Extranet. To sign in to the Extranet, go to https://extranet.phaseforward.com .	4.7.1
<i>Getting Started</i>	The <i>Getting Started</i> document: <ul style="list-style-type: none"> • Provides a summary of each Clintrial module, a description of the relationships between modules, and descriptions of key concepts. • Describes how to install, upgrade, and de-install the Clintrial software. • Describes how to configure the Clintrial application. • Provides information and procedures for customizing the Windows Registry. • Explains how to use the Medika Sample Studies. 	4.7.1
<i>Admin and Design</i>	The <i>Admin and Design</i> guide describes how to use: <ul style="list-style-type: none"> • The Admin module to work with user accounts, access rights, parameters, and system administration tools. • The Design module to set up and maintain Clintrial application objects, such as protocols, panels, and study books. 	4.7.1

Title	Description	Last updated
<i>Secure Configuration Guide</i>	The <i>Secure Configuration Guide</i> provides an overview of the security features provided with the Clintrial application including details about the general principles of application security, as well as how to install, configure, and use the Clintrial application securely.	4.7.1
<i>Reference Guide</i>	<p>The <i>Reference Guide</i> provides:</p> <ul style="list-style-type: none"> • Definitions of the Oracle database tables that store Clintrial metadata and clinical data. • Descriptions of the use of PL/SQL for Clintrial-specific procedures. • Explanations of data types and naming conventions. • Information on using SQL, setting up custom menus, and running batch jobs. • A glossary of terms. 	4.7.1
<i>Manage, Classify, and Lab Loader</i>	<p>The <i>Manage, Classify, and Lab Loader</i> guide describes how to use:</p> <ul style="list-style-type: none"> • The Manage module to perform data management tasks such as coding (including integration with the Central Coding application), global modification, validation, auditing, and batch loading of clinical data. • The Classify module to track, review and solve for values that fail automatic coding; to audit the contents of a coding thesaurus protocol; and to build and test effective thesaurus algorithms. • The Lab Loader module to batch load laboratory data and to set up Lab Loader objects. 	4.7.1
<i>Enter, Resolve, and Retrieve</i>	<p>The <i>Enter, Resolve, and Retrieve</i> guide describes how to use:</p> <ul style="list-style-type: none"> • The Enter module to enroll subjects, enter and edit data, verify data, and work with reports. • The Resolve module to identify, track, and report data discrepancies, as well as how to customize the Resolve module, including writing rules that reference data items. • The Retrieve module to extract clinical data from the database and work with query results. 	4.7.1
<i>Multisite</i>	<p>The <i>Multisite</i> guide describes:</p> <ul style="list-style-type: none"> • How to distribute codelists and protocols. • How to set up a replication environment. • How other Clintrial modules work differently in a Multisite environment. 	4.7.1

Title	Description	Last updated
<i>Quick Reference for Enter</i>	The <i>Quick Reference for Enter</i> document lists Enter module menu commands and shortcut keys.	4.7.1

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 visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

CHAPTER 1

The Clintrial software overview

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What is the Clintrial software?

The Clintrial software is a comprehensive clinical research system for the collection, management, and review of clinical trials data. The Clintrial software is designed for use by companies that must both:

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

The Clintrial software allows you to unify all of your clinical data collection and management, regardless of source or phase of development (pre- or post-market).

The Clintrial software consists of a set of integrated modules that allow you to create metadata, and to collect, manage, and review clinical data according to your study needs.

- **The Clintrial core modules**—Essential parts of the basic Clintrial product.

Using the Clintrial core modules, you can efficiently manage clinical data.

For more information, see *Core modules* (on page 4).

- **The Clintrial extended modules**—Valuable additions to the data management capabilities of the core modules.

You can purchase and install extended modules as needed.

For more information, see *Extended modules* (on page 7).

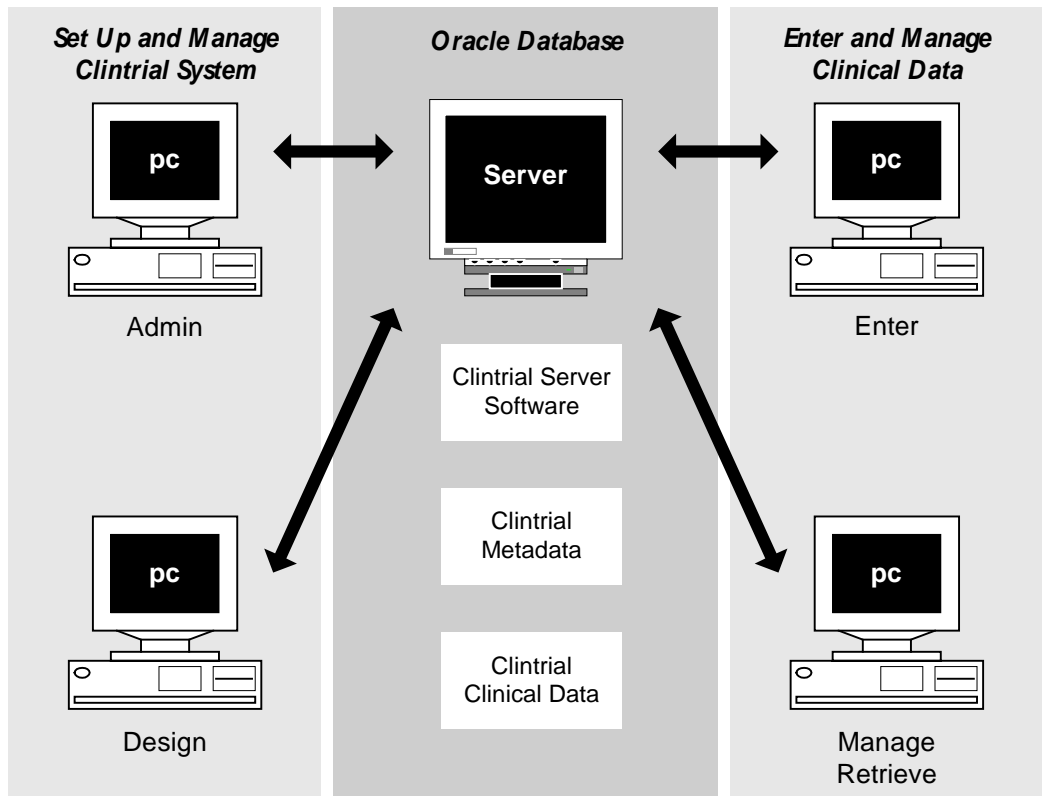
The Clintrial software provides a user interface that allows you to enter, verify, edit, and retrieve clinical data using data-entry windows called study pages, which look like pages from case report forms (CRFs).

Client/server architecture

The Clintrial software uses client/server computer networking technology to store and manage data in an Oracle database.

Most tasks are initiated using the Clintrial modules on clients that are connected to a server. Third-party tools can also reside on clients/servers.

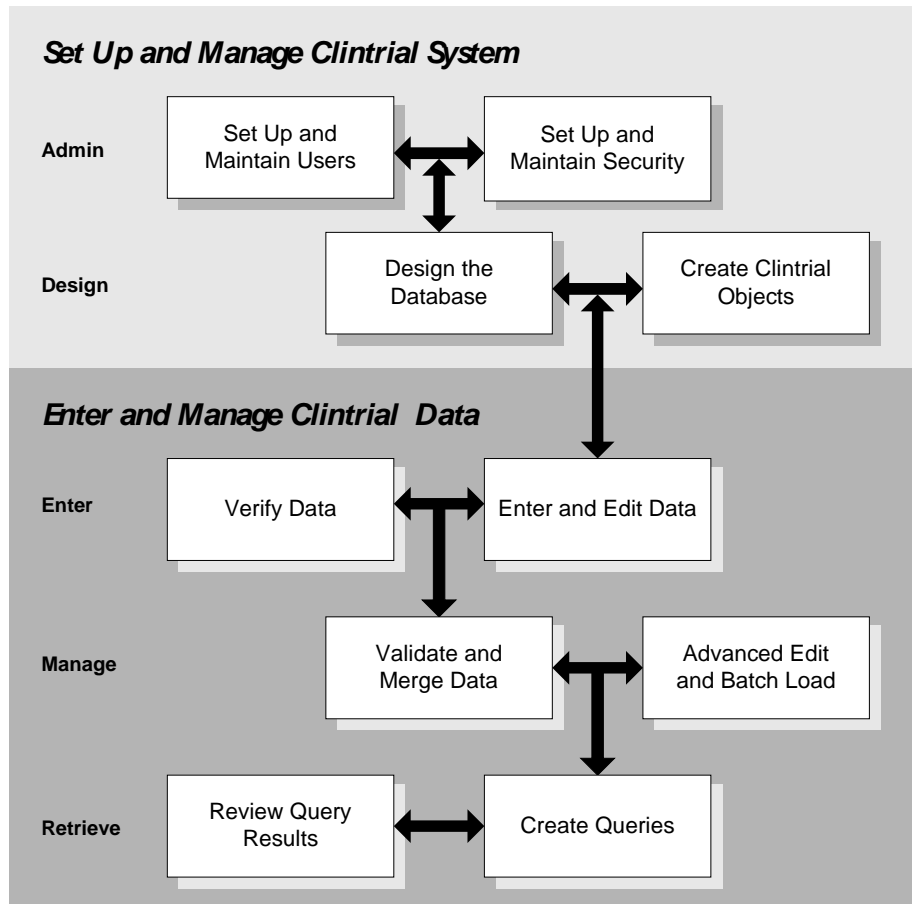
The server computer runs the Clintrial server software and stores the Clintrial metadata and clinical data in an Oracle database.



Core modules

The Clintrial software consists of these interacting core modules:

- Admin module
- Design module
- Enter module
- Manage module
- Retrieve module



About the Admin module

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

- Create user accounts and usergroup accounts.
- Manage passwords.
- Set up and manage access rights for users, usergroups, and protocols for all Clintrial software modules.
- Set system parameters.

- Monitor database space.
- Produce auditing reports for users and security.
- Produce reports about system activities.

About the Design module

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

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

About the Enter module

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

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

About the Manage module

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

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

About the Retrieve module

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

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

Extended modules

Extended modules, which provide added functionality include:

- Classify module
- Multisite module
- Lab Loader module
- Resolve module

About the Classify module

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

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

About the Lab Loader module

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

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

About the Multisite module

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

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

About the Resolve module

Use the Resolve extended module to manage discrepancy and resolution capabilities that support the

work you perform in other Clintrial software modules. You can:

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

Enter is accessible through the **Switchboard** module or from the Windows **Start** menu, and is installed when the Clintrial client module is installed.

For more information, see the Clintrial on-line Help.

Clintrial 4.7 compatibility with other Oracle Health Sciences products

Clintrial is compatible with several other Oracle products, including:

- Clintrial Integration Solution (CIS).
- Central Coding.

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

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

Clinical data management

The Clintrial software provides the tools to store clinical data, ensure data accuracy and consistency, and access data for reports and analysis throughout the phases of clinical trials. You can:

- Model a clinical research study by creating database structures that are stored in an Oracle database account.
- Create data-entry windows, called study pages, which represent pages in paper CRFs.
- Group related study pages in study books that correspond to the CRF for the study.
- Enter, verify, and edit clinical data, or batch load and screen clinical data.
- Code clinical data using the Oracle Central Coding application or the Clintrial Classify extended module.
- Verify and validate clinical data.
- Identify, manage, and resolve discrepancies in the clinical data.
- Audit changes to clinical data and metadata, beginning at a specified point in the data management process.
- Retrieve clinical data for analysis and reports.

Key benefits

The Clintrial software expedites the mandatory approval process for new products and shortens time-to-market by allowing you to do the following:

- Meet the extensive data management requirements of a clinical trial.
- Tailor your clinical data management system to meet your unique data management needs and conform to your SOPs.
- Build checks to ensure data quality.
- Standardize data definitions.

The Clintrial software helps you to conduct clinical trials in accordance with Good Clinical Practice (GCP) guidelines.

How the Clintrial software provides flexibility

You can design your clinical database and organize clinical data to meet your data management needs and workflow. For example, you can:

- Define database objects that are specific to a clinical trial, or create a library of objects to standardize clinical trials.
- Refine and revise your data definitions.
- Establish standard objects, such as panels, to store demographic data that facilitate analysis of similar studies and data pooling.

How the Clintrial software provides security

You can assign rights to users and to studies, to determine the level of access to clinical data definitions and clinical data in studies. For example, you can:

- Assign rights to a data-entry operator to allow that person to enter data in only one study.
- Deny the right to edit or delete data in a study.
- Audit changes to user access.

How the Clintrial software standardizes data

You can standardize the data definitions for clinical data and the study pages that you use to collect data. You can make decisions about database design once, and then store the design to use as a prototype for other clinical trials.

For example, you can define database objects that are common to all of your clinical trials.

You can also standardize clinical data by:

- Requiring data-entry operators to select values from predefined codelists of valid codes for data.
- Translating terms into codes from standard coding dictionaries, using Oracle's Central Coding or Clintrial coding.

Examples of supported standard dictionaries include:

- Medical Dictionary for Regulatory Activities (MedDRA and MedDRAJ).
- Coding Symbols for a Thesaurus of Adverse Reaction Terminology (COSTART).
- World Health Organization Adverse Reaction Terminology (WHOART).
- World Health Organization Drug Dictionary (WHO-DD).
- World Health Organization Drug Dictionary C Format (WHO-DD C).
- Data File for Ethical Drugs (Coding Table) from Iyaku-Joho-Kenkyujo, Inc. (JDrug).

How the Clintrial software ensures data accuracy

You can check data for accuracy, consistency, and logic by:

- Defining valid ranges for clinical data values (range checking).
- Checking data through double-entry (verification).
- Running site-defined checks for certain conditions on clinical data (validation).
- Manipulating data with data-entry processing procedures.

How the Clintrial software audits data

You can set up the Clintrial software to begin auditing changes to clinical data at various points in the data management cycle. For example, auditing can begin as soon as data is entered, or only after data has been merged.

How the Clintrial software helps review data

You can retrieve clinical data from database tables with:

- Query By Form.
- Query By Panel.
- Ad Hoc Query.
- Query By SQL.

For example, you can create a Query By Form and save the query results in a Microsoft Excel spreadsheet for further analysis.

The Clintrial data

You work with two types of data:

- Metadata
- Clinical data

Metadata defines the Clintrial objects and their relationships. A Clintrial object is a data structure such as a panel, an item, or a codelist.

Metadata describes how the data in a study is collected and stored. Controlling metadata is the primary method that is used to standardize clinical data.

You use the Design module to define metadata, and you can use metadata reports to display or print information about metadata that is associated with a clinical study, such as database object descriptions, and metadata structures.

Clinical data is information about a subject that is collected on a CRF during a clinical trial (for example, demographic data, previous medications, or laboratory test results).

You use the Enter, Manage, Retrieve, Lab Loader, and Resolve modules to enter and manage clinical data.

Relationship to the Oracle database

Both metadata and clinical data are stored in the Oracle database:

- Metadata is stored in data dictionary tables.

Using the Design module, you create objects that are stored in data dictionary tables.

Using the Enter, Manage, and Retrieve modules, you can access the objects and parameters.

- Clinical data is stored in clinical data tables.

Using the Enter, Manage, Retrieve, and Resolve modules, users enter, edit, manage, and query the clinical data in the clinical data tables.

About the Clintrial protocol

A Clintrial protocol is an Oracle account that serves as a logical container to organize:

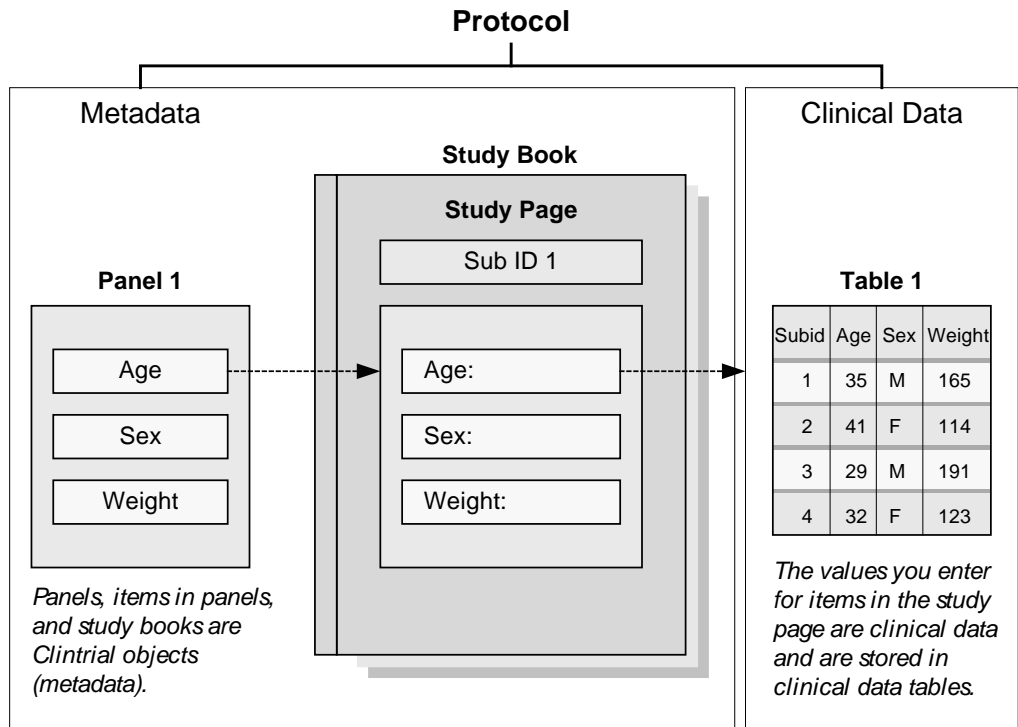
- Metadata that is used to manage the data in the protocol.
- Clinical data, flags, and notes that are associated with clinical data.
- One or more views of the clinical data that is stored in the protocol.

Example

In the Design module, you set up the protocol account for a study. Then, you define the metadata that:

- Describes the objects (called items) in which to store data.
- Describes how to store data (in objects called panels).
- Sets up an electronic representation of a CRF (in an object called a study book).

In the Enter module, data-entry operators use the study book to enter clinical data into clinical data tables.



How the Clintrial software stores clinical data

In the Design module, you create items and panels to tell the Clintrial software how to store clinical data in Oracle database tables.

About items

An **item** is a Clintrial object that stores a piece of data, such as the data collected in a single field on a study page, or a single field in a batch-loaded file. For example, a study page for concomitant medications might contain the following items:

- **DRUG**—The name of a concomitant medication.
- **DOSE**—The dosage for the concomitant medication.

You define items within panels, and each item corresponds to one column in a clinical data table. For example, the DRUG item would be stored in one column in the clinical data table for the MEDS panel.

About panels

A **panel** is a collection of logically or clinically related items.

For example, the items DRUG and DOSE might be grouped together in a MEDS panel.

Types of clinical data tables

When you install a panel, the following clinical data tables are created:

- **Update table**—When data is first entered, it is stored in the update table until it is validated. Users can verify, screen, edit, code, and validate data in the update table.
- **Data table**—After data is validated in the update table, it can be merged (moved) to the data table. Users can edit, code, and validate data in the data table.
- **Audit table**—While auditing is in effect, each time data is changed or deleted, a copy of the data before it was modified or deleted is stored in the audit table. Data in the audit table cannot be changed.

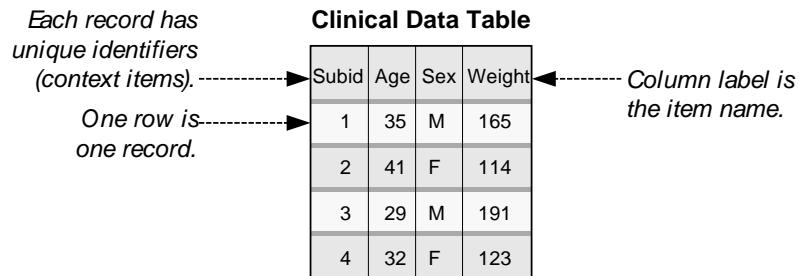
Note: Data for a record can be stored in the update table or the data table, but not in both.

About records

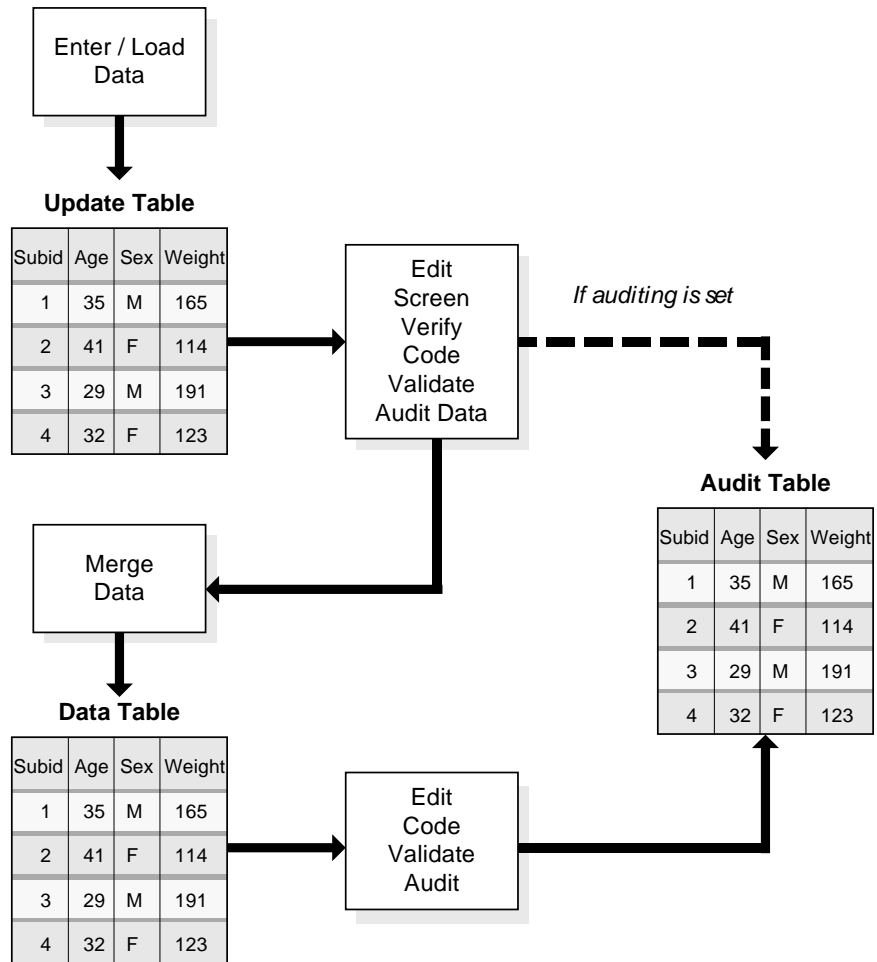
Clinical data is stored in records in the clinical data tables. A **record** corresponds to one row in a database table. Depending on the panel type, the data that is collected in a study page is stored in one or more records in the database. A database table can contain the following panel types:

- One record per subject (in tables for a Type 1 panel).
- Multiple records per subject (in tables for a Type 2 panel).
- One record per subject visit (in tables for a Type 3 panel).
- Multiple records per subject visit (in tables for a Type 4 panel).
- Subject enrollment records (in tables for a Type 5 panel).
- Records that are not related to a specific subject (in tables for a Type 0 panel).

Structure of a clinical data table



Data flow within the Clintrial software



Types of users

Clintrial users are categorized according to:

- Their roles in clinical data research and clinical data management.
- The types of tasks they perform.

The Clintrial documentation refers to the following types of users. You might use different job titles, or assign tasks and roles in a different way. For example, one person can perform both data manager and designer tasks.

- **The Clintrial administrator**
 - Maintains user accounts and manages security for all of the Clintrial modules.
 - Sets system-wide parameters and default user parameters.
 - Manages the Clintrial database instance.
- **Designer**
 - Designs the Clintrial studies.
- **Programmer**
 - Uses PL/SQL to build rules, derivations, and data-entry processing procedures.
- **Data-entry operator**
 - Enters data from paper CRFs into the Clintrial study books.
 - Verifies data.
 - Edits unmerged data in the update table.
- **Data manager**
 - Batch loads clinical data.
 - Manages the clinical data.
 - Validates and merges records.
 - Makes global modifications.
 - Codes data.
 - Retrieves clinical data from the database and produces reports.
- **Medical reviewer**
 - Uses query tools to retrieve data from the database for record review or statistical analysis.

Starting a module

To access the Clintrial software and its online Help topics, you must start a Clintrial module.

- 1 Select **Start > Programs**.
- 2 Select the Clintrial program group, then select the module.

The Database Connection dialog box appears.



- 3 Enter your user name, password, and Oracle Net Service name for the database you will use. If you do not know this information, contact your Clintrial administrator.

Note: The next time you start a Clintrial module, the Database Connection dialog box displays the most recently used user name and database service name.

The Clintrial module basic tasks

The basic tasks for using the Clintrial modules include:

- Using Switchboard.
- Setting the protocol.
- Switching databases.
- Changing your password.
- Exiting the module.

Using Switchboard

Using Switchboard, you can start any of the installed Clintrial modules from the Run menu.

- When you start Switchboard, provide a user name, password, and database service name.
- Each time you start a different Clintrial module from Switchboard, the Clintrial software uses the database connection information that you provided when you started Switchboard.

For more information, see the Clintrial Basics online Help.

Note: Menu commands in the modules are available only if you have the appropriate access rights.

Setting a protocol

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

- When you first connect to the database, the Set Protocol dialog box appears.
- Select the protocol in which to work.

If you do not know the protocol to use, see your Clintrial administrator.

Note: The next time you start the protocol is selected automatically.

Switching databases

- 1 Close all open windows.
- 2 Select **File > Connect**.

For more information, see the Clintrial Basics online Help.

Re-ordering columns in list windows

For windows which display list grid views, such as list of logs in Manage or list of Discrepancies in Resolve, you may use the mouse to drag columns to new positions to tailor the view to your needs. For example, you can change the column order in a Discrepancy window by dragging and dropping the most significant columns to the left portion of the open window.

Changing your password

To change your password, select **File > Password**.

For more information, see the Clintrial Basics online Help.

Accessing the Server Registry Information

You can access the Server Registry Information report from any Clintrial module. This report lists the version, patch level and build ID for the Clintrial core server and each module installed in the application.

- 1 Select **Help > About**.
- 2 Click **More**.

The Server Registry Information dialog box appears.

Exiting a module

To exit a module, select **File > Exit**.

The main window of the module closes and the Clintrial software disconnects you from the database.

For more information, see the Clintrial Basics online Help.

About Help

Each Clintrial module includes Help, which contains:

- Context-sensitive help for windows and dialog boxes.
- Procedural instructions for tasks.
- Brief overviews of concepts.
- Descriptions of menus and options.
- A glossary of Clintrial terms.

Note: A Clintrial Help file is installed automatically for each module.

Searching for information

- 1 Select **Help > Help Topics**.


The Help Topics dialog box appears.

- 2 To find a topic in the Help, do one of the following:
 - To view topics by category, select the **Contents** tab.
 - To view a list of index entries, select the **Index** tab.
 - To search for specific words in the Help, select the **Find** tab.

Getting help on windows and dialog boxes

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

- Press **F1**.

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

CHAPTER 2

Preparing to install or upgrade the server to this release

In this chapter

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Clintrial Database Server Hardware and software requirements

Core Server hardware requirements

Hardware	Minimum	Recommended
Processor	Intel Pentium 200 MHz	Intel Pentium 550. Note: See Microsoft recommended hardware specifications if you are running the Clintrial client on a supported server operating system.
Display	Clintrial software: SVGA (1024 x 768 resolution; 256 colors) Required for Design and Multisite modules. Oracle 10g or 11g: Video Adapter - 256 colors.	Clintrial software: SVGA (1024 x 768 resolution; 256 colors) Recommended for all modules. Oracle 10g or 11g: Video Adapter - 256 colors.
Hard Drive	Clintrial software: 400 MB (200 MB for the default Clintrial tablespaces - may double during installation due to temporary file storage). Oracle 10g or 11g: Total 2.5 GB. Data Files: 1.03 GB. Oracle Home Drive: 905 MB. System Drive: 3.1 MB. Linux OS: Oracle Database 10.2 and 11.2 software: 2.5 GB of available disk space Data Files: 1.2 GB of free space /tmp directory: 400MB of free space	512 MB Hardware requirements for the database server vary according to trial size and trial configuration.

Hardware	Minimum	Recommended
Memory	Clintrial software: 256 MB RAM. Oracle 10g or 11g: 256 MB RAM. Virtual Memory: Double RAM. Linux OS: 1024 MB Required swap space 1GB.	Clintrial software: 512 MB RAM Oracle 10g or 11g: 512 MB RAM. Virtual Memory: Double RAM. Linux OS: Swap space should be twice the amount of RAM for systems with 2 GB of RAM or less and between one and two times the amount of RAM for systems with more than 2 GB.
Network	10 Mbps NIC.	100 Mbps NIC.

Core Server software requirements

Software	Supported
Operating system	<p>Microsoft Windows platforms:</p> <ul style="list-style-type: none"> • Microsoft Windows 2003 SP2 Enterprise Edition (32 bit). • Microsoft Windows 2008 Enterprise Edition (64 bit). <p>Note: Because the Clintrial database does not use platform-dependent Oracle functionality, Oracle also supports running the database on the following additional Windows operating systems.</p> <ul style="list-style-type: none"> • Microsoft Windows 2003 SP2 Standard Edition (32 bit). • Microsoft Windows 2003 SP2 Datacenter Edition (32 bit). • Microsoft Windows 2008 Standard Edition (64 bit). • Microsoft Windows 2008 Datacenter Edition (64 bit). <p>Note: the Clintrial database was validated on Windows 2003 SP2 Server Enterprise Edition and Microsoft Windows 2008 Enterprise Edition (64 bit).</p> <p>UNIX platforms:</p> <ul style="list-style-type: none"> • Red Hat® Linux® Advanced Server 3.0. • Red Hat® Linux® Advanced Server 4.0. <p>Note: Oracle's Clintrial database was validated on Red Hat Linux AS 4.0.</p> <p>Validation was performed using both 32 and 64 bit operating systems.</p> <p>Note: Red Hat® Linux® Advanced Server 7.2 is <i>not</i> supported.</p> <p>Note: Because the Clintrial database does not use any platform-dependent Oracle functionality, Oracle also supports running the database on the following AIX, Solaris, and HP-UX operating systems.</p> <ul style="list-style-type: none"> • Sun Solaris™ 2.8 and 2.9. • HP-UX 11. • IBM RISC SYSTEM/6000: AIX 5L.

Software	Supported
Database	<p>Oracle 10.2 or 11.2 Personal, Standard or Enterprise Edition with Patch Set 10.2.0.5 or 11.2.0.1.</p> <p>Note: the LabLoader module requires an Oracle 10.2.0.5 database to support some advanced functionality. If your implementation of Clintrial 4.7.1 does not include LabLoader, you can use the Clintrial application with an Oracle 10.2.0.4 database.</p> <ul style="list-style-type: none"> • Oracle 10.2 or 11.2 Database Server. • Oracle 10.2 or 11.2 Net Services with TCP/IP. • SQLPlus. • Oracle 10.2 or 11.2 Utilities: Export, Import, Data Pump, and SQLLoader are required if needed for export or import in the Design module, or batch loading in the Manage or Lab Loader modules. <p>If upgrading the Oracle software, the Database Upgrade Assistant and Migration Utility are required.</p> <p>Note: The Clintrial application has been validated on Oracle 10.2.0.5 and 11.2.0.1.</p> <p>For more information, see the Oracle 10.2 or 11.2 documentation for your supported platform and operating system. To check these requirements, visit the Oracle Website at http://www.oracle.com.</p>
Remote	N/A
Anti virus	Recommended.
Browser	N/A
Other	Adobe® Acrobat® Reader 6.x or higher (available from www.adobe.com).

Clintrial Client hardware and software requirements

Client hardware requirements

Hardware	Minimum	Recommended
Processor	Intel® Pentium® 166	Intel Pentium 266
Display	The Clintrial software: SVGA (1024 x 768 resolution; 256 colors) Required for Design and Multisite modules. The Oracle® 10g and 11g: Video Adapter - 256 colors.	The Clintrial software: SVGA (1024 x 768 resolution; 256 colors) Recommended for all modules. The Oracle 10g and 11g: Video Adapter - 256 colors.
Hard Drive	The Clintrial software: 200 MB to install all modules, sample study, and documentation.	N/A.
Memory	256 MB.	512 MB.
Network	10 Mbps NIC.	100 Mbps.

Client software requirements

Software	Supported
Operating System	<p>Microsoft® Windows® platforms:</p> <ul style="list-style-type: none"> • Microsoft Windows 7 Enterprise Edition (32/64 bit) • Microsoft Windows 7 Professional Edition (32/64 bit) <p>Note: Because the Clintrial client does not leverage any version-dependent Windows functionality, Oracle also supports running the client on the following additional Windows operating systems:</p> <ul style="list-style-type: none"> • Microsoft Windows 2003 SP2 Server, Enterprise Edition (32 bit). • Microsoft Windows 2008 Server, Enterprise Edition (64 bit). • Microsoft Windows Vista® • Microsoft Windows XP® Pro (with Service Pack 3 or below). • Microsoft Windows XP® Pro (with Service Pack 3 or below). • Microsoft Windows 2003 SP2 Standard Edition (32 bit). • Microsoft Windows 2003 SP2 Datacenter Edition (32 bit). • Microsoft Windows 2008 Standard Edition (64 bit). • Microsoft Windows 2008 Datacenter Edition (64 bit). <p>Note: the Clintrial client verification was carried out on the following Windows operating systems:</p> <ul style="list-style-type: none"> • Microsoft Windows 7 Enterprise Edition (32/64 bit) • Microsoft Windows 7 Professional Edition (32/64 bit) • Microsoft Windows Vista® • Microsoft Windows XP® Pro (with Service Pack 3 or below). • Microsoft Windows 2008 Server, Enterprise Edition (64 bit).

Software	Supported
Database	<p>The Oracle® 10.2 and 11.2 Client, Personal, Standard, or Enterprise Edition with Patch Set 10.2.0.5 or 11.2.0.1.</p> <ul style="list-style-type: none"> • Access to an Oracle database instance configured to run the Clintrial software. • The Oracle 10.2 or 11.2 Net Services with TCP/IP. • Oracle 10.2 or 11.2 Utilities: Export, Import, Data Pump, and SQLLoader are required if needed for export or import in the Design module, or batch loading in the Manage or Lab Loader modules. <p>Note: the LabLoader module requires an Oracle 10.2.0.5 database to support some advanced functionality. If your implementation of Clintrial 4.7.1 does not include LabLoader, you can use the Clintrial application with an Oracle 10.2.0.4 database.</p> <p>Note: The Clintrial application has been validated on the Oracle 10.2.0.5 and 11.2.0.1 software.</p>
Remote Connect	N/A.
Anti Virus	Recommended.
Browser	N/A.
Other	Adobe® Acrobat® Reader 6.x or higher (available from www.adobe.com).

Using the Oracle database with the Clintrial Core Server software

When installing or upgrading to Clintrial 4.7.1, you may choose to use either a Unicode or non-Unicode database for Oracle 10.2.0.5 or 11.2.0.1. If you plan on using non-English languages or multiple languages, a Unicode database is appropriate.

The Oracle database

The new Oracle database must be created with the following requirements, before you install the Clintrial software:

- The **compatible** parameter must be equal to or begin with **10.2.0** or **11.2.0**.
- There must be at least one temporary tablespace in the database that holds **temporary contents**.
- If you are a global company and want to use a Unicode database, you must set the **character set** to **Unicode (AL32UTF8)** and set the **nls_length_semantics** to **CHAR** in the Oracle database's **All Initialization Parameters**.

Note: An example of the effect this setting has on data in a Clintrial Unicode protocol is the setting of **varchar2(2000)** (4000 bytes) for an item (usually a text item) in panel using the Design module. In a language using Western characters (like English or French), where each character takes no more than 2 bytes, this sets the limit at 2000 characters. In Japanese, a character requires 3 bytes or more, so the limit could be as few as 1333 characters (4000 bytes divided by 3).

If an existing Oracle database does not meet the above requirements, you must delete the Oracle database instance and recreate it.

Note: For a list of features that are specific to Oracle 10g or 11g, see the Oracle database *New Features* documentation.

You must also set other database initialization parameters to run the Clintrial software. You can include these parameters in your database creation, upgrade, or adjustment, or you can wait and change the parameters just before you install or upgrade to the Clintrial 4.7.1 software. For more information, see *Required database instance parameters* (on page 38).

Note: Choose a method of creating the database that allows you to manipulate the database parameters. Pre-configured databases might not allow you to do this.

For the recommended space and other parameter settings, see your system administrator.

Recommendations for creating and upgrading the Oracle Database

Review this section if you are creating a new Oracle 10.2 or 11.2 database or upgrading an existing Clintrial database to the Oracle 10.2 or 11.2 software.

Oracle recommends reviewing your Oracle 10.2 or 11.2 documentation before you perform a new installation or an upgrade. Oracle also recommends that you test the Clintrial software and the Oracle 10.2 or 11.2 software before you upgrade or install the software in a production environment.

Note: Clintrial 4.7 does not support Oracle transparent data encryption.

Upgrading an existing Clintrial database to Oracle 10.2.0.5 or 11.2.0.1

Oracle recommends that you upgrade the entire database to Oracle 10.2.0.5 or 11.2.0.1 rather than creating a new instance of the database and using export/import. The *Oracle Migration* guide describes how to upgrade your entire database.

If you choose to use Unicode databases, after you upgrade your existing databases to 10.2.0.5 or 11.2.0.1, you should create new Unicode 10.2.0.5 or 11.2.0.1 databases and export/import your upgraded databases using Oracle Data Pumps to the new 10.2.0.5 or 11.2.0.1 Unicode databases.

If you decide not to use Unicode databases, when using Multisite Distribution, if you export databases from and then import them to a different Oracle release, you must manually recreate all Multisite database links after you upgrade to the Clintrial 4.7.1 software.

Whether or not you use Unicode, if your Clintrial upgrade includes Multisite Replication, you must reschedule the time and the date for replication for all sites. If you do not, the status will not be updated.

For details, see the document entitled *Multisite*, **Chapter 5: Replication**, the section entitled "Scheduling replication".

After your upgrade to Oracle 10.2.0.5 or 11.2.0.1 (Unicode or non-Unicode) invalid packages, functions, and synonyms can be listed in all_object (select owner, object_name, object_type from all_objects where status = 'INVALID')

The following is the note from the Oracle 10.2.0.5 readme file:

Note: When the 10.2.0.5 patch set is applied to an Oracle Database 10g Standard Edition database, there may be 54 invalid objects after the **utlpr.sql** script runs. These objects belong to the unsupported components and do not affect the database operation.

Ignore any messages indicating that the database contains invalid recycle bin objects similar to the following:

BIN\$4IzJWlt9gfgMFeM2hVSoA==\$0

Most of the invalid objects will become valid after running the below SQL*Plus commands.

To upgrade an existing database to Oracle 10.2.0.5 or 11.2.0.1, do the following:

- 1 Run the following SQL*Plus commands:
 - a C:\>SET ORACLE_SID=db_ct47
 - b C:\> sqlplus /NOLOG

- c **SQL> CONNECT SYS AS SYSDBA**
 - d Enter password: **SYS_password**
 - e **SQL> SHUTDOWN IMMEDIATE**
 - f **SQL> STARTUP UPGRADE**
 - g **SQL> @ORACLE_BASE\ORACLE_HOME\rdbms\admin\catupgrd.sql**
- 2 Check the log files for errors.
 - 3 If necessary, rerun the **catupgrd.sql** script after correcting any errors.
 - 4 Restart the database:
 - a **SQL> SHUTDOWN IMMEDIATE**
 - b **SQL> STARTUP**
 - 5 Run the **utlrlp.sql** script to recompile all invalid PL/SQL packages now instead of when the packages are accessed for the first time.

SQL> @ORACLE_BASE\ORACLE_HOME\rdbms\admin\utlrlp.sql

The Oracle 9.2 software and subsequent releases support locally managed tablespaces. If you are upgrading from a previous version of the Oracle software, you can take advantage of this feature by migrating your existing tablespaces.

Several database requirements must be set **prior** to installing the Clintrial software. For more information, see *Installing a new Clintrial database* (on page 36) and *Database storage parameters* (on page 37).

Exporting and importing an entire database

This is the only option to migrate the old Oracle 9.2 or 10.2 database to a Unicode database. You cannot change the Oracle database character set after the database has been created.

Before exporting the database

Before exporting the database, do the following:

- 1 Back up the original database.
- 2 Update the Oracle version to 10.2.0.5 or 11.2.0.1.
- 3 Migrate a Clintrial 4.5 database from Oracle 9 to the new Oracle version.

Note: If you are upgrading a Clintrial 4.6 database, it is already Oracle 10.2. Make sure it is 10.2.0.5.

- 4 If you are converting the database to UNICODE, check the existing database to determine whether it uses **BYTE** or **CHAR**. For more information, see the Oracle Database documentation. If the database is already **CHAR**, skip to Step 8.
- 5 If the database is using **BYTE**, change the **NLS_LENGTH_SEMANTICS** parameter from **BYTE** to **CHAR**.
- 6 Restart the database and make sure the **NLS_LENGTH_SEMANTICS** is **CHAR**.
- 7 Run the **ChangeByteToChar.sql** file against the database. Modify the file if necessary. For more information, see *ChangeByteToChar.sql* (on page 34).

- 8 For Clintrial 4.5 database, login as **sys** and execute the following:

```
CREATE OR REPLACE DIRECTORY export_dump_dir AS 'D:\oradump\';
GRANT READ, WRITE ON DIRECTORY export_dump_dir TO sys;
```

Note: Actual commands could be different in Unix and Windows. Please reference Oracle database documentation for specific commands.

- 9 If you are upgrading a Multisite environment, ensure:

- There are no partially imported protocols.
- There are no partially imported codelists.
- There are no panels marked for revision.
- There are no distributed objects open for revision.
- All replicated accounts are halted.

ChangeByteToChar.sql

Below are the contents of the **ChangeByteToChar.sql**. Modify the file as necessary.

```
set feedback off
set verify off
set serveroutput on
set termout on

exec dbms_output.put_line('Start generating columns to be altered');

--drop table sys.columns_to_char;
--/
create table sys.columns_to_char(s_owner varchar2(40),
s_table_name varchar2(40),
s_column_name varchar2(40),
s_data_type varchar2(40),
s_char_length number,
s_updated varchar2(1 char));
/
insert into sys.columns_to_char
select C.owner, C.table_name, C.column_name, C.data_type, C.char_length, 'N'
from all_tab_columns C, all_tables T
where C.owner = T.owner
and C.table_name = T.table_name
and C.data_type in ('VARCHAR2', 'CHAR')
and C.char_used = 'B'
and T.TABLESPACE_NAME is not null
and T.STATUS = 'VALID'
and T.DROPPED = 'NO'
and T.owner not in
('DBSNMP', 'MGMT_VIEW', 'SYSMAN', 'TRACESVR', 'AURORA$ORB$UNAUTHENTICATED',
'AURORA$JIS$UTILITY$', 'OSE$HTTP$ADMIN', 'MDSYS', 'MDDATA', 'ORDSYS', 'OUTLN',
'ORDPLUGINS', 'SI_INFORMTN_SCHEMA', 'CTXSYS', 'WKSYS', 'WKUSER', 'WK_TEST',
'REPADMIN', 'LBACSYS', 'DVF', 'DVSYS', 'ODM', 'ODM_MTR', 'DMSYS', 'OLAPSYS',
'WMSYS', 'ANONYMOUS', 'XDB', 'EXFSYS', 'DIP', 'TSMYSYS', 'SYSTEM', 'SYS');
/
commit;
/
declare
cursor c1 is select rowid,s.* from sys.columns_to_char s where s_updated='N';
v_statement varchar2(255);
v_nc number(10);
v_nt number(10);
begin
execute immediate
```

```

'select count(*) from sys.columns_to_char where s_updated='N' into v_nc;
execute immediate
'select count(distinct s_table_name) from sys.columns_to_char where
s_updated='N' into v_nt;
dbms_output.put_line
('ALTERing ' || v_nc || ' columns in ' || v_nt || ' tables');
for r1 in c1 loop
v_statement := 'ALTER TABLE "' || r1.s_owner || '"."' || r1.s_table_name;
v_statement := v_statement || ' modify (" ' || r1.s_column_name || ' "';
v_statement := v_statement || r1.s_data_type || '(' || r1.s_char_length;
v_statement := v_statement || ' CHAR)';

-- dbms_output.put_line(v_statement);
execute immediate v_statement;
update sys.columns_to_char set s_updated = 'Y' where rowid=r1.rowid;
Commit;
end loop;
dbms_output.put_line('Done');
end;
/

```

Export steps

- 1 Open a DOS window and go to the folder where you want to store the exported dump file. (e.g. D:\oradump)
- 2 From the command line, type and execute the following:

```
expdp 'sys/password@dbct45 as sysdba' full=Y directory=export_dump_dir
dumpfile=ct45.dmp logfile=expdpct45.log
```
- 3 Check the log file for errors. If there are errors, correct them and rerun the export command until it runs without errors.

Before importing the database

Before you import the database, do the following:

- Follow the Oracle database documentation to create a new Unicode database (if applicable).
- If there is a Multisite environment, make sure that the database instance names remain the same in the new database.
- Create the Clintrial tablespaces by running CTTSPACE.SQL.
- Make sure all the data files are auto-extended and have enough space.

Import steps

To import the newly exported database:

- 1 Open a DOS window and navigate to the folder that contains the exported dump file.
- 2 If a folder does not already exist, use the following command to create one:

```
CREATE OR REPLACE DIRECTORY export_dump_dir AS 'D:\oradump\';
GRANT READ, WRITE ON DIRECTORY export_dump_dir TO sys;
```
- 3 From the command line, type and execute the following:

```
impdp 'sys/password@dbct45 as sysdba' full=Y directory=export_dump_dir
dumpfile=ct45.dmp logfile=impdpct45.log
```
- 4 Check the log file. Ignore all the “object already exists” errors.

After importing the database

- 1 Recompile all invalid objects.

For example:

```
C:\> sqlplus /NOLOG
SQL> CONNECT SYS AS SYSDBA
Enter password: SYS_password
SQL> @ORACLE_BASE\ORACLE_HOME\rdbms\admin\utlrlp.sql
```

Note: For more detailed information and step by step instructions, see the Oracle database documentation.

- 2 After the import has finished, check the upgraded database to ensure the upgrade was successful. If necessary, restore the backup, correct the errors and repeat all the steps.
- 3 Run the server **Clintrial Installation Wizard** and select the **Upgrade** option to upgrade the database to Clintrial 4.7.1.

Installing a new Clintrial database

If you are installing the Clintrial software and the Oracle 10.2 or 11.2 database software for the first time (that is, not upgrading from a previous release), Oracle recommends that you do the following:

- 1 Install the Oracle 10.2.0.5 or 11.2.0.1 software.
- 2 Use the Oracle Database Configuration Assistant to create the database.

Note: Oracle recommends that you do not use a pre-configured or starter database for the Oracle 10.2.0.5 or 11.2.0.1 database.

A pre-configured database does not allow you to set the required database parameters prior to database creation.

Some of the required parameter settings (such as including the compatible parameter set to **10.2.0** or **11.2.0**) are difficult to reset after you have created the database.

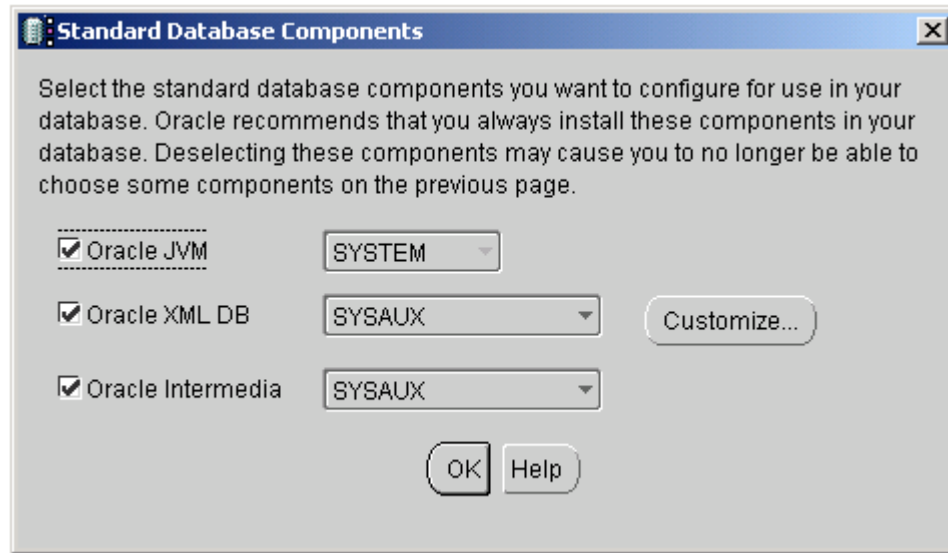
The following information assumes that you are using the Oracle Database Configuration Assistant to create the Oracle 10.2.0.5 or 11.2.0.1 database. The information is presented in the order in which the tool prompts for information.

You must install the Oracle server software before you install the Clintrial server software.

Note: The database character set value and the initialization parameters indicated below are of particular importance. Additional parameter settings that are required by the Clintrial software, can be set during the Oracle installation or after the database is created. For the complete list of database instance parameters that you can set after the Oracle 10.2.0.5 or 11.2.0.1 software installation or upgrade, see Required database instance parameters.

Use the following information to help guide the initial installation or upgrade of the Oracle 10.2.0.5 or 11.2.0.1 database software:

- Create a **Custom Database**, not a **Data Warehouse**, **General Purpose** or **Transaction Processing** database.
- Ensure that all default Standard Database Components are selected.



- If you are going to create a Unicode database, the Database Character Set should be the AL32UTF8 Unicode character set. If you are not going to use Unicode, the National Character set can be set as desired.

This is set in the **Character Set** tab.

- Set the following parameters with the values given, so that they are set at database creation. Use the **All Initialization Parameters** button to set '**compatible**' = **10.2.0** or **11.2.0**.

Database storage parameters

The following storage parameters may not be set by the Configuration Manager in the Oracle 10g or 11g software, but should be configured prior to installing the Clintrial software:

- The USER tablespace can be removed because it is not used by the Clintrial software.
- The SYSTEM tablespace must be PERMANENT and online.
 - Set its storage parameter as follows:

Enable Logging: Yes

All other settings can be adjusted for your environment.

- The TEMP tablespace must be of Type TEMPORARY, and the **Set as Default Tablespace** must **not** be checked.
- If you are using MANUAL undo management, create a tablespace for the Rollback Segments (for example, RBS).

This tablespace must be PERMANENT and Online.

- Set its storage parameter as follows:

Enable Logging: Yes

Retrieving the Oracle database instance name

Note: Oracle recommends that the Global Name, the Clintrial Site Name, and the Site Service Name be identical to the database instance name.

You can view the database instance name, which is set during the creation of the database, by using the following command in SQL*Plus:

```
SQL>SHOW parameter db_name
```

Required database instance parameters

Parameter	Oracle 10.2 or 11.2 setting
compatible	10.2.0 or 11.2.0
db_file_multiblock_read_count	16
deferred_segment_creation	false (Oracle 11.2 only)
dml_locks	500
job_queue_processes	10 (minimum)
max_enabled_roles	150
open_cursors	256 minimum. Larger values are recommended for medium to large databases.
open_links	4 minimum Oracle's default value is 4. If Clintrial Multisite is going to be used, larger values are recommended.
open_links_per_instance	4 minimum Oracle's default value is 4. If Clintrial Multisite is going to be used, larger values are recommended.
processes	100 plus the maximum number of concurrent users.
shared_pool_size	9000000 minimum. 20000000 and higher are recommended for medium to large databases.
sort_area_size	131072 minimum. Larger values are recommended for medium to large databases.

Restarting the database instance

In the following procedures:

- *<password>* is the password for the SYS user.
- *<instance>* is the name of the instance (or service name) you connect to.
- On UNIX-based systems and on Windows 2003, enter the following commands:

```
% sqlplus /nolog
```

```
SQL> connect sys/<password>@<instance> as sysdba
```

```
SQL> startup
```

```
SQL> exit
```

Alternatively, on Windows 2003 systems, use the **Services** dialog box to restart the Oracle database service.

For more information, see the Oracle database documentation.

Preparing the Oracle database server to use the Export/Import utilities with the Clintrial software

To make sure that the Clintrial software can access the Dump Directory and the Log Directory on a UNIX or Linux Oracle database server, create a Windows share on the Linux or UNIX machine.

To do this, you can either set up NFS, or use a utility such as Samba on Linux. Oracle recommends using a utility such as Samba.

Neither Linux nor UNIX can connect to UNC paths. Therefore, you must create a symbolic link from the absolute path to a new path that matches the UNC path.

On a Linux server use Samba to do the following:

- 1 Create a Samba share.
- 2 Add users to the Samba share.
- 3 Create a symbolic link to the shared directory.

For example, if the UNC path is `\\linuxdb\ct_dir_dump`, enter:

```
ln -s <full_pathname_to_directory_in_linux> /linuxdb/ct_dir_dump
```

(where *linuxdb* is the machine name and *ct_dir_dump* is the symbolic link to the shared directory)

When you run the script **ctdirect.sql** during installation or upgrade to set up the directories, you must specify forward slashes in the directory name.

If you attempt to write a log file to a directory to which you do not have WRITE privileges, you receive an error message.

Note: Regardless of the server operating system, allow READ and WRITE access to the physical folder designated as the DATA PUMP directory to every Clintrial user required to do import and export. The directory should be accessible from the Oracle server and from Client PCs. This is mandated by Oracle.

Multisite naming conventions

The Oracle Net Services Names

If you are using Multisite Distribution, or Multisite Distribution and Multisite Replication, the Oracle Net Services Names and the Global Database Names must adhere to the following conventions:

- **Unique**—Must be unique across all database instances in a Multisite environment.
- **Consistent**—Used to access database instances running the Multisite module must be consistent across all database instances in a Multisite environment.
- **Fully qualified**—Must be fully qualified.

A fully qualified Oracle Net Services Name would be in this format:

```
<database_name>.<company_name>.com.
```

For more information, see the Oracle *Master Glossary*.

- **Length**—Maximum of 60 characters.

Multisite naming conventions

Note: Oracle recommends that the Global Name, the Clintrial Site Name, and the Site Service Name be identical to the database instance name.

The database instance name, which is set when the database is created, can be viewed by using the following command in SQL*Plus:

```
SQL>SHOW parameter db_name
```

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

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

The Clintrial Site Name (Site in the Multisite Site browser) is defined during the Clintrial Core Server installation and captured in the CTINST.log file. It may be viewed by using the following command in SQL*Plus:

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

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

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

CHAPTER 3

Performing a new installation of the Clintrial Server software

In this chapter

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Installing the Clintrial Core Server and additional modules	48
Post-installation actions	63

Overview of the Clintrial Server installation

- 1 *Create a Clintrial main installation directory* (on page 44).
- 2 *Create shared directories for use of the Oracle Data Pump Export and Import utilities* (on page 44).
- 3 *Create tablespace data files with the `cttspace.sql` script* (on page 44).
- 4 *Shut down the Oracle database* (on page 46).
- 5 *Restart the Oracle database* (on page 46).
- 6 *Run the Clintrial software installation wizard* (on page 48).
- 7 *Verify your complete Server installation* (on page 62).
- 8 *Run the import/export directory creation script* (on page 112).
- 9 *Set up protocols for added functionality* (on page 114).

Note: All scripts record the time stamps for the start and end of an activity. When you review a log file, verify that both of these time stamps exist.

Preparing for the installation

- 1 Backup your Oracle database.
- 2 Upgrade your Oracle database to Oracle 10.2.0.5 or 11.2.0.1.
- 3 If desired, create a new Oracle database using Unicode.
- 4 *Set file permissions so that the `cttspace.sql` script is writeable.* (on page 44)
- 5 *Shut down the Oracle database instance.* (on page 46)
- 6 *Set the database instance parameters* (on page 38).
- 7 *Restart the Oracle database instance.* (on page 39)
- 8 *Retrieve the Oracle database instance name.* (on page 38)

Before installing the server software

Before beginning the installation, check the Oracle Software Delivery Cloud (<https://edelivery.oracle.com>) or the Download Center (<https://extranet.phaseforward.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.

If you are installing on UNIX or Linux platforms and you have more than one database instance on a server, make sure that the default SID is the database instance for the Clintrial software.

On supported versions of Windows, back up your Oracle database before proceeding with the Clintrial installation. For more information, see the Oracle database documentation

Running a script from a Windows directory

When using SQL*Plus on a Windows server, you need an alias in the current directory, with the shortcut property **Start in** either blank or with the full path. You must do one of the following:

- Change to the installation directory in DOS, and then run SQL*Plus from DOS.
- Create and configure a shortcut for SQL *Plus in the installation directory.

To configure and use a SQL*Plus shortcut:

- 1 Create the SQL*Plus shortcut.
- 2 Right-click the **SQL*Plus shortcut** icon.
- 3 From the pop-up menu, select **Properties**.
- 4 The SQL*Plus Properties dialog box appears.
- 5 Select the **Shortcut** tab.
- 6 Clear the **Start in** field, and then click **OK**.
- 7 Copy the SQL*Plus shortcut to each installation directory. Then, when you run the upgrade script for a module, open SQL*Plus using the shortcut in the installation directory for that module.

Create a Clintrial main installation directory

To create the main installation directory `\ct4server\ct47`:

- On a Windows server, use Windows Explorer to add the `ct4server\ct47` folders to the `$ORACLE_HOME` directory.
- On UNIX or Linux systems, enter the following commands:


```
% cd $ORACLE_HOME
% mkdir -p ct4server/ct47
```

Create shared directories for use of the Oracle Data Pump Export and Import utilities

If you are going to use the Oracle Data Pump Export and Import utilities for migration or upgrade, you must create shared directories for the reading and writing of dump files.

Note: You do not have to use these Oracle utilities, which were added in Oracle 10.2. The same Oracle utilities which were used in Clintrial 4.6 are still available. For more information, *Exporting and importing codelists and protocols in Clintrial 4.7* (on page 112).

Create tablespace data files with the `cttspace.sql` script

Before you run the installation wizard, you should create tablespace data files for the Clintrial software.

Note: If you have not created tablespaces before you run the installation wizard, it creates them. However, running the `cttspace.sql` script to create these data files gives you more flexibility in how they are created.

Use the `cttspace.sql` script to create these data files. By default, this script prompts for the system password, the path name where the tablespace data files are created, and the data file extension. You can modify this script as follows:

- If all the data files are created in the same location, you can comment out the prompt that asks for the path name, and then insert the path name as a variable.
For more information, see the comments in the `cttspace.sql` script.
- If all the data files have the same extension, you can comment out the prompt that asks for the extension, and then insert the extension as a variable.

For more information, see the comments in the `cttspace.sql` script.

Note: You can change the initial sizes of tablespaces and associated storage parameters to meet your data storage needs.

To create tablespaces:

- 1 Optionally, edit the `cttspace.sql` file.

- 2 If you are using the default tablespace sizes in the **cttspace.sql** file, make sure that you have at least 185 MB of disk space.
- 3 If you have changed the initial tablespace sizes, make sure that you have the appropriate amount of free disk space.
- 4 Start SQL*Plus from the module's installation directory and log on to the database instance.
- 5 Run the **cttspace.sql** script to create the tablespace data files:

SQL> @cttspace

You are prompted to enter **language_option**.

- 6 Enter **e** or **j** (for English or Japanese). These are the only valid options.
- 7 Press **Enter** to accept the default, or enter the log file name.

You are prompted to enter a connection string.

- 8 Enter the **@** symbol followed by the instance (or service) name to connect to.

You are prompted to enter the Oracle SYSTEM Account Password.

- 9 Enter the Oracle SYSTEM Account Password.

If you use the default method for typing the path for the tablespace data files, you are prompted to enter the full path.

Caution: You must include the trailing delimiter (such as “\”) in the path. Otherwise, the last subdirectory name in the path is included in the file name. For example:

C:\oracle\Database\Files

The trailing delimiter is specific to the operating system on which the script is running.

- 10 If you use the default method for typing the file extension of the tablespace data files, you are prompted to enter the file extension.

You can enter the file extension with or without the period.

For example, if the name of the database instance is ora1025b, the file extension could be:

.ORA1025B

In this example, the **cttspace.sql** script creates the following tablespace data files in the C:\Ora102\Database\Files\ subdirectory:

CT_META_D.ORA1025B

CT_META_I.ORA1025B

CT_DATA_D.ORA1025B

CT_DATA_I.ORA1025B

CT_USERS.ORA1025B

- 11 When the script has finished creating the tablespace data files, review the log file for Oracle errors.

Shut down the Oracle database

Using the Oracle SQL*Plus utility, shut down the Oracle database instance that you will be using with the Clintrial software.

<password> is the password for the SYS user. <instance> is the name of the instance (service name) you connect to.

- On UNIX or Linux systems, enter the following commands:

```
% sqlplus /nolog  
SQL> connect sys/<password>@<instance> as sysdba  
SQL> shutdown immediate  
SQL> exit
```
- On a Windows server, enter the following commands:

```
C:\ sqlplus sys/<password>@<instance>as sysdba  
SQL> shutdown immediate  
SQL> exit
```

Alternatively, on Windows 2003, use the **Services** dialog box to shut down the Oracle database service.

The Oracle service stops, shutting down the database instance.

For more information, see your Oracle documentation.

Restart the Oracle database

In the following procedures:

- <password> is the password for the SYS user.
- <instance> is the name of the instance (or service name) you connect to.
- On UNIX-based systems and on Windows 2003, enter the following commands:

```
% sqlplus /nolog  
SQL> connect sys/<password>@<instance> as sysdba  
SQL> startup  
SQL> exit
```

Alternatively, on Windows 2003 systems, use the **Services** dialog box to restart the Oracle database service.

For more information, see the Oracle database documentation.

Using the Japanese version of the Clintrial Installation Wizard on an English Windows Operating System

If you choose Japanese as the setup language when you start to run the Clintrial Installation Wizard to install or upgrade Clintrial 4.7.1, and it displays the message:

The Japanese won't be displayed properly. Please refer to the user documentation.

you are trying to run the Japanese version of the wizard on an English Windows Operating System.

Use this procedure to view Japanese on English OS:

- 1 From the Windows Control Panel, choose **Regional and Language Options**.
- 2 Click on **Language** tab.
- 3 Select the checkbox **Install files for East Asian languages**.
- 4 Click on **OK** and follow prompted instructions.
(If it requires a restart the Windows, do so.)
- 5 Return to the Control Panel's **Regional and Language Options**.
- 6 Click on **Advanced** tab.
- 7 Make sure that Japanese code page is selected from Code page conversion tables.
- 8 Select **Japanese** from the dropdown list under **Select a language to match the language version of the non-Unicode programs you want to use**.
- 9 Click on **OK** and re-boot Windows.

You may now run the Clintrial Installation Wizard, and the Japanese characters will be displayed correctly on the English OS.

Installing the Clintrial Core Server and additional modules

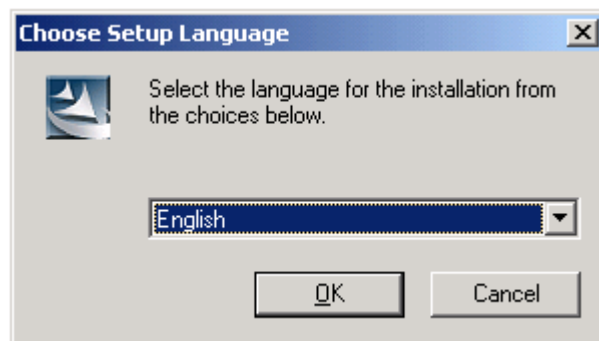
- 1 *Run the Clintrial software installation wizard* (on page 48).
- 2 *Verify your complete Server installation* (on page 62).

Note: All scripts record the time stamps for the start and end of an activity. When you review a log file, verify that both of these time stamps exist.

Run the Clintrial installation wizard

Note: The server installation and upgrade wizard is a 32-bit application. If you need to install the server application on a machine with a 64-bit operating system, you should do so from a 32-bit networked computer, and then connect to the server with Oracle credentials.

- 1 Navigate to the location of the installation files and double-click **CTServerInstaller.exe**.
For the first-time installation, the **Choose Setup Language** window appears.



If you want to choose a language other than English on an English operating system, the proper language pack must be installed and the Windows default language must be changed. For example, if you want to conduct the installation in Japanese, the Asian language pack must be installed and the default language must be changed to Japanese.

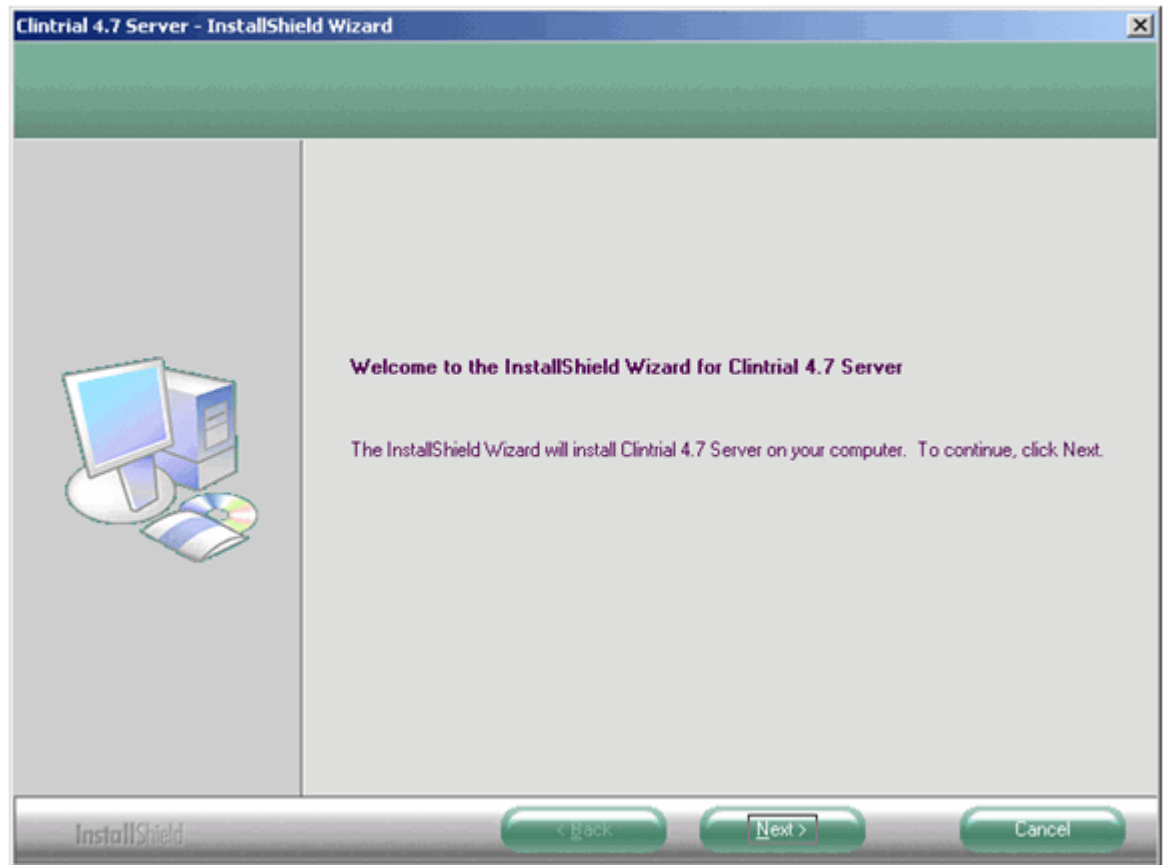
For more information, see your Windows documentation.

- 2 Select the language you want the wizard to use during setup. This also the language that will be used for the labels and descriptions for codelists and tags.

Note: The language for the application post-setup is chosen later.

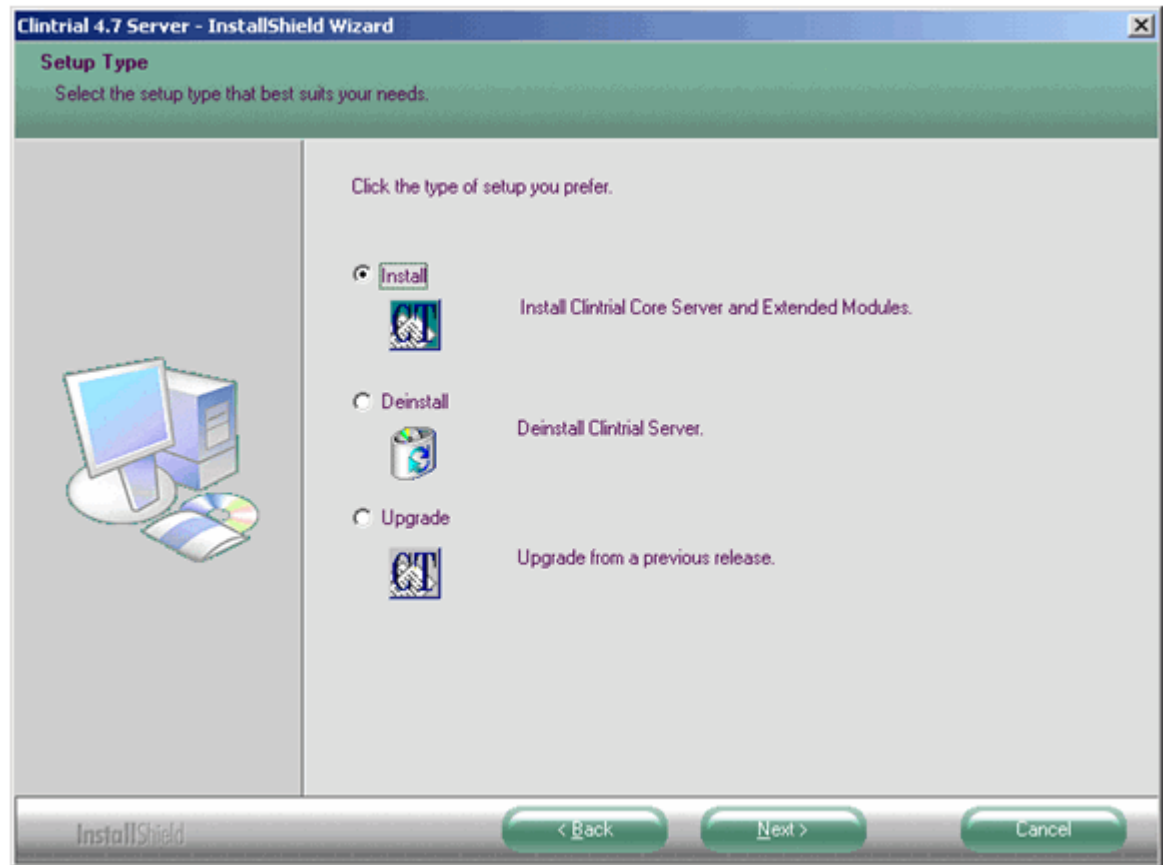
- 3 Click **Next**.

The **Welcome** window appears.



- 4 Click **Next**.

The **Setup type** window appears.



Note: Upgrade and deinstallation procedures using the wizard are described in sections below.

- 5 To install the Clintrial server, click **Install**, then **Next**.

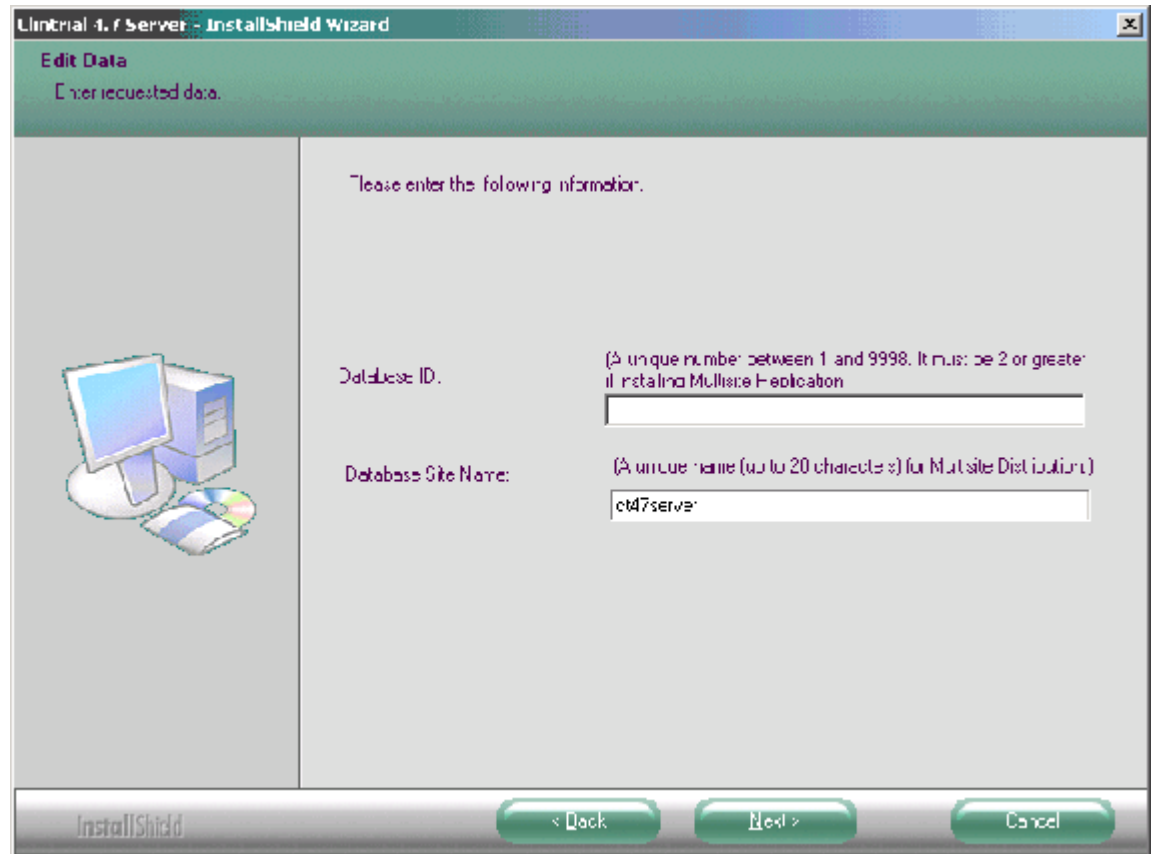
The first **Edit data** window, which asks for information on the Oracle database, appears.

- 6 Enter the following information:
 - **Database Connection String** as it is defined in the **tnsnames.ora** file.
 - Oracle database **SYS password**.
 - Oracle database **SYSTEM password**.
- 7 Click **Next**.

If there are no tablespaces found in the Oracle database described in the previous window, a dialog will ask whether you want to create default tablespaces. Click **Yes**.

Caution: If there are no Clintrial tablespaces, the installation will fail.

Otherwise, the second **Edit data** dialog will display prompting for more information on the database instance.



8 Enter the following information:

- **Database Identifier.** A **Database Identifier** of 1 should only be used for a stand-alone database instance. If the database instance is to be used with Multisite Replication, enter a unique number between 2 and 9998. Make sure that the values you enter are unique at each site in a Multisite environment.
- **Database Site Name.**

Note: Oracle recommends that the **Global Name**, the **Clintrial Site Name**, and the **Site Service Name** be identical to the Oracle database instance name.

You can view the Oracle database instance name, set during the creation of the database, by using the following SQL*Plus command:

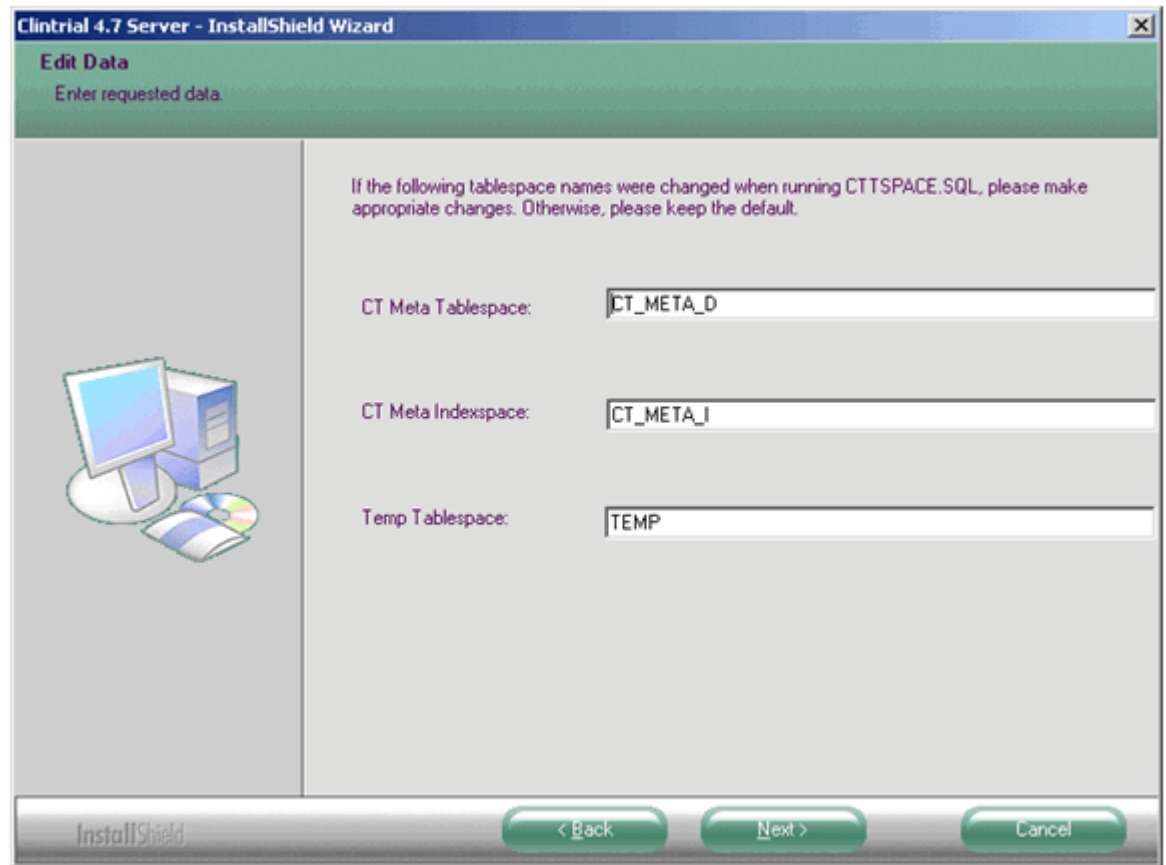
```
SQL>SHOW parameter db_name
```

Caution: The **Site Name** can contain alphanumeric characters or an underscore (_), and must begin with an alphabetic letter. It cannot be an Oracle reserved word.

If you plan on installing Multisite Distribution, each **Site Name** in a Multisite environment must be unique.

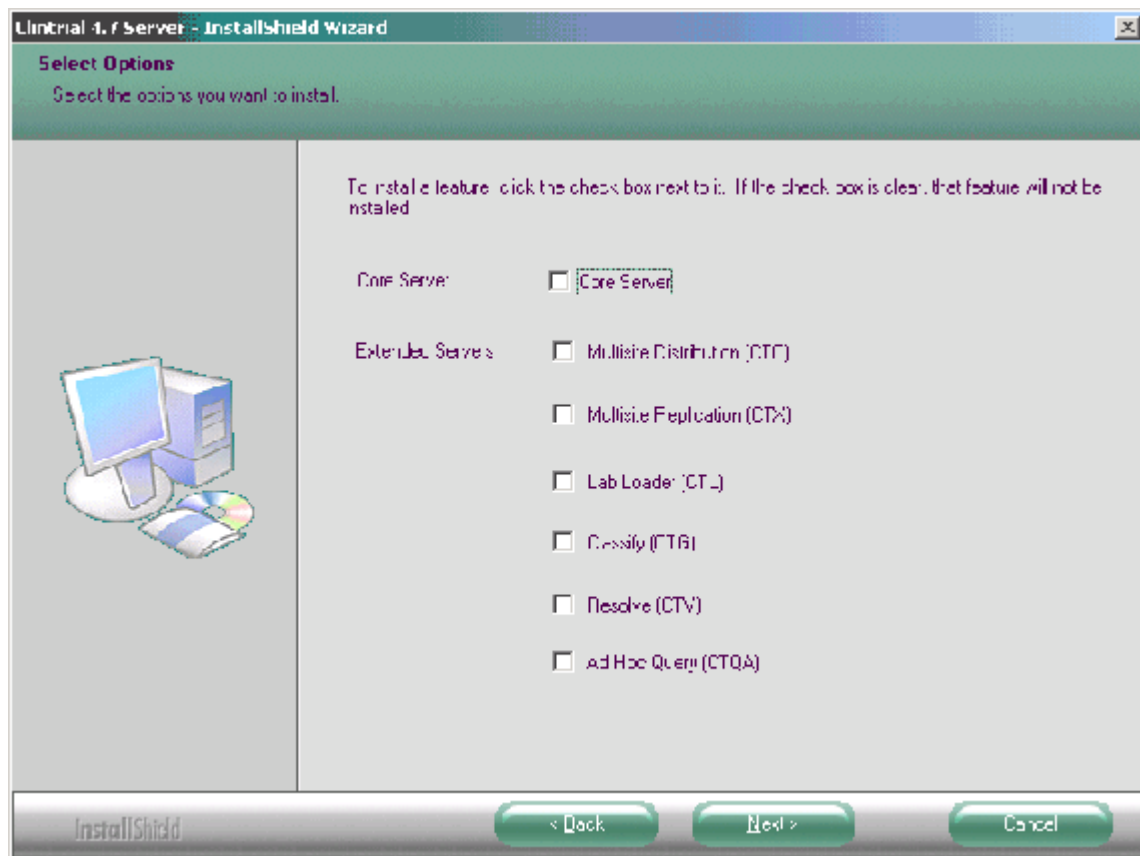
9 Click **Next**.

The third **Edit data** window asking for information on the Oracle tablespaces.



- 10 If you changed the listed tablespace names when you ran the CTTSPACE.SQL script, change the names listed here. Otherwise, keep the defaults.
- 11 Click **Next**.

The **Select Options** window appears.



12 Select the options you want to install.

13 Click **Next**.

The **Edit Data** window for the CTSYS and CTPROC accounts appears.

Clintrial 4.7 Server - InstallShield Wizard

Edit Data
Enter requested data

Please enter the following information.

For security reasons, please specify passwords for the following account(s).

Account Name:	Password:	Confirm Password:
CTSYS:	<input type="password"/>	<input type="password"/>
CTPROC:	<input type="password"/>	<input type="password"/>

InstallShield < Back Next > Cancel

14 Enter and confirm the passwords for the CTSYS and CTPROC accounts.

- **CTSYS** system account—Clintrial System Administrator account.
- **CTPROC** system account—stores internal Clintrial software procedures.

These account passwords are necessary for all installations.

15 Click **Next**.

The **Edit Data** window for the Clintrial core accounts appears.

16 Enter and confirm the passwords for the Clintrial core accounts.

- If you have decided to use the same password for all of the Clintrial core accounts, check the box, enter, and confirm the password.
- If you want different passwords for accounts, enter and confirm the password for each account.

- **CTS** system account—contains database-wide information about protocol accounts, flags, notes, user accounts, and user privileges.

- **CTSD** system account—contains database-wide information about protocol-specific metadata definitions; for example, item and panel attributes for all installed panels.

- **CTSCODES** system account—contains database-wide codelist information.

- **CISUSER** account—issued by the CIS synchronization process to transfer information to and from the InForm application.

This account does not store information. If you have no plans to use CIS, you may leave these fields blank.

- **PXFR_SEND** system account—contains protocol metadata when the protocol is exported.
- **PXFR_RECV** system account—contains protocol metadata when the protocol is imported.
- **CXFR_SEND** system account—contains codelists when they are exported.
- **CXFR_RECV** system account—contains codelists when they are imported. Contains

database-wide information about protocol-specific metadata definitions; for example, item and panel attributes for all installed panels.

- 17 Click **Next**.

The **Edit Data** window for the Clintrial accounts of Clintrial extended servers appears.

Clintrial 4.7 Server - InstallShield Wizard

Edit Data
Enter requested data

Please enter the following information.

Use the same password for other accounts of Clintrial extended servers
(CTSRM CTSRP CTCLASSIFY REVIEWADMIN)

Password: Confirm Password:

CTSRM: Password: Confirm Password:

CTSRP: Password: Confirm Password:

CTCLASSIFY: Password: Confirm Password:

REVIEWADMIN: Password: Confirm Password:

This database will be used as a Master Site .

InstallShield < Back Next > Cancel

- 18 Enter and confirm the passwords for the extended server accounts.

- If you have decided to use the same password for all of the Clintrial extended server accounts, check the box, enter, and confirm the password.
- If you want different passwords for accounts, enter and confirm the password for each account. You need only enter and verify passwords for extended modules you are installing.

- **CTSRM** Multisite account—created automatically when you install the Distribution (CTC) server component of Multisite.

This account stores information that is used to manage distribution across multiple sites. If you are not installing Multisite Distribution, leave the CTSRM password blank.

- **CTSRP** Multisite account—created automatically when you install the Replication (CTX) server component of Multisite.

This account stores information that is used to manage replication across multiple sites.

- **CTCLASSIFY** Classify account—created automatically when you install Classify.

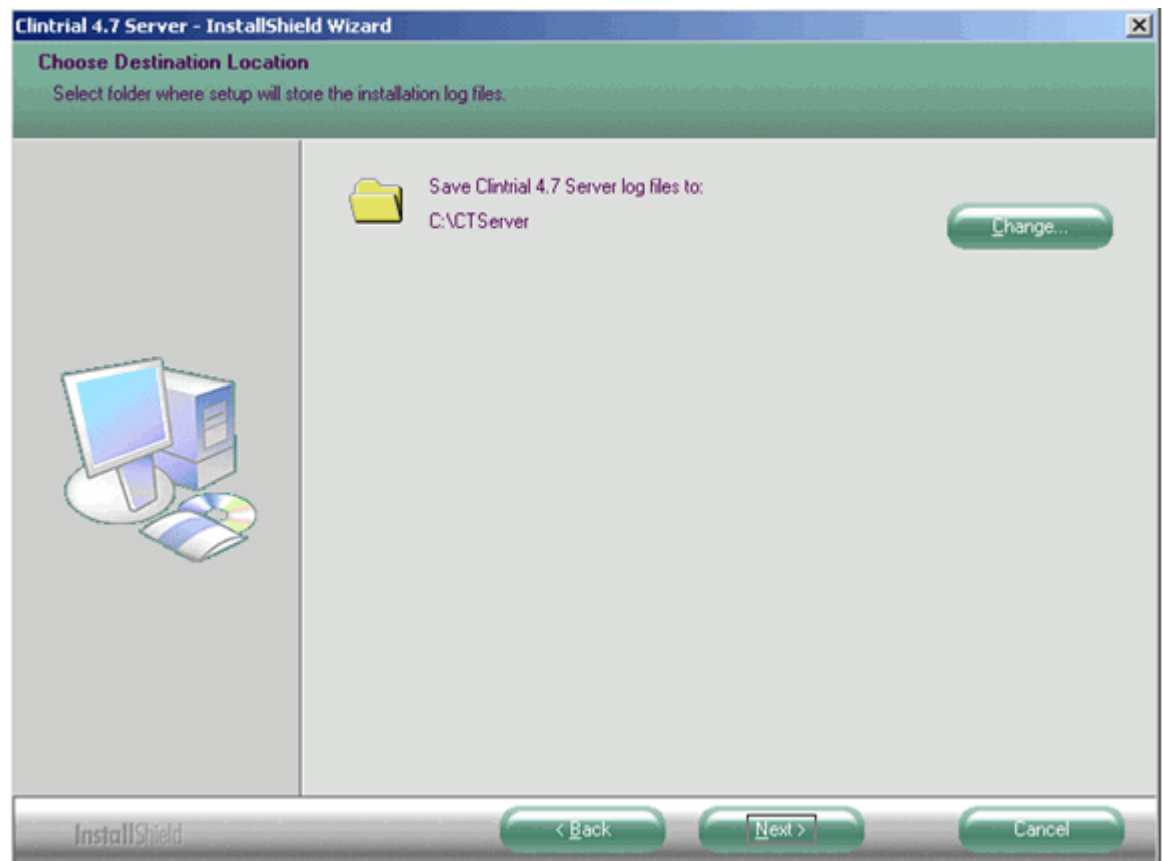
This account stores information about Classify-specific objects, such as omissions.

- **REVIEWADMIN** Retrieve account—created automatically when you install Retrieve.

This account stores information for Ad Hoc reporting in the Retrieve module.

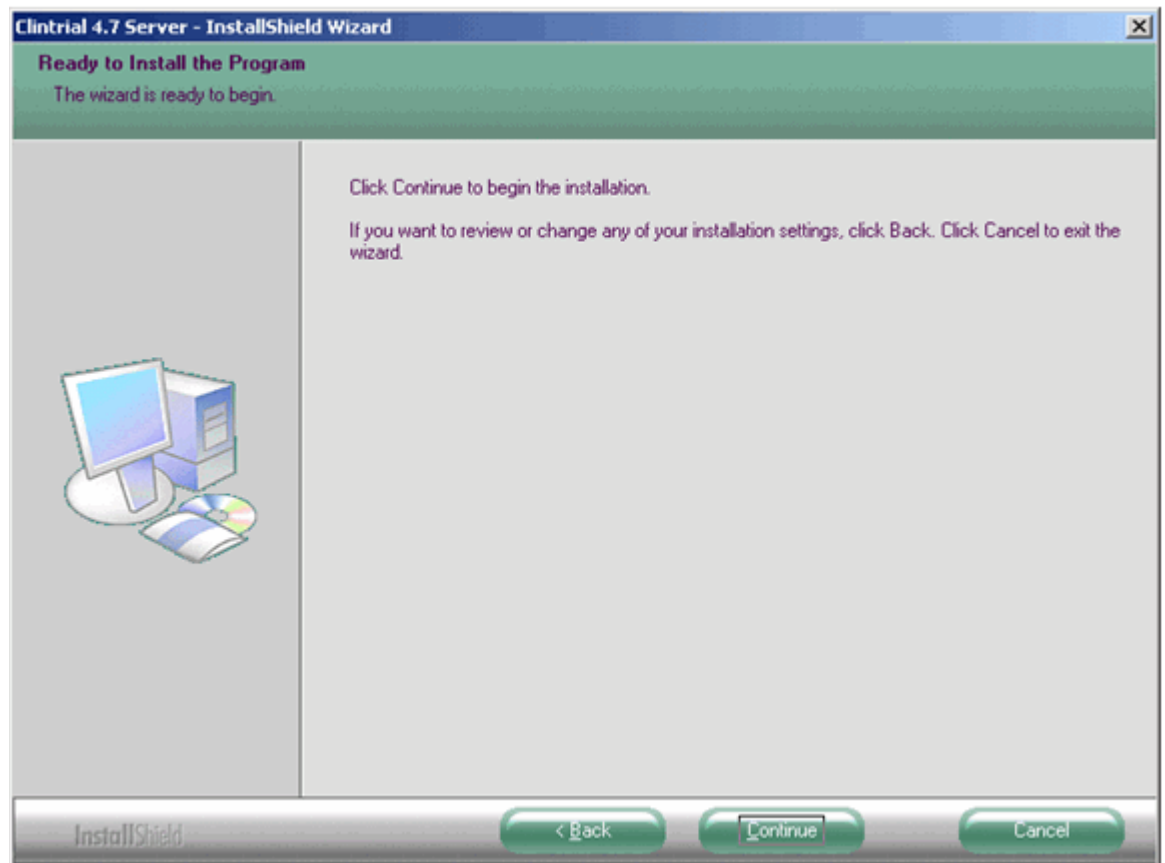
- Click on the checkbox at the bottom of the window if this database will be used for the Multisite Replication Master Site and replication is being installed.

The **Choose Destination Location** window appears. This is the folder where the installation log files will be stored.



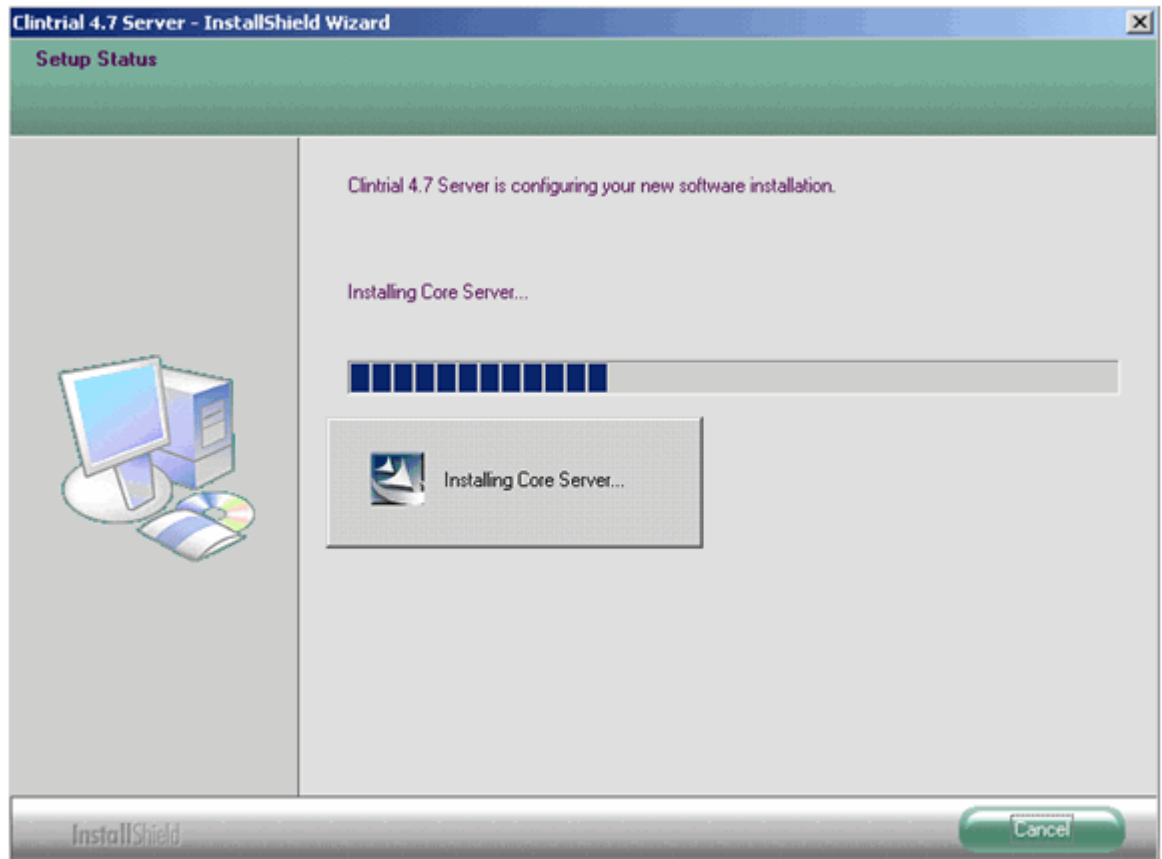
- 19 Accept the default location, or click **Change** to select a different folder.
- 20 Click **Next**.

The **Ready to Install** window appears.



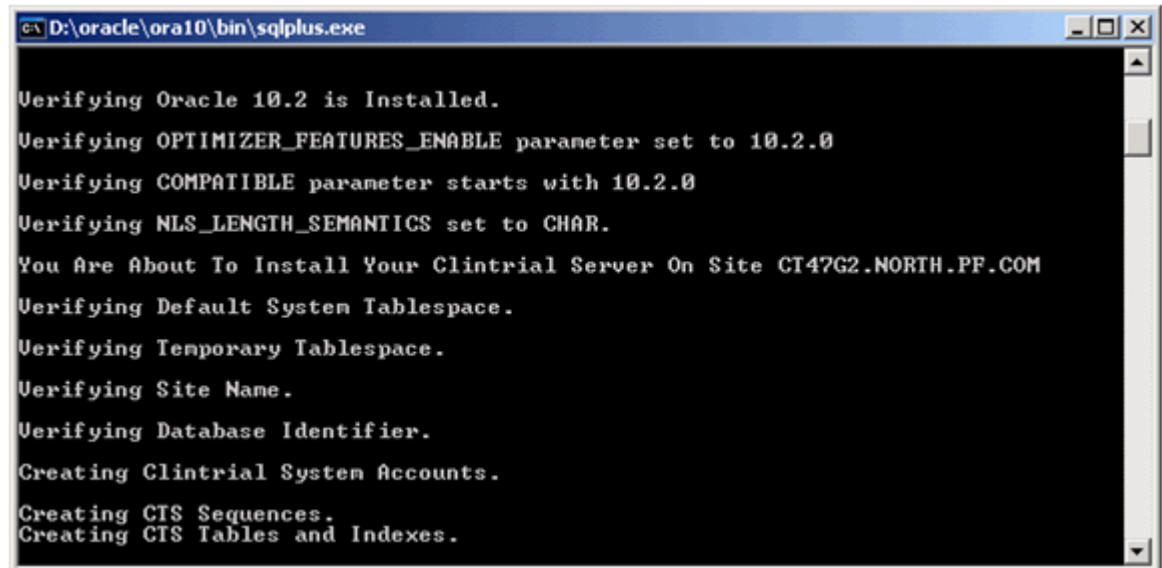
- 21 Click on **Continue** to begin installation. Otherwise, click on **Back** to modify the selections.

The **Setup Status** window appears.

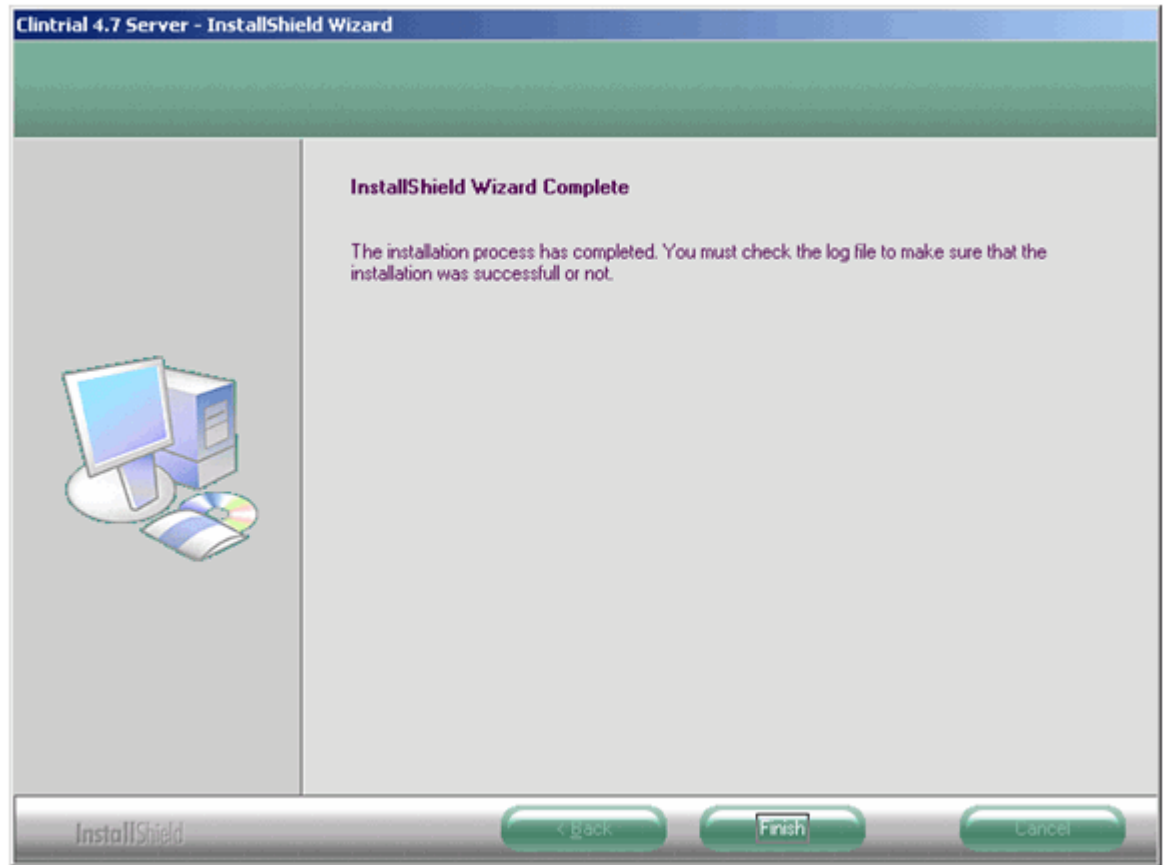


- 22 Click **Cancel** to abort the installation, or wait as the installation continues.

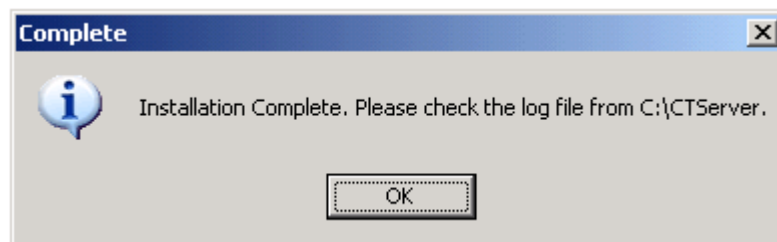
At the same time, a DOS status dialog will also display indicating the processes for each module.



After the installation is finished, the **InstallShield Wizard Complete** window appears.



- 23 Click **Finish** and the **Complete** dialog will display, reminding you where the log files were written.



- 24 Click **OK**.
- 25 Check the log files to make sure all the installations are successful.
Installation complete!

Verify your complete Server installation

- 1 Start SQL*Plus and log onto the database as SYSTEM.
- 2 Enter the following SQL statement:

```
SQL> select * from cts.registry;
```

SQL*Plus returns information about the Clintrial modules that are currently installed on the database.

For example, if you have installed all the Clintrial modules, the results should look similar to the following:

CT_OP	STATUS	MODDATE	VERSION	PATCH_LEVEL	BUILD_ID
CT	1	XX-MAY-12	4.7	3	4.7.1.40XX
CTC	1	XX-MAY-12	4.7	1	4.7.1.40XX
CTX	1	XX-MAY-12	4.7	1	4.7.1.40XX
CTG	1	XX-MAY-12	4.7	1	4.7.1.40XX
CTL	1	XX-MAY-12	4.7	1	4.7.1.40XX
CTV	1	XX-MAY-12	4.7	1	4.7.1.40XX
CTQA	1	XX-MAY-12	4.7	1	4.7.1.40XX

Post-installation actions

If you are using Central Coding

If you are planning to use the Oracle Central Coding application, you must specifically grant permissions via Access Control Lists (ACLs) for the HTTP requests.

To use the Central Coding application with Oracle 11.2, you must explicitly grant permissions via ACLs to enable the HTTP request to connect to the Central Coding server.

- 1 Login to the Oracle Clintrial database as SYS.
- 2 Execute code similar to the following:

```
BEGIN
DBMS_NETWORK_ACL_ADMIN.CREATE_ACL (
acl => 'ct_cc.xml',
description => 'Sample ACL for Central Coding',
principal => 'CTPROC',
is_grant => TRUE,
privilege => 'connect');
end;
/
BEGIN
DBMS_NETWORK_ACL_ADMIN.ASSIGN_ACL (
acl => 'ct_cc.xml',
host => '<Central Coding Server'');
END;
/
```

For further information on using Network ACLs, see the Oracle *Database Security Guide*, "Managing Fine-Grained Access in PL/SQL Network Utility Packages".

Create a verify function to ensure that passwords meet security standards

You can create a password verification function to ensure that passwords meet the standards contained in the Clintrial system parameters or a database profile. This function can be assigned in the Clintrial application using the Admin system parameters, or be part of an Oracle database profile created for users or usergroups.

The *Oracle Database Security Guide* describes a method for enforcing password complexity for database user accounts. Briefly, the database administrator creates a password verification function and associates it with a user profile. In the Clintrial application, you also can associate the function using the system parameter in the Admin module. The sample given in the *Oracle Database Security Guide* associates this function with the DEFAULT profile. However, there are special considerations when applying this methodology to Clintrial.

- Non-user accounts, such as system accounts and the accounts for each protocol, use the DEFAULT database profile. The passwords are assigned during installation or upgrade, and encrypted. The resulting encrypted password strings are not constrained to specific characters, and therefore you cannot expect any verification function which relies on character comparisons, such as checking for the existence of at least one number and one non-number to work correctly. For that reason, Oracle strongly suggests that you do not add a verification function to the DEFAULT profile.
- In the case where the Clintrial PASSWORD_ENCRYPTION system parameter is set to No in the Admin module, an encryption verification function can be created and assigned using the

Admin module. At least one additional profile must be created for use with Clintrial users, and that profile also can be associated with the verification function. For example, the below command creates a new profile. When creating users in Admin, you should create a profile like the below example and set additional profile limits like those in the DEFAULT profile:

```
CREATE PROFILE CT_USER_PROFILE LIMIT
PASSWORD_VERIFY_FUNCTION <function_name>;
```

- In the case where the PASSWORD_ENCRYPTION system parameter is set to Yes, the verification function should not be associated with any profiles which are used for Clintrial users in the Admin module system parameters. Similar to the Protocol account case, the encrypted passwords would not function as expected.

This new system parameter that has been added (PASSWORD_VFY_FUNC) allows the Administrator to specify the name of a password verification function which will be called from Clintrial before the encryption of the password. The function is applied to all Clintrial users created in Admin during creation of the users as well as modification of the password by either the Administrator or the user.

The function must have the same parameters as described in the Oracle database documentation. It does not have to be installed into the **SYS** account. The value of the system parameter should specify the owner and function name, for example, **SYS.CT_VFY_FUNC**. Additionally, execute privileges on this function must be granted to the system account **CTPROC**, using this command:

```
Grant execute on <function_name> to CTPROC;
```

For the Clintrial system account **CTSYS**, the function cannot be defined and called until after core server installation has succeeded, so the initial **CTSYS** password supplied during installation is not checked in this way.

Example verify function

```
CREATE OR REPLACE FUNCTION verify_function_11G_1
(username varchar2,
 password varchar2,
 old_password varchar2)
RETURN boolean IS
  n boolean;
  m integer;
  differ integer;
  isdigit boolean;
  ischar boolean;
  ispunct boolean;
  db_name varchar2(40);
  digitarray varchar2(20);
  punctarray varchar2(25);
  chararray varchar2(52);
  i_char varchar2(10);
  simple_password varchar2(10);
  reverse_user varchar2(32);

BEGIN
  digitarray:= '0123456789';
  chararray:= 'abcdefghijklmnopqrstuvwxyABCDEFGHIJKLMNOPQRSTUVWXYZ';

  -- Check for the minimum length of the password
  IF length(password) < 8 THEN
    raise_application_error(-20001, 'Password length less than 8');
  END IF;

  -- Check if the password is same as the username or username(1-100)
```

```

IF NLS_LOWER(password) = NLS_LOWER(username) THEN
    raise_application_error(-20002, 'Password same as or similar to user');
END IF;
FOR i IN 1..100 LOOP
    i_char := to_char(i);
    if NLS_LOWER(username) || i_char = NLS_LOWER(password) THEN
        raise_application_error(-20005, 'Password same as or similar to user
name ');
    END IF;
END LOOP;

-- Check if the password is same as the username reversed

FOR i in REVERSE 1..length(username) LOOP
    reverse_user := reverse_user || substr(username, i, 1);
END LOOP;
IF NLS_LOWER(password) = NLS_LOWER(reverse_user) THEN
    raise_application_error(-20003, 'Password same as username reversed');
END IF;

-- Check if the password is the same as server name and or servername(1-100)
select name into db_name from sys.v$database;
if NLS_LOWER(db_name) = NLS_LOWER(password) THEN
    raise_application_error(-20004, 'Password same as or similar to server
name');
END IF;
FOR i IN 1..100 LOOP
    i_char := to_char(i);
    if NLS_LOWER(db_name) || i_char = NLS_LOWER(password) THEN
        raise_application_error(-20005, 'Password same as or similar to server
name ');
    END IF;
END LOOP;

-- Check if the password is too simple. A dictionary of words may be
-- maintained and a check may be made so as not to allow the words
-- that are too simple for the password.
IF NLS_LOWER(password) IN ('welcome1', 'database1', 'account1', 'user1234',
'password1', 'oracle123', 'computer1', 'abcdefg1', 'change_on_install') THEN
    raise_application_error(-20006, 'Password too simple');
END IF;

-- Check if the password is the same as oracle (1-100)
simple_password := 'oracle';
FOR i IN 1..100 LOOP
    i_char := to_char(i);
    if simple_password || i_char = NLS_LOWER(password) THEN
        raise_application_error(-20007, 'Password too simple ');
    END IF;
END LOOP;

-- Check if the password contains at least one letter, one digit
-- 1. Check for the digit
isdigit:=FALSE;
m := length(password);
FOR i IN 1..10 LOOP
    FOR j IN 1..m LOOP
        IF substr(password,j,1) = substr(digitarray,i,1) THEN
            isdigit:=TRUE;
            GOTO findchar;
        END IF;
    END LOOP;
END LOOP;

IF isdigit = FALSE THEN
    raise_application_error(-20008, 'Password must contain at least one

```

```

digit, one character');
END IF;
-- 2. Check for the character
<<findchar>>
ischar:=FALSE;
FOR i IN 1..length(chararray) LOOP
  FOR j IN 1..m LOOP
    IF substr(password,j,1) = substr(chararray,i,1) THEN
      ischar:=TRUE;
      GOTO endsearch;
    END IF;
  END LOOP;
END LOOP;
IF ischar = FALSE THEN
  raise_application_error(-20009, 'Password must contain at least one \
digit, and one character');
END IF;

<<endsearch>>
-- Check if the password differs from the previous password by at least
-- 3 letters
IF old_password IS NOT NULL THEN
  differ := length(old_password) - length(password);

  differ := abs(differ);
  IF differ < 3 THEN
    IF length(password) < length(old_password) THEN
      m := length(password);
    ELSE
      m := length(old_password);
    END IF;

    FOR i IN 1..m LOOP
      IF substr(password,i,1) != substr(old_password,i,1) THEN
        differ := differ + 1;
      END IF;
    END LOOP;

    IF differ < 3 THEN
      raise_application_error(-20011, 'Password should differ from the \
old password by at least 3 characters');
    END IF;
  END IF;
END IF;
-- Everything is fine; return TRUE ;
RETURN(TRUE);
END;
/
CREATE PROFILE CT_USER_PROFILE1 LIMIT PASSWORD_VERIFY_FUNCTION
verify_function_11G_1;
/

```

CHAPTER 4

Upgrading the server to this release

In this chapter

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Overview

You can upgrade to the Clintrial 4.7.1 software from the Clintrial 4.5 or Clintrial 4.6 software. If you are using a release earlier than the Clintrial 4.5 software, you must first upgrade to the Clintrial 4.5 software and then upgrade to the current release.

The following Clintrial server modules can be upgraded:

- Core server.
- Multisite Distribution server.
- Multisite Replication server.
- Classify server.
- Lab Loader server.

Note: The Ad Hoc Query feature and the Resolve module are upgraded as part of the Core upgrade.

Upgrade options

You can upgrade to the Clintrial 4.7.1 software in one of two ways:

- Upgrade the entire Clintrial 4.5, 4.6, or 4.7 database instance to the Clintrial 4.7.1 database instance, as described in this chapter.
- Export codelists and protocols from the current Clintrial database instance, then import codelists and protocols into a Clintrial 4.7.1 database instance.

For more information, see *Limitations of upgrading by import* (on page 69).

Note: Oracle recommends that you upgrade the entire database instance.

When considering these upgrade options, keep in mind the following requirements:

- Do not export to a temporary tablespace.
Oracle recommends that you export using a tablespace that does not exist in the Clintrial 4.7 database instance.
- If you plan to use Multisite Distribution with your existing Clintrial Multisite 4.5, 4.6, or 4.7 configuration, you must upgrade all database instances.

For more information, see the Design section in the *Admin and Design* guide and the Design Help.

Limitations of upgrading by import

Exporting protocols from a Clintrial 4.5, 4.6, or 4.7 database instance, and then importing them into a Clintrial 4.7.1 database instance by using the Oracle Import/Export utility requires many steps.

Oracle recommends that you upgrade the entire database instance.

If you are using external tables for view protocols, you cannot export or import these protocols.

If you perform a full database export from a non-Unicode database in a Clintrial 4.5 or Clintrial 4.6 application (or a Unicode Clintrial 4.7 on Oracle 10.2.0.4 to Clintrial 4.7.1 on Oracle 11.2), and import to a Unicode database in a Clintrial 4.7.1 application, you must run the `prv_sys.sql` script to re-grant Select privileges on the SYS tables for the core modules.

If you are using the Multisite module, you must also perform these grants:

```
grant select on sys.dba_db_links to prv$wxrm;  
grant select on sys.dba_tablespace to prv$wxrm;  
grant select on sys.dba_objects to prv$wxrm;  
grant select on sys.dba_source to ctsrm;
```

For more information, contact the Global Support Center.

Before you begin the upgrade

Before beginning the installation, check the Oracle Software Delivery Cloud (<https://edelivery.oracle.com>) or the Download Center (<https://extranet.phaseforward.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.

If you are installing on UNIX or Linux platforms and you have more than one database instance on a server, make sure that the default SID is the database instance for the Clintrial software.

On supported versions of Windows, back up your Oracle database before proceeding with the Clintrial installation. For more information, see the Oracle database documentation

Before upgrading the database instance

- 1 Verify that the Clintrial software 4.5, 4.6, or an earlier release of 4.7 software is installed.
If you are using a release earlier than Clintrial 4.5, you must first upgrade to a Clintrial 4.5 or 4.6 release, and then upgrade to the Clintrial 4.7.1 software.
- 2 Back up the database instance.
- 3 Check the Oracle and the Clintrial requirements.
- 4 Upgrade to the Oracle database 10.2.0.5 or Oracle database 11.2.0.1 software.
- 5 Decide if you want to use an Oracle Unicode database. If so, refer to **Preparing to install or upgrade to this release** (on page 23).
- 6 Migrate your Clintrial database to the Oracle 10.2.0.5 or Oracle 11.2.0.1 software.

Backing up your Clintrial database

Back up your Clintrial 4.5, 4.6, or 4.7 database instance at the following stages in the upgrade process:

- Before migrating from an earlier release of the Oracle database software to the Oracle 10.2.0.5 or Oracle 11.2.0.1 software.
- Before running the script to upgrade your Clintrial 4.5, 4.6, or 4.7 server to the Clintrial 4.7.1 core server.

Checking other requirements

Confirm the following:

- Your environment meets the hardware and software requirements for the Clintrial software and the Oracle 10.2.0.5 or Oracle 11.2.0.1 database software.
- You have upgraded to Oracle 10.2.0.5 or Oracle 11.2.0.1 database software.
- Your environment can support a Clintrial server installation.
- All protocol and codelists imports are completed.
- No panels are marked for revision.
- If you are using Multisite Distribution, no protocols or codelists are open for revision.
- If you are using Multisite Replication, all replication accounts are aborted.

Running a script from a Windows directory

If you are running a Windows server, do one of the following:

- Change to the installation directory in DOS, and then run SQL*Plus from DOS.
- Create and configure a shortcut for SQL*Plus in the installation directory.

To configure and use a SQL*Plus shortcut:

- 1 Create the SQL*Plus shortcut.

- 2 Right click the **SQL*Plus shortcut** icon.
- 3 From the pop-up menu, select **Properties**.
- 4 The SQL*Plus Properties dialog box appears.
- 5 Select the **Shortcut** tab.
- 6 Clear the **Start in** field, and then click **OK**.

Copy the SQL*Plus shortcut to each installation directory, and then, when running the upgrade script for a module, open SQL*Plus using the shortcut.

After checking all the requirements listed in the previous sections, you can migrate from the Oracle 9.2.0.6 software to the Oracle 10.2.0.5 or Oracle 11.2.0.1 software, as described in your Oracle documentation.

Upgrade tips and considerations

The following are some tips and considerations to keep in mind when upgrading to this release of the Clintrial software:

- Carefully read Chapter 2. Ensure that your database objects meet the necessary criteria.
- Consider the impact on any custom changes made to Clintrial software objects outside the Clintrial software. Any changes made outside the Clintrial software could cause the upgrade to fail. For example, dropping tables or changing views to reference external objects could cause the upgrade to fail.
- Check your tables, views, packages, and functions to ensure all are present and valid.
- Check the upgrade log for errors when the upgrade completes. If the upgrade completes successfully, your registry entry will indicate release 4.7. However, there could still be errors written to the upgrade log.

For information on protocols that you need to import for additional Clintrial software functionality, see *Protocols for added functionality* (on page 114).

Upgrading the Clintrial software using the upgrade wizard

Important: When running the server installer for upgrading the Clintrial server, the following requirements must be completed first:

- The Oracle database must be updated to the specified version (Oracle 10.2.0.5 or 11.2.0.1). See *Preparing to install or upgrade to this release* (on page 23) for how to upgrade the Oracle database.

Note: The upgrade only upgrades the following Clintrial servers:

Clintrial English 4.5, 4.6, or 4.7

Clintrial Japanese 4.5

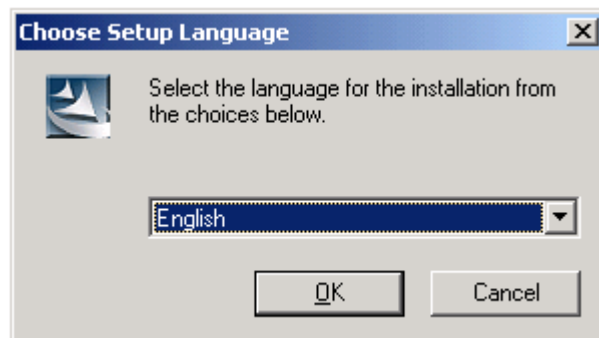
- If you are a global company and want to use a Unicode database, you must set the **character set** to **Unicode (AL32UTF8)** and set the **nls_length_semantics** to **CHAR** in the Oracle database's **All Initialization Parameters**.

Note: An example of the effect this setting has on data in a Clintrial Unicode protocol is the setting of **varchar2(2000)** (4000 bytes) for an item (usually a text item) in panel by using the Design module. In a language using Western characters (like English or French), where each character takes no more than 2 bytes, this sets the limit at 2000 characters. In Japanese, a character requires 3 bytes or more, so the limit could be as few as 1333 characters (4000 bytes divided by 3).

Running the Clintrial upgrade wizard

1. Navigate to the location of the installation files and double-click **CTServerInstaller.exe**.

For the first-time upgrade, the **Choose Setup Language** window appears.



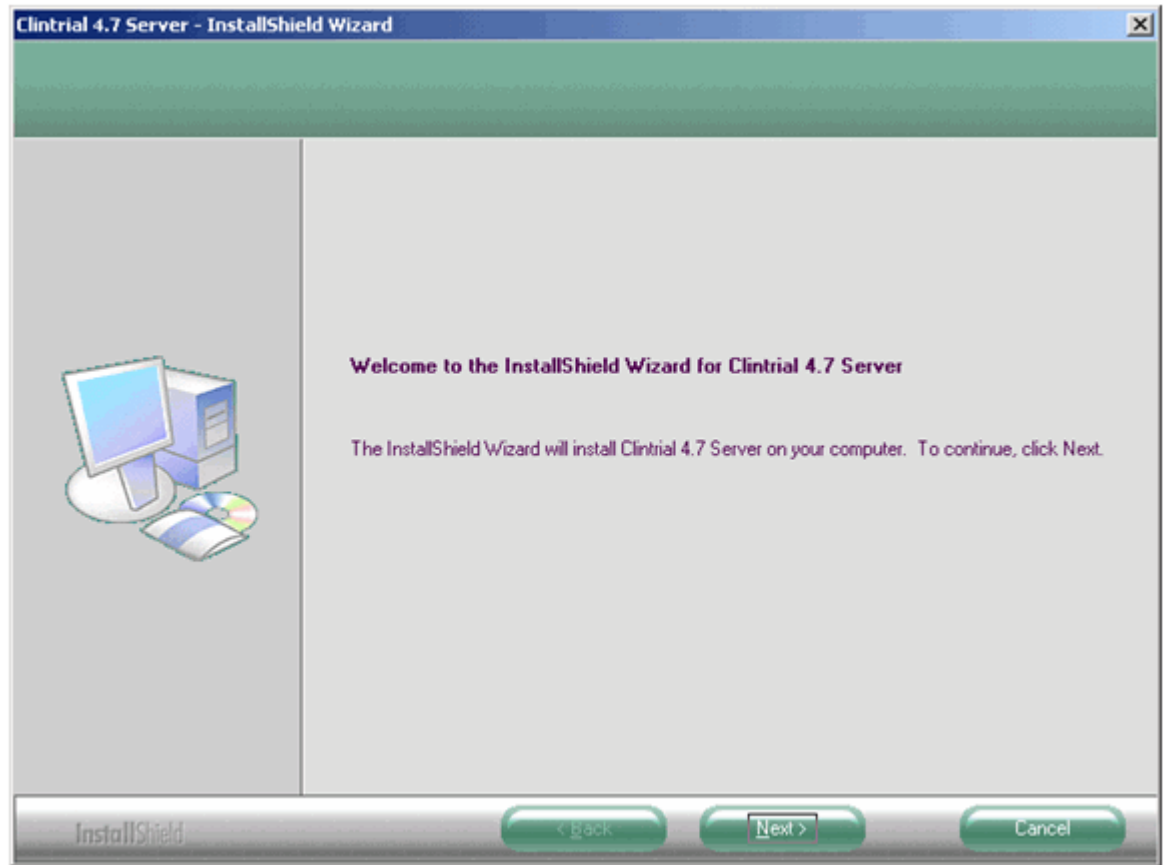
If you want to choose a language other than English on an English operating system, the proper language pack must be installed and the Windows default language must be changed. For example, if you want to conduct the installation in Japanese, the Asian language pack must be installed and the default language must be changed to Japanese.

For more information, see your Windows documentation.

2. Select the language you want the wizard to use during setup. This also the language that will be used for the labels and descriptions for codelists and tags.

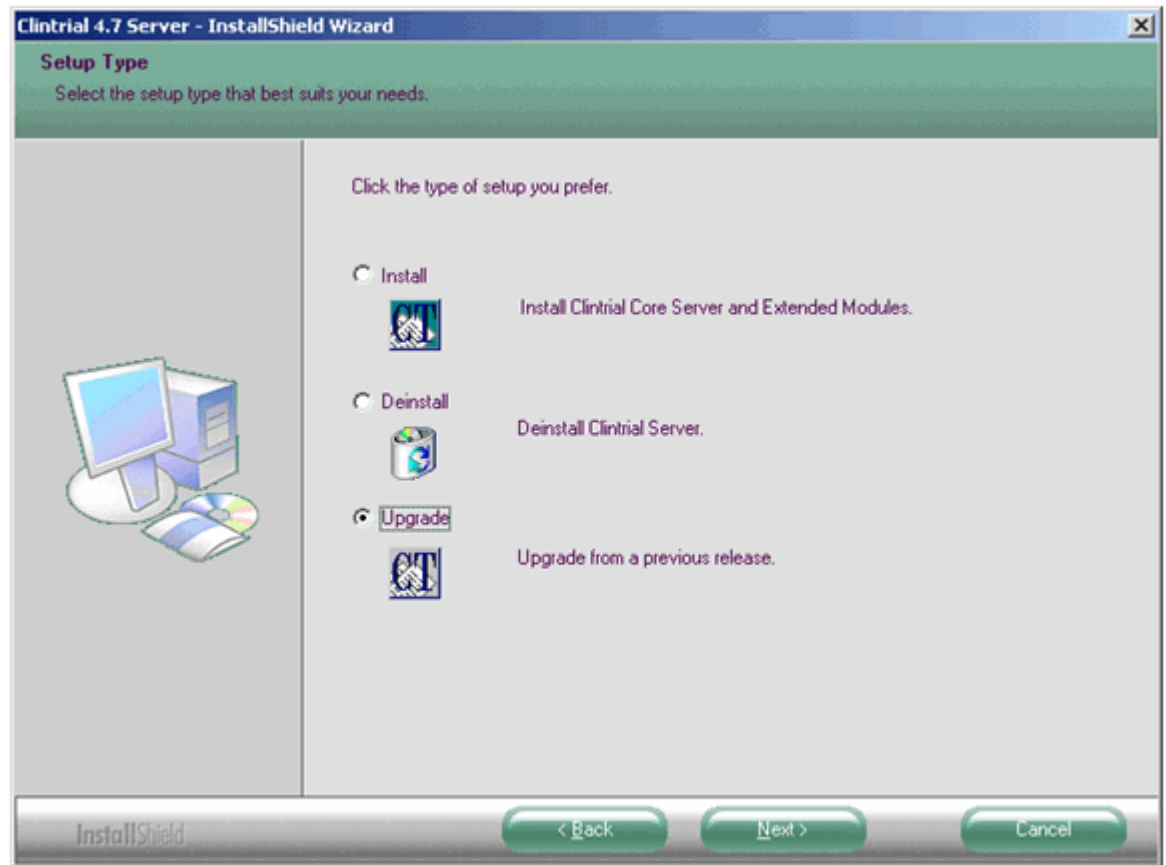
- 3 Click **Next**.

The **Welcome** window appears.



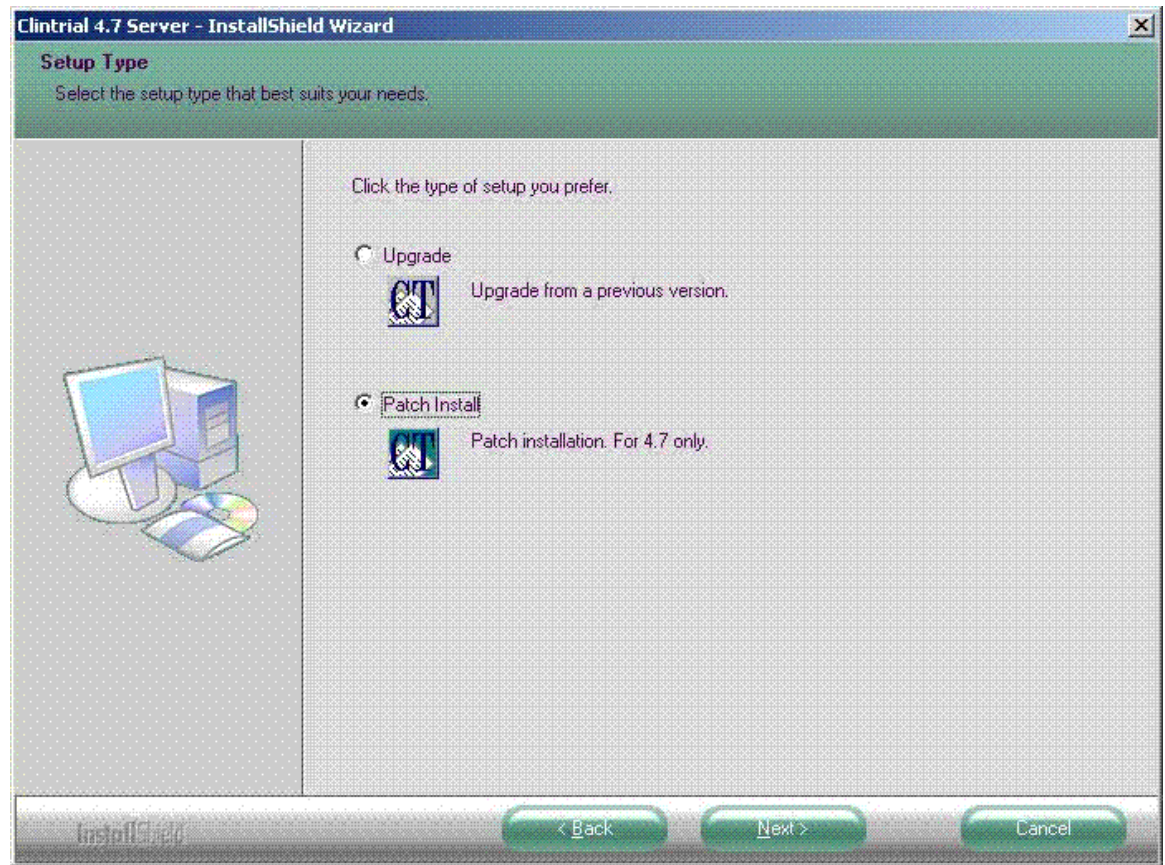
- 4 Click **Next**.

The **Setup type** window appears.



- 5 To upgrade the server, select the **Upgrade** button.
- 6 Click **Next**.

The Setup Type window appears.



- 7 Select **Upgrade from a previous version** if you want to upgrade from a release prior to Clintrial 4.7. Select **Patch installation For 4.7 only** if you want to upgrade from a Clintrial 4.7 release.
- 8 Click **Next**.

The first **Edit data** window, which asks for information on the Oracle database, appears.

9 Enter the following information:

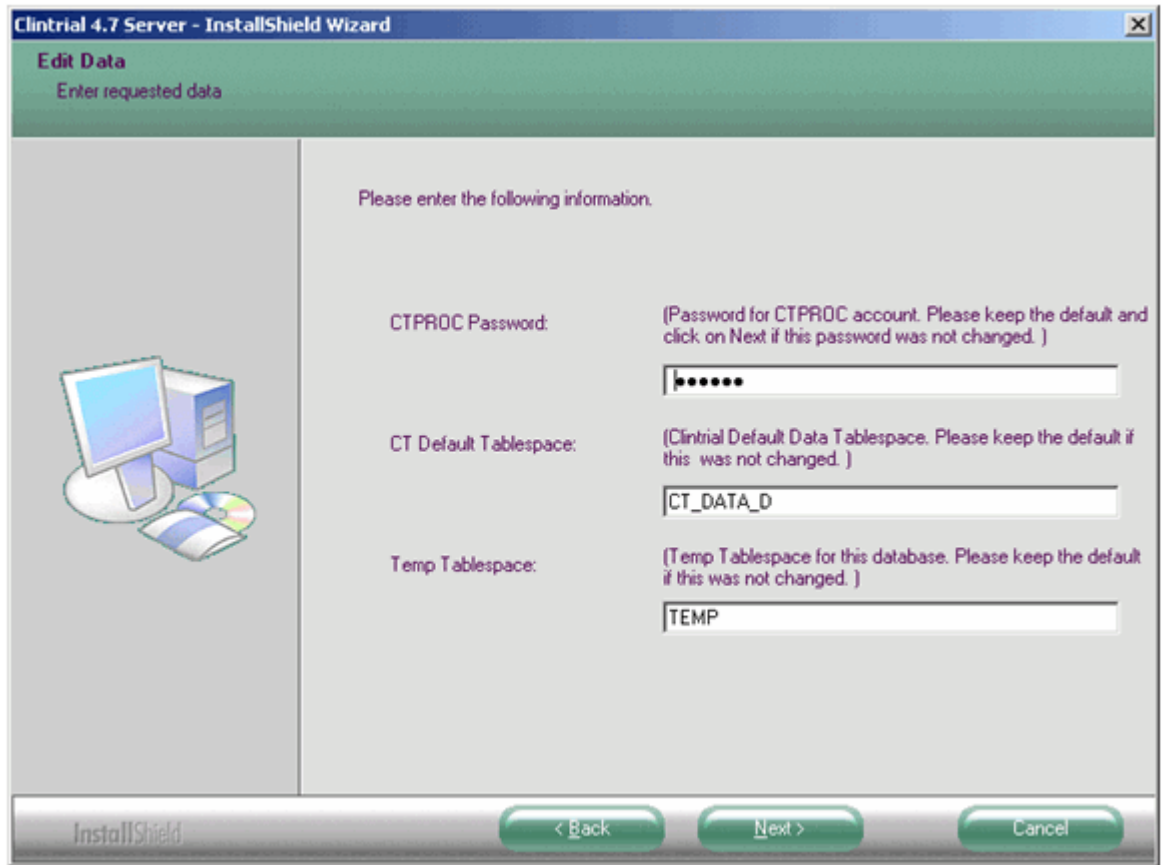
- **Database Connection String** as it is defined in the **tnsnames.ora** file.
- Oracle **SYS** password.
- Oracle **SYSTEM** password.

10 Click **Next**.

If there are no tablespaces found in the Oracle database described in the previous window, a dialog will ask whether you want to create default tablespaces. Click on **Yes**.

Caution: if there are no Clintrial tablespaces, the installation will fail.

Otherwise, the second **Edit data** dialog will display prompting for more information on the database instance.

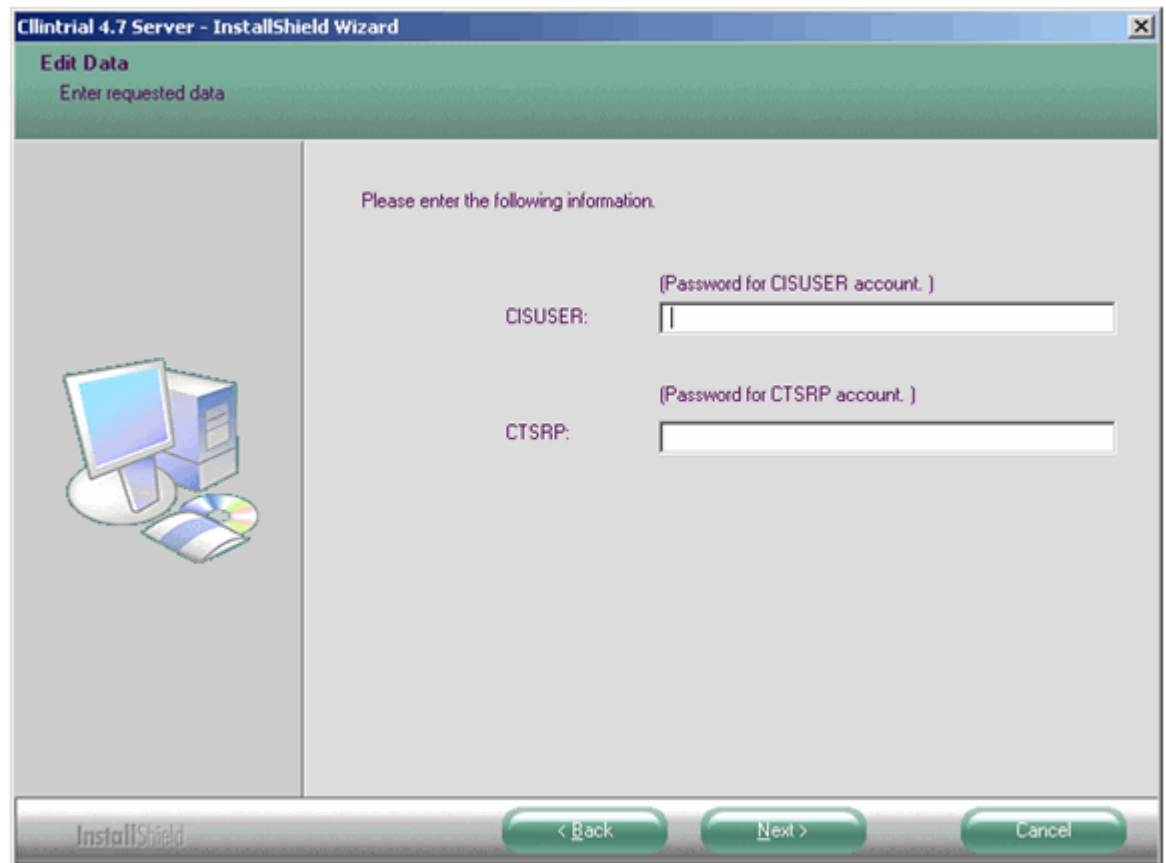


11 Enter the following information:

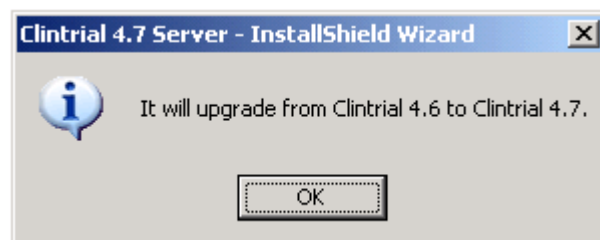
- **CTPROC Password.** Password for the CTPROC account. Keep the default if you didn't change the initial default password.
- **CT Default Tablespace.** Clintrial default data tablespace. Keep the default if you didn't change the initial default name.
- **Temp Tablespace.** Temporary tablespace for this database. Keep the default if you didn't change the default name.

12 Click **Next**.

The Edit Data window for the CISUSER and CTSRP displays.

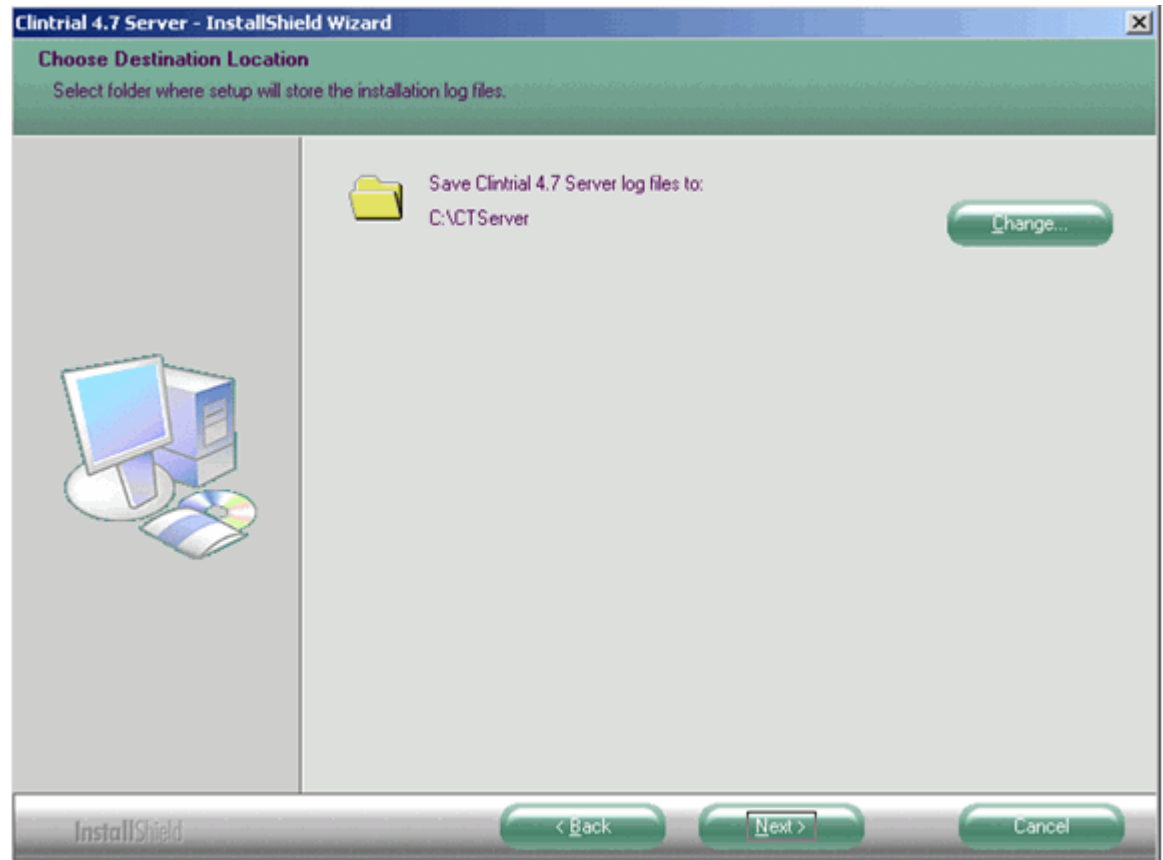


If there was no changes for the default values a small dialog will display the version of the server to be upgraded.



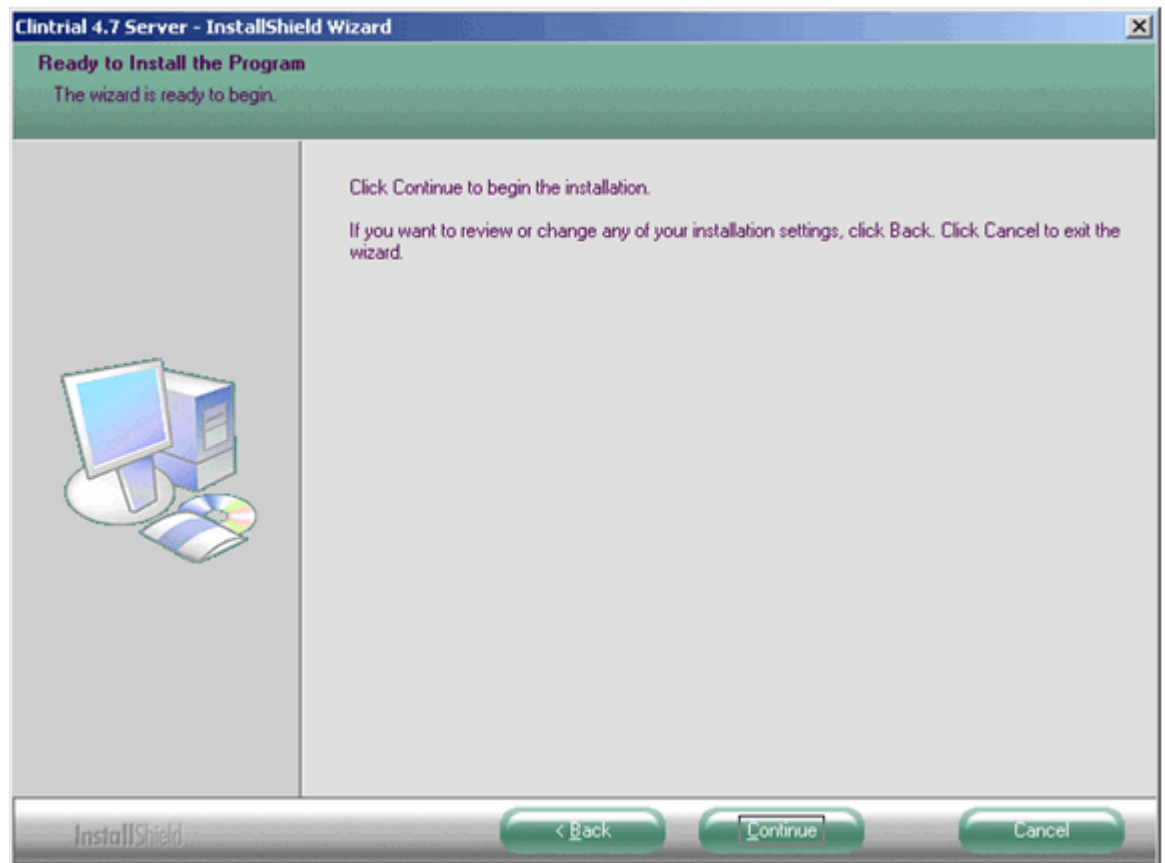
13 Click OK.

The **Choose Destination Location** dialog will display. The specified location will store the upgrade log files.



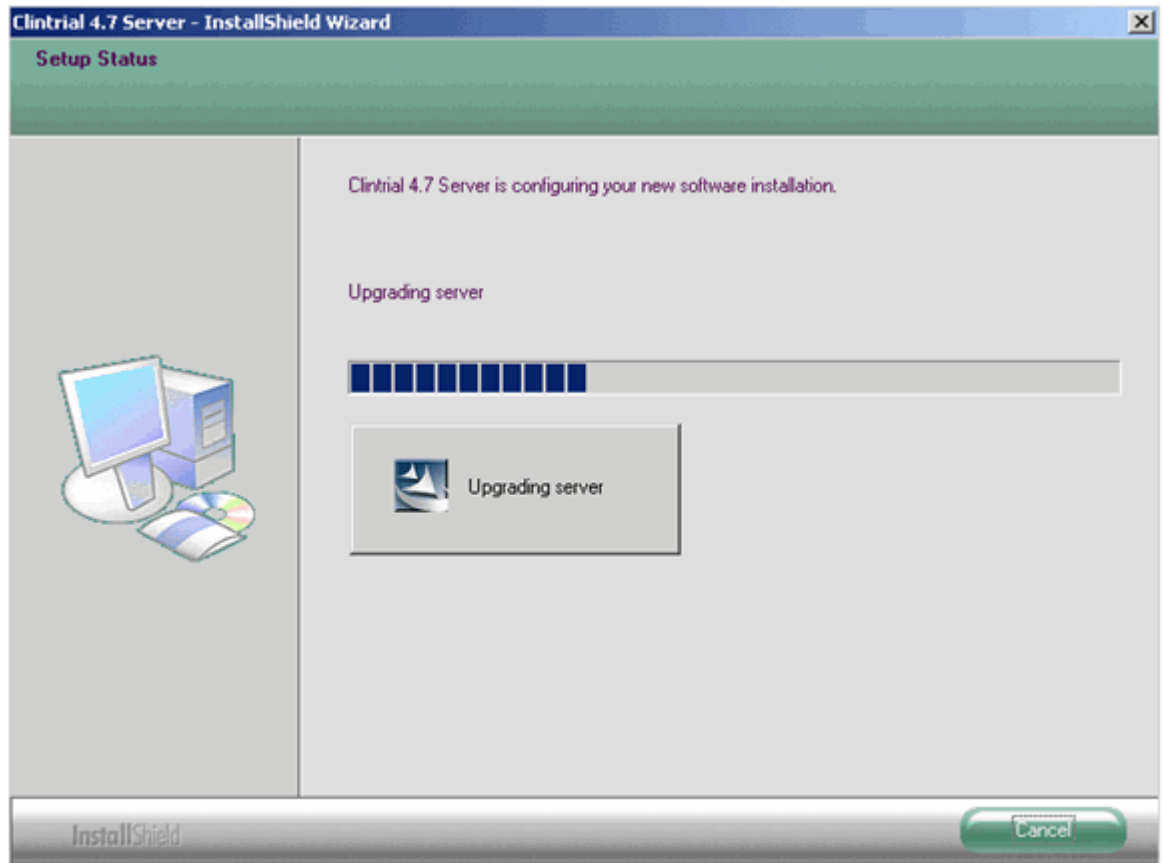
14 Click **Next**.

The **Ready to Install** window appears.



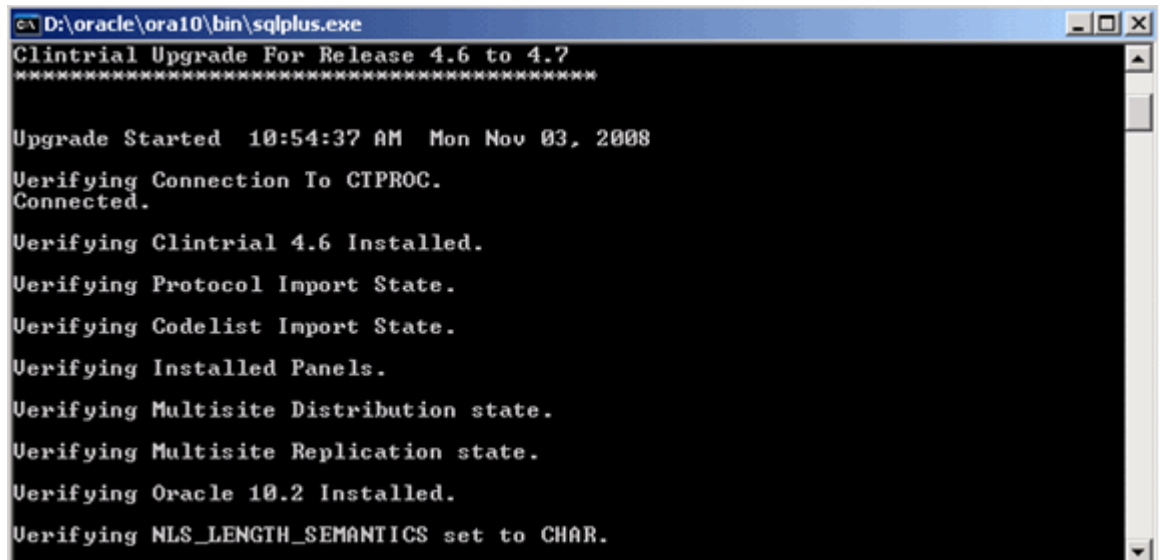
- 15 Click on **Continue** to begin the upgrade. Otherwise, click on **Back** to modify the selections.

The **Setup Status** window appears.

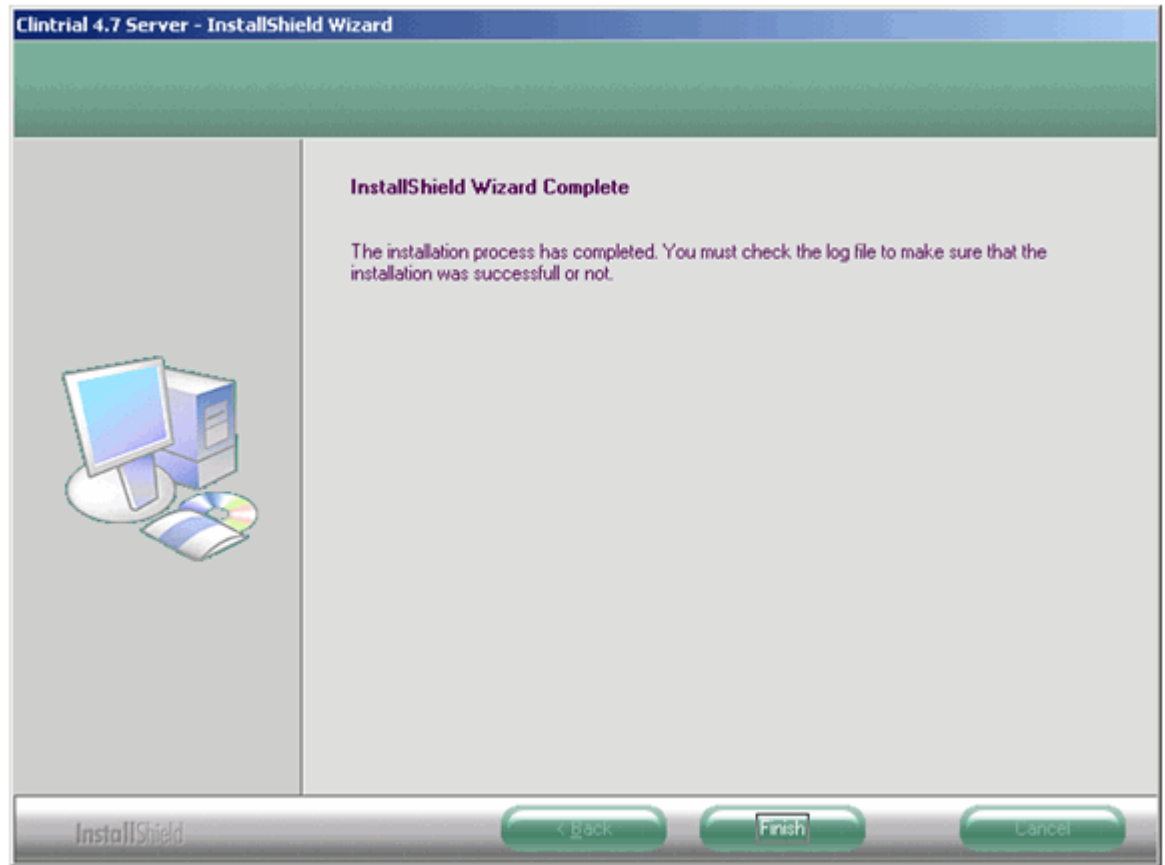


- 16 Click **Cancel** to abort the upgrade, or wait as the upgrade continues.

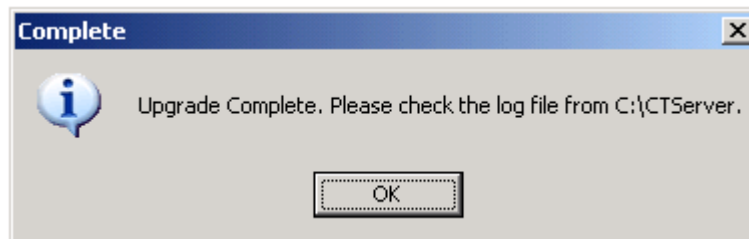
At the same time, a DOS status dialog will also display indicating the processes for each module.



After the upgrade is finished, the **InstallShield Wizard Complete** window appears.



- 17 Click **Finish** and a small **Complete** dialog will display, reminding you where the log files were written.



- 18 Click **OK**.
- 19 Check the log files to make sure all the upgrades are successful.

Details of the Clintrial server upgrade from Clintrial 4.5, 4.6, or 4.7 to 4.7.1

For ClintrialJ 4.5 to Clintrial 4.7, the changes would include those from 4.5 to 4.6 and earlier releases of 4.7 (as documented in the *Clintrial Getting Started* guides) as well as those described below. Any additional changes which only affect ClintrialJ 4.5 are also included below.

The following describes the changes when upgrading from Clintrial 4.6 or 4.7 to Clintrial 4.7.1:

Core Server

- Changed Database Semantics to CHAR semantics
- Added CISUSER (J only)

New Packages to support Central Coding:

- ct_ccprc.sqlh
- ct_soap.sqlh
- ct_ccode.sqlh

New Parameters

- System
 - SERVER_LANG (internal)
- Protocol
 - USE_CENTRAL_CODING
 - CC_HOST

New Table

CTS.PARAM_DESCRIPTION—holds language dependant descriptions of the parameters.

- SELECT privileges on this table are granted to all Clintrial users.
- CTS.OBJINDEX.I25 (previous description column) is now obsolete and is set to null.
- Both English and Japanese parameter descriptions are inserted into this table.

New Codelist Row

Added to CTS_CULTURE for ja-JP

Exception Messages; CTS.EXCEPTION_MESSAGE

- Added Rows for both English and Japanese. The Japanese rows now have a language_id of 2.
- Added additional rows for new messages (15)

Modified Packages:

- Modified for Central Coding
 - Ct_proto—additional execute privilege
 - Ct_panl2vdelete requests if panel deinstalled
 - Ct_gbldevdelete requests for deleted records (.sql,.sql)

- Ct_gble2—cause request resend for key changes
- Ct_encodvcreate different encoding proc if CC
- ct_panl1
- ct_impp
- ct_targe
- ct_targc
- Modified for Globalization—use byte functions
 - Ct_valid (both SP0 and SP0a)
 - Ct_syntx
- Modified for other bug fixes For more information, see Clintrial 4.7.1 *Release Notes*:
 - ct_util—CTG-28
 - ct_testm—CTG-28
 - ct_audit—CTG-28
 - ct_expp—CTG-338

Extended Modules

- Resolve and Lab Loader
Inserted the E and J versions of the parameter descriptions
- Classify
 - Inserted the E and J versions of the parameter descriptions.
 - Modified packages to support J version:
 - Ctg_con
 - Ctg_lex
- Multisite Replication
Modified ctx_con for new version
- Multisite Distribution and Ad Hoc Query
No changes

The Lab Loader upgrade procedure from Clintrial 4.5 was changed to include an additional package, and to remove obsolete transfer packages in Clintrial 4.7 SP0a.

Verifying your server upgrade to Clintrial 4.7.1

After you have verified your upgrade, see the sections *Running the import/export directory creation script* (see "*Run the import/export directory creation script*" on page 112) and *Set up protocols for added functionality* (on page 114) to continue with the upgrade.

- 1 Start SQL*Plus and log onto the database as SYSTEM.
- 2 Enter the following SQL statement:

```
SQL> select * from cts.registry;
```

SQL*Plus returns information about the Clintrial modules that are currently installed on the database.

For example, if you have installed all the Clintrial modules, the results should look similar to the following:

CT_OP	STATUS	MODDATE	VERSION	PATCH_LEVEL	BUILD_ID
CT	1	XX-MAY-12	4.7	3	4.7.1.40XX
CTC	1	XX-MAY-12	4.7	1	4.7.1.40XX
CTX	1	XX-MAY-12	4.7	1	4.7.1.40XX
CTG	1	XX-MAY-12	4.7	1	4.7.1.40XX
CTL	1	XX-MAY-12	4.7	1	4.7.1.40XX
CTV	1	XX-MAY-12	4.7	1	4.7.1.40XX
CTQA	1	XX-MAY-12	4.7	1	4.7.1.40XX

Post-upgrade actions

Recreating Multisite Distribution database links

If you decide not to use Unicode databases, when using Multisite Distribution, if you export databases from and then import them to a different Oracle release, you must manually recreate all Multisite database links after you upgrade to the Clintrial 4.7.1 software.

Rescheduling Multisite Replication

Whether or not you use Unicode, if your Clintrial upgrade includes Multisite Replication, you must reschedule the time and the date for replication for all sites. If you do not, the status will not be updated.

For details, see the document entitled *Multisite*, **Chapter 5: Replication**, the section entitled "Scheduling replication".

Upgrading Data Discrepancy Forms (DDFs)

You need to perform the tasks below only if you have customized Data Discrepancy Forms (DDFs) in a prior release of Clintrial.

- 1 Upgrade from the installed version of PowerBuilder to PowerBuilder 12.5 on the Clintrial **Client** computer you wish to use for DDF customization. See your PowerBuilder documentation for upgrade instructions.
- 2 Copy the latest **ctv_rept.pbl** with your changes to a new directory. References to **ctv_rept.pbl** in the rest of this document refer to the one in the new directory.
- 3 Start PowerBuilder 12.5.
- 4 Click the **New** icon.
- 5 In the window that appears, select the **Workspace** tab and click the **Workspace** icon.
- 6 It will ask you for a new workspace file name. Navigate to the directory where you put the copied **ctv_rept.pbl** and type in a name for the workspace, e.g. DDF.
- 7 Click on the **Library** icon.
- 8 Select the **ctv_rept.pbl** in the new directory in the left-side window.
- 9 In the right-side window, double-click on the application in **ctv_rept.pbl** named **default**.
You will be asked if you want to add this target to your current workspace.
- 10 Click **Yes**.
You will be asked to select a library and application.
- 11 Select the application in **ctv_rept.pbl** (which is named **default** in the original **ctv_rept.pbl**) and click **Next**.
The next window displays the search path and shows the **ctv_rept.pbl** file.
- 12 Click **Next**.
The next window tells you that PowerBuilder applications are now stored in files called Targets.

It asks for a file name for the new Target.

- 13 You can accept the suggested name (or change it if you prefer) and click **Finish**.

You will next be told that the application requires migration.

- 14 Click **OK**.

The migration messages will appear in the bottom section of the PowerBuilder window.

- 15 Right-click in this area and choose **Save** to save the messages in case there are any later questions about the success of the migration.

SOME of the lines that appear include:

```
----- Migrate: Migrate of target default
```

```
Inspecting application dependencies . . .
```

```
Creating type c:\ALL\DCFTest\Ctv_rept.pbl(discrepancy_form_print)
```

```
Creating type c:\ALL\DCFTest\Ctv_rept.pbl(default)
```

```
Creating type c:\ALL\DCFTest\Ctv_rept.pbl(gf_ctv_nvl)
```

```
. . .
```

```
Rebuilding type ( pass 1 )
```

```
c:\ALL\DCFTest\Ctv_rept.pbl(discrepancy_form_print)
```

```
Rebuilding type ( pass 1 ) c:\ALL\DCFTest\Ctv_rept.pbl(default)
```

```
Rebuilding type ( pass 1 ) c:\ALL\DCFTest\Ctv_rept.pbl(gf_ctv_nvl)
```

```
. . .
```

```
Inspecting application dependencies
```

```
Rebuilding type ( pass 2 )
```

```
c:\ALL\DCFTest\Ctv_rept.pbl(discrepancy_form_print)
```

```
Rebuilding type ( pass 2 ) c:\ALL\DCFTest\Ctv_rept.pbl(default)
```

```
Rebuilding type ( pass 2 ) c:\ALL\DCFTest\Ctv_rept.pbl(gf_ctv_nvl)
```

```
Regenerating c:\ALL\DCFTest\Ctv_rept.pbl(discrepancy_form_print)
```

```
Regenerating c:\ALL\DCFTest\Ctv_rept.pbl(default)
```

```
Regenerating c:\ALL\DCFTest\Ctv_rept.pbl(gf_ctv_nvl)
```

```
----- Finished Migrate of target default
```

- 16 Choose **File > Close** to close the application and return to the Library window.

- 17 In the left-side window, select **ctv_rept.pbl**.

- 18 From the menu, select **Entry > Library > Build Runtime Library**

- 19 In the dialog box, make sure **Machine Code** is **NOT** checked and the **Build Type** is **Incremental**.
The **Resource Name** is typically empty.

- 20 Click **OK**.

If you have a previous version of **ctv_rept.pbd** in the directory, you will be asked if it is okay to

replace it.

- 21 Click **Yes**.
- 22 Check the informational messages at the bottom of the PowerBuilder window. There should not be any errors.
- 23 Find the directory on your system where Clintrial 4.7.1 is installed. Rename the **ctv_rept.pbl** and **ctv_rept.pbd** files that are there to indicate they are the original ones and from what patch level of Clintrial 4.7. If you prefer, you can put them in some other directory with the same information.
- 24 Copy the **ctv_rept.pbl** and **ctv_rept.pbd** files that you migrated to PowerBuilder 12.5 from the directory where you were working to the directory where Clintrial 4.7.1 is installed.
- 25 Exit PowerBuilder 12.5.
- 26 Test the Resolve module's use of your DDF.

If you are using Central Coding

If you are planning to use the Oracle Central Coding application, you must specifically grant permissions via Access Control Lists (ACLs) for the HTTP requests.

To use the Central Coding application with Oracle 11.2, you must explicitly grant permissions via ACLs to enable the HTTP request to connect to the Central Coding server.

- 1 Login to the Oracle Clintrial database as SYS.
- 2 Execute code similar to the following:

```
BEGIN
DBMS_NETWORK_ACL_ADMIN.CREATE_ACL (
acl => 'ct_cc.xml',
description => 'Sample ACL for Central Coding',
principal => 'CTPROC',
is_grant => TRUE,
privilege => 'connect');
end;
/
BEGIN
DBMS_NETWORK_ACL_ADMIN.ASSIGN_ACL (
acl => 'ct_cc.xml',
host => '<Central Coding Server>');
END;
/
```

For further information on using Network ACLs, see the Oracle *Database Security Guide*, "Managing Fine-Grained Access in PL/SQL Network Utility Packages".

Create a verify function to ensure that passwords meet security standards

You can create a password verification function to ensure that passwords meet the standards contained in the Clintrial system parameters or a database profile. This function can be assigned in the Clintrial application using the Admin system parameters, or be part of an Oracle database profile created for users or usergroups.

The *Oracle Database Security Guide* describes a method for enforcing password complexity for database user accounts. Briefly, the database administrator creates a password verification function and associates it with a user profile. In the Clintrial application, you also can associate the function using the system parameter in the Admin module. The sample given in the *Oracle Database Security Guide* associates this function with the DEFAULT profile. However, there are special considerations when

applying this methodology to Clintrial.

- Non-user accounts, such as system accounts and the accounts for each protocol, use the DEFAULT database profile. The passwords are assigned during installation or upgrade, and encrypted. The resulting encrypted password strings are not constrained to specific characters, and therefore you cannot expect any verification function which relies on character comparisons, such as checking for the existence of at least one number and one non-number to work correctly. For that reason, Oracle strongly suggests that you do not add a verification function to the DEFAULT profile.
- In the case where the Clintrial PASSWORD_ENCRYPTION system parameter is set to No in the Admin module, an encryption verification function can be created and assigned using the Admin module. At least one additional profile must be created for use with Clintrial users, and that profile also can be associated with the verification function. For example, the below command creates a new profile. When creating users in Admin, you should create a profile like the below example and set additional profile limits like those in the DEFAULT profile:

```
CREATE PROFILE CT_USER_PROFILE LIMIT  
PASSWORD_VERIFY_FUNCTION <function_name>;
```

- In the case where the PASSWORD_ENCRYPTION system parameter is set to Yes, the verification function should not be associated with any profiles which are used for Clintrial users in the Admin module system parameters. Similar to the Protocol account case, the encrypted passwords would not function as expected.

This new system parameter that has been added (PASSWORD_VFY_FUNC) allows the Administrator to specify the name of a password verification function which will be called from Clintrial before the encryption of the password. The function is applied to all Clintrial users created in Admin during creation of the users as well as modification of the password by either the Administrator or the user.

The function must have the same parameters as described in the Oracle database documentation. It does not have to be installed into the **SYS** account. The value of the system parameter should specify the owner and function name, for example, **SYS.CT_VFY_FUNC**. Additionally, execute privileges on this function must be granted to the system account **CTPROC**, using this command:

```
Grant execute on <function_name> to CTPROC;
```

For the Clintrial system account **CTSYS**, the function cannot be defined and called until after core server installation has succeeded, so the initial **CTSYS** password supplied during installation is not checked in this way.

Example verify function

```
CREATE OR REPLACE FUNCTION verify_function_11G_1  
(username varchar2,  
 password varchar2,  
 old_password varchar2)  
RETURN boolean IS  
  n boolean;  
  m integer;  
  differ integer;  
  isdigit boolean;  
  ischar boolean;  
  ispunct boolean;  
  db_name varchar2(40);  
  digitarray varchar2(20);  
  punctarray varchar2(25);  
  chararray varchar2(52);
```

```

i_char varchar2(10);
simple_password varchar2(10);
reverse_user varchar2(32);

BEGIN
digitarray:= '0123456789';
chararray:= 'abcdefghijklmnopqrstuvwxyABCDEFGHIJKLMNOPQRSTUVWXYZ';

-- Check for the minimum length of the password
IF length(password) < 8 THEN
    raise_application_error(-20001, 'Password length less than 8');
END IF;

-- Check if the password is same as the username or username(1-100)
IF NLS_LOWER(password) = NLS_LOWER(username) THEN
    raise_application_error(-20002, 'Password same as or similar to user');
END IF;
FOR i IN 1..100 LOOP
    i_char := to_char(i);
    if NLS_LOWER(username)|| i_char = NLS_LOWER(password) THEN
        raise_application_error(-20005, 'Password same as or similar to user
name ');
    END IF;
END LOOP;

-- Check if the password is same as the username reversed

FOR i in REVERSE 1..length(username) LOOP
    reverse_user := reverse_user || substr(username, i, 1);
END LOOP;
IF NLS_LOWER(password) = NLS_LOWER(reverse_user) THEN
    raise_application_error(-20003, 'Password same as username reversed');
END IF;

-- Check if the password is the same as server name and or servername(1-100)
select name into db_name from sys.v$database;
if NLS_LOWER(db_name) = NLS_LOWER(password) THEN
    raise_application_error(-20004, 'Password same as or similar to server
name');
END IF;
FOR i IN 1..100 LOOP
    i_char := to_char(i);
    if NLS_LOWER(db_name)|| i_char = NLS_LOWER(password) THEN
        raise_application_error(-20005, 'Password same as or similar to server
name ');
    END IF;
END LOOP;

-- Check if the password is too simple. A dictionary of words may be
-- maintained and a check may be made so as not to allow the words
-- that are too simple for the password.
IF NLS_LOWER(password) IN ('welcome1', 'database1', 'account1', 'user1234',
'password1', 'oracle123', 'computer1', 'abcdefg1', 'change_on_install') THEN
    raise_application_error(-20006, 'Password too simple');
END IF;

-- Check if the password is the same as oracle (1-100)
simple_password := 'oracle';
FOR i IN 1..100 LOOP
    i_char := to_char(i);
    if simple_password || i_char = NLS_LOWER(password) THEN
        raise_application_error(-20007, 'Password too simple ');
    END IF;
END LOOP;

-- Check if the password contains at least one letter, one digit

```

```

-- 1. Check for the digit
isdigit:=FALSE;
m := length(password);
FOR i IN 1..10 LOOP
  FOR j IN 1..m LOOP
    IF substr(password,j,1) = substr(digitarray,i,1) THEN
      isdigit:=TRUE;
      GOTO findchar;
    END IF;
  END LOOP;
END LOOP;

IF isdigit = FALSE THEN
  raise_application_error(-20008, 'Password must contain at least one
digit, one character');
END IF;
-- 2. Check for the character
<<findchar>>
ischar:=FALSE;
FOR i IN 1..length(chararray) LOOP
  FOR j IN 1..m LOOP
    IF substr(password,j,1) = substr(chararray,i,1) THEN
      ischar:=TRUE;
      GOTO endsearch;
    END IF;
  END LOOP;
END LOOP;
IF ischar = FALSE THEN
  raise_application_error(-20009, 'Password must contain at least one \
digit, and one character');
END IF;

<<endsearch>>
-- Check if the password differs from the previous password by at least
-- 3 letters
IF old_password IS NOT NULL THEN
  differ := length(old_password) - length(password);

  differ := abs(differ);
  IF differ < 3 THEN
    IF length(password) < length(old_password) THEN
      m := length(password);
    ELSE
      m := length(old_password);
    END IF;

    FOR i IN 1..m LOOP
      IF substr(password,i,1) != substr(old_password,i,1) THEN
        differ := differ + 1;
      END IF;
    END LOOP;

    IF differ < 3 THEN
      raise_application_error(-20011, 'Password should differ from the \
old password by at least 3 characters');
    END IF;
  END IF;
END IF;
-- Everything is fine; return TRUE ;
RETURN(TRUE);
END;
/
CREATE PROFILE CT_USER_PROFILE1 LIMIT PASSWORD_VERIFY_FUNCTION
verify_function_11G_1;
/

```


CHAPTER 5

Installing, upgrading, and maintaining the client software

In this chapter

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Installing the Oracle client software

This section applies to customers who are installing the Oracle 10.2 or Oracle 11.2 client software for the first time or upgrading the Oracle client software.

Important configuration information

If you have multiple Oracle Homes on your computer, make sure the Default Oracle Home is set to the Oracle client that matches the version of the Oracle database to which you are connecting. The Default Oracle Home can be changed using the Universal Installer.

Note: If you attempt to use the Clintrial client with the Oracle 11.2 client to connect to an Oracle 9.2 or Oracle 10.2 database, you receive the following error message:

Oracle 11g client is not installed or Oracle 11g is not the Primary Oracle Home on your machine.

You should completely close out of the Clintrial client before attempting the database connection again.

Review the NLS_LANG setting for the Oracle client prior to using the Clintrial software. The Oracle database uses the client's NLS_LANG setting to determine the character set that the client is sending and to determine if character set conversion is necessary. If the NLS_LANG setting is not correct, data integrity and consistency might be compromised.

For example, if you are using the Windows Japanese client, and the SQL scripts or control files you will use to load data into the new or upgraded Clintrial database will be in **ANSI**, then the NLS_LANG setting for the client could be either the default **JAPANESE_JAPAN.JA16SJIS** or **JAPANESE_JAPAN.JA16SJISTILDE**.

If, on the other hand, you are using the Windows Japanese client, and the SQL scripts or control files you will use to load data into the new or upgraded Clintrial database will be in **UTF-8**, then the NLS_LANG setting for the client should be **JAPANESE_JAPAN.AL32UTF8**.

The NLS_LANG equivalents for the Windows English client are:

- **ANSI - AMERICAN_AMERICA.WE8MSWIN1252**
- **UTF-8 - AMERICAN_AMERICA.AL32UTF8**

For more information, on the SQL scripts and control files for loading data, see **Chapter 30: Control Files** in Clintrial 4.7 *Manage, Classify, and LabLoader* guide.

Installing or upgrading the Clintrial client software

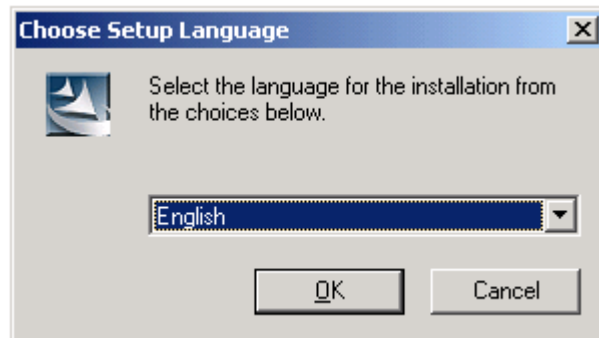
Note: There is no upgrade per se for the client to go from Clintrial 4.5 or 4.6 to 4.7. You may leave older clients undisturbed on your computer if desired, or remove them using the Windows Control Panel. You can then install the Clintrial 4.7 Client, using the instructions in Installing or upgrading the Clintrial 4.7 client software.

Note: The client installation and upgrade wizard is a 32-bit application. If you need to install the Client application on a machine with a 64-bit operating system, you should do so from a 32-bit networked computer, then connect to the server with Oracle credentials.

Use this procedure to install or upgrade the client software:

- 1 Navigate to the location of the installation files and double-click **CT4Setup.exe**.

For the first-time installation, the **Choose Setup Language** window displays.

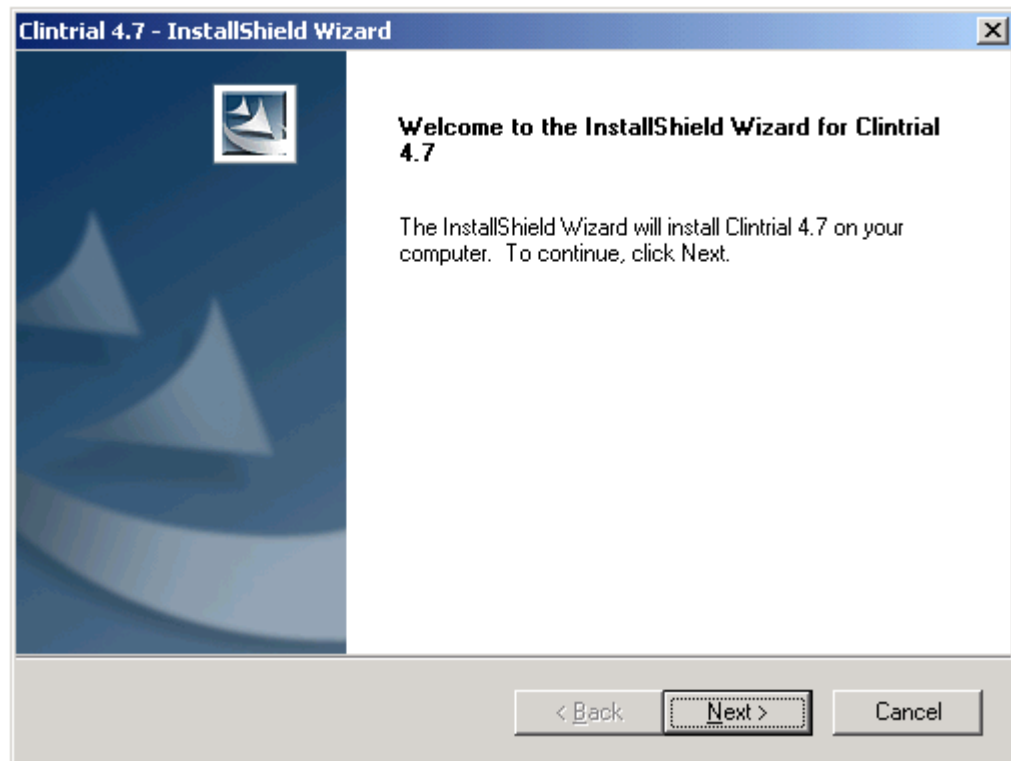


If you want to choose a language other than English on an English operating system, the proper language pack must be installed and the Windows default language must be changed. For example, if you want to conduct the installation in Japanese, the Asian language pack must be installed and the default language must be changed to Japanese.

For more information, see your Windows documentation.

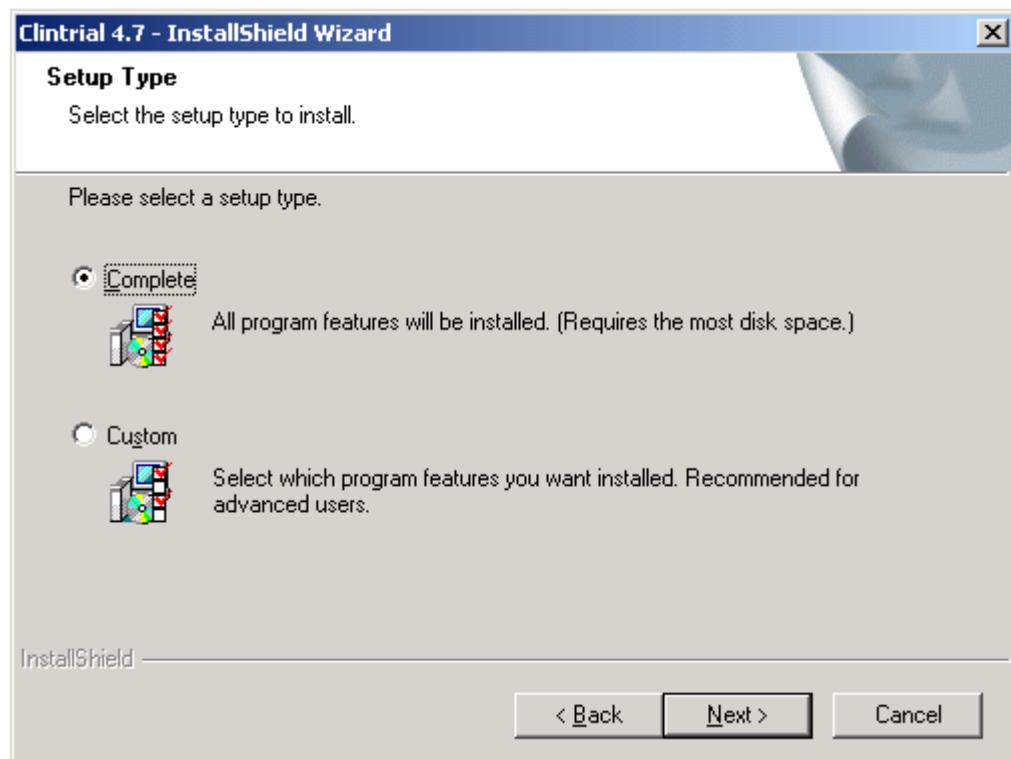
- 2 Select the language you want the wizard to use during setup. This is also the language that will be used for the labels and descriptions for codelists and tags.

The **Welcome** window for the Clintrial setup program appears.

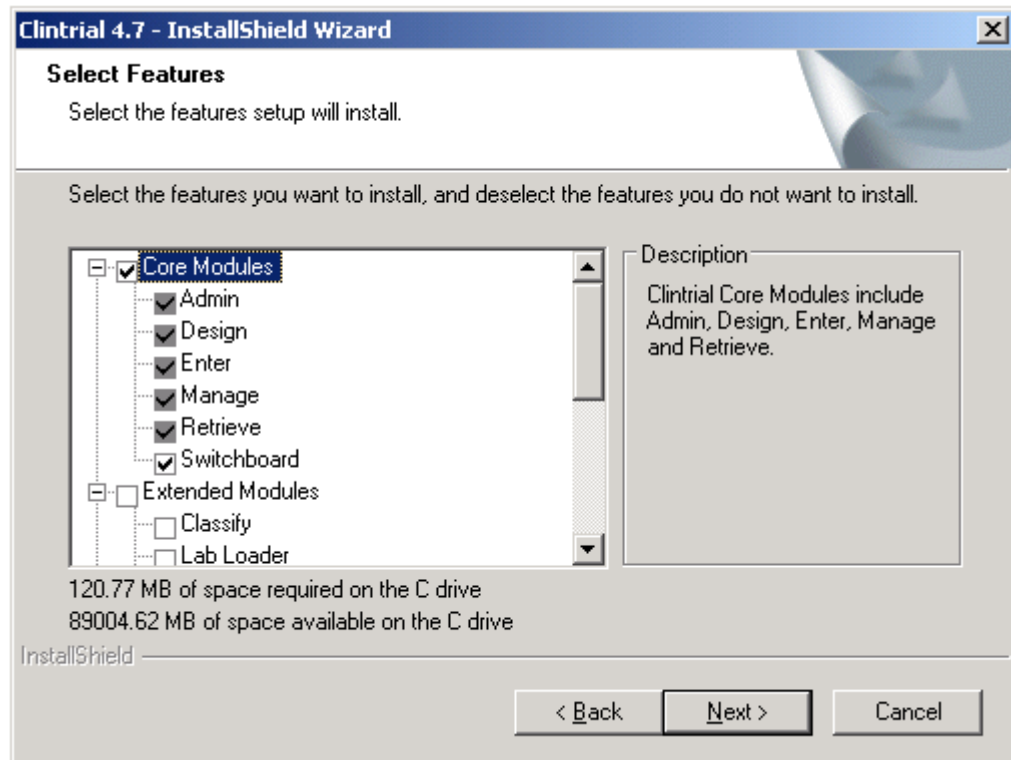


- 3 Click **Next**.

The **Setup Type** window appears.

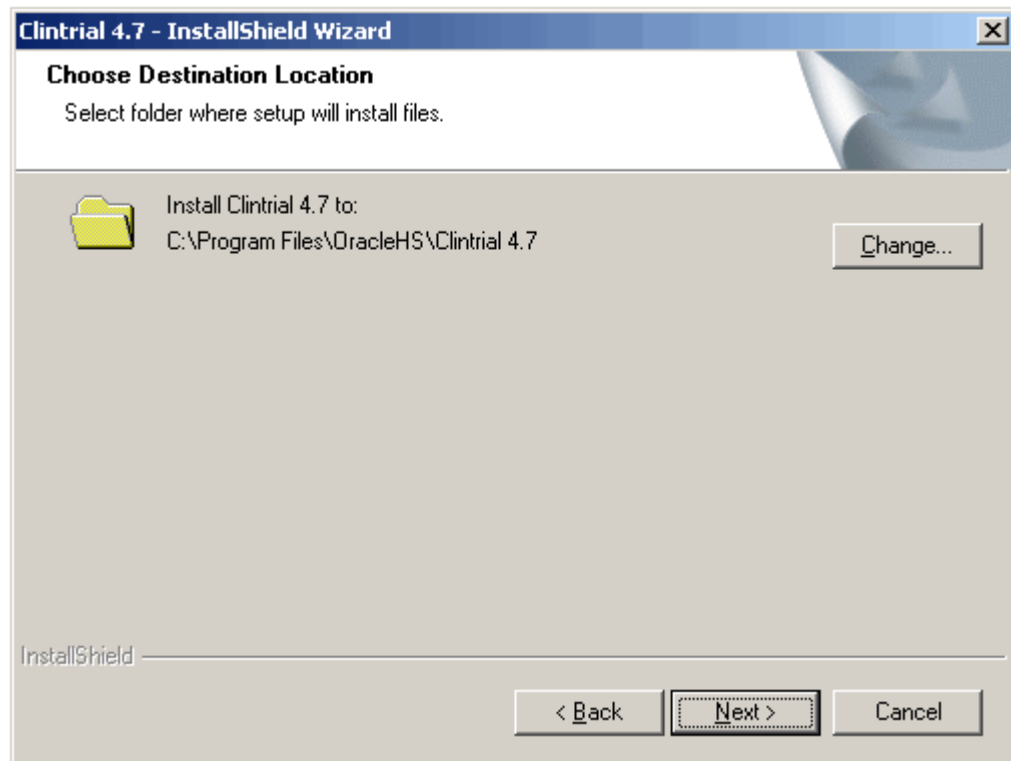


- 4 Select **Complete** to install all the modules.
Select **Custom** to choose which modules you want to install.
If you selected **Custom**, the **Select Features** window appears.



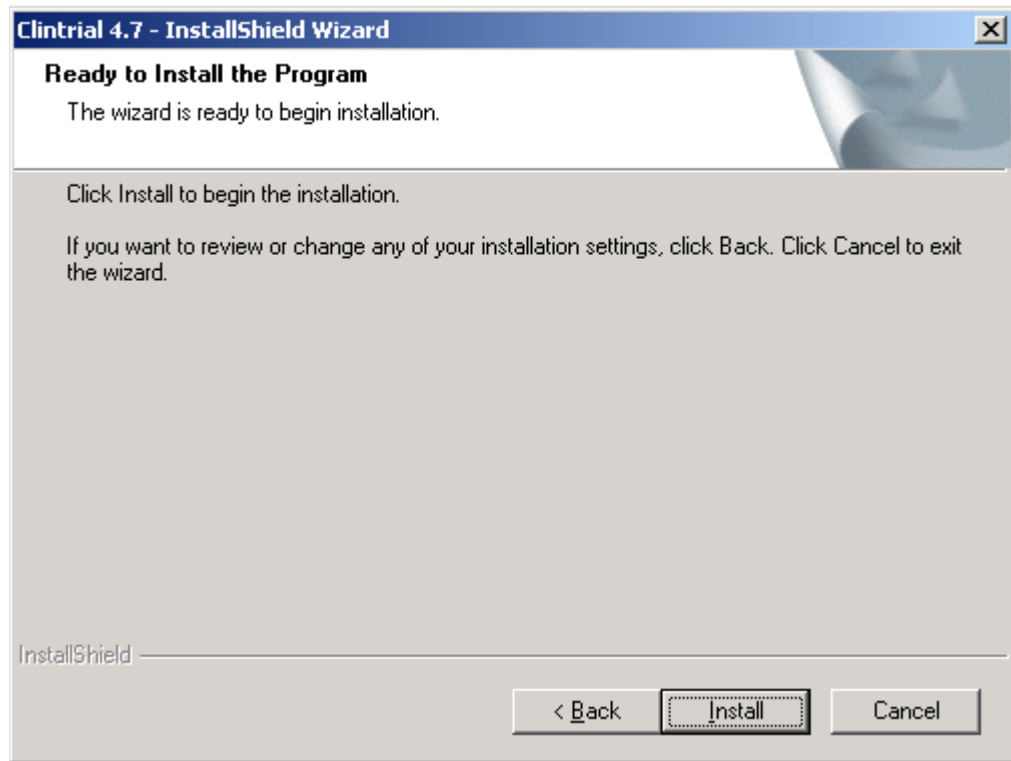
- 5 Select the components to install.
- 6 When you have completed selecting the features, click **Next**.

The **Choose Destination Location** window appears. This is the folder where Setup will install the files.



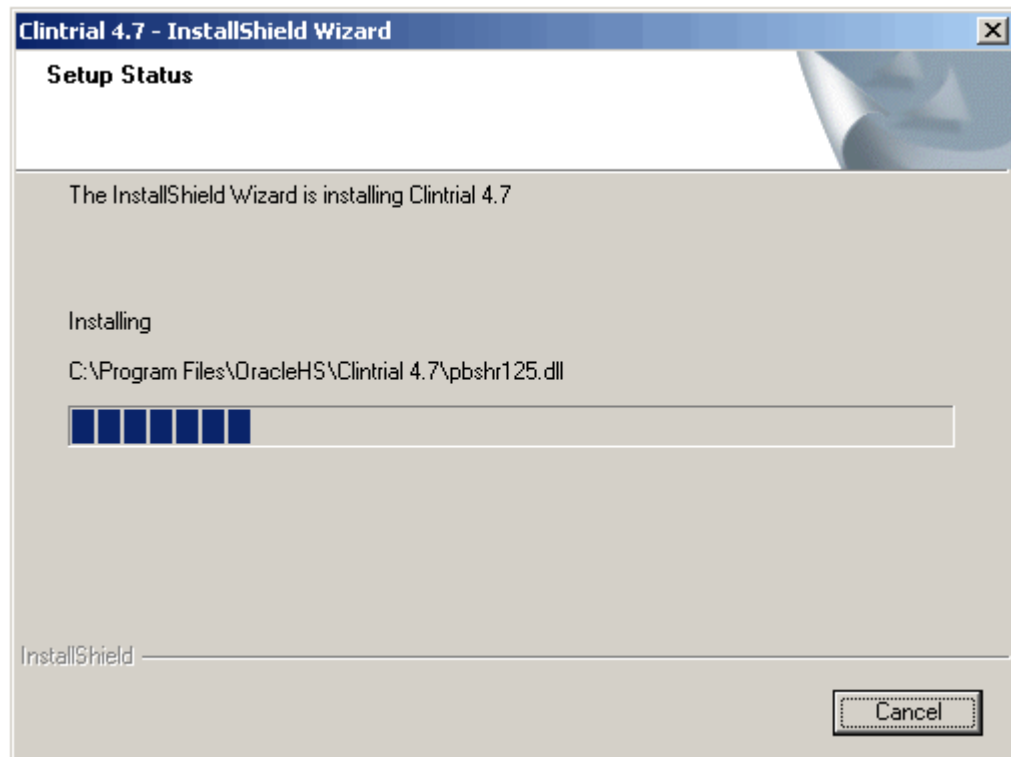
- 7 Accept the default location, or click **Change** to select a different folder.
- 8 Click **Next**.

The **Ready to Install** window appears.

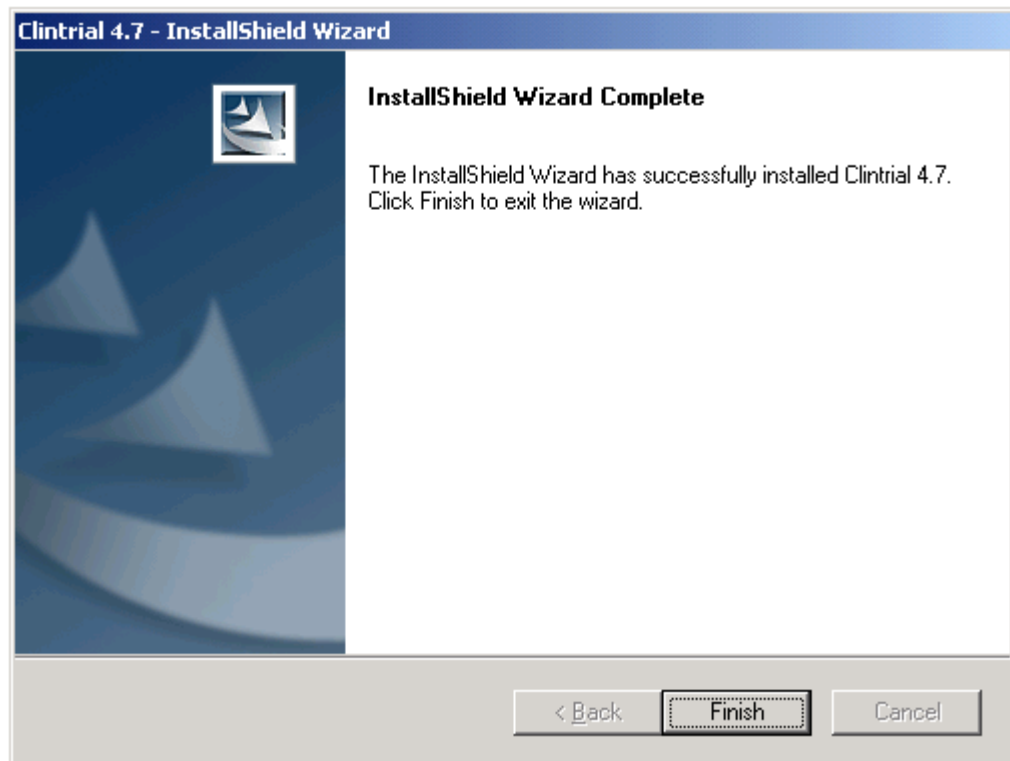


- 9 Click on **Continue** to begin installation. Otherwise, click on **Back** to modify the selections.

The **Setup Status** window appears.



After the installation is finished, the **InstallShield Wizard Complete** window appears.

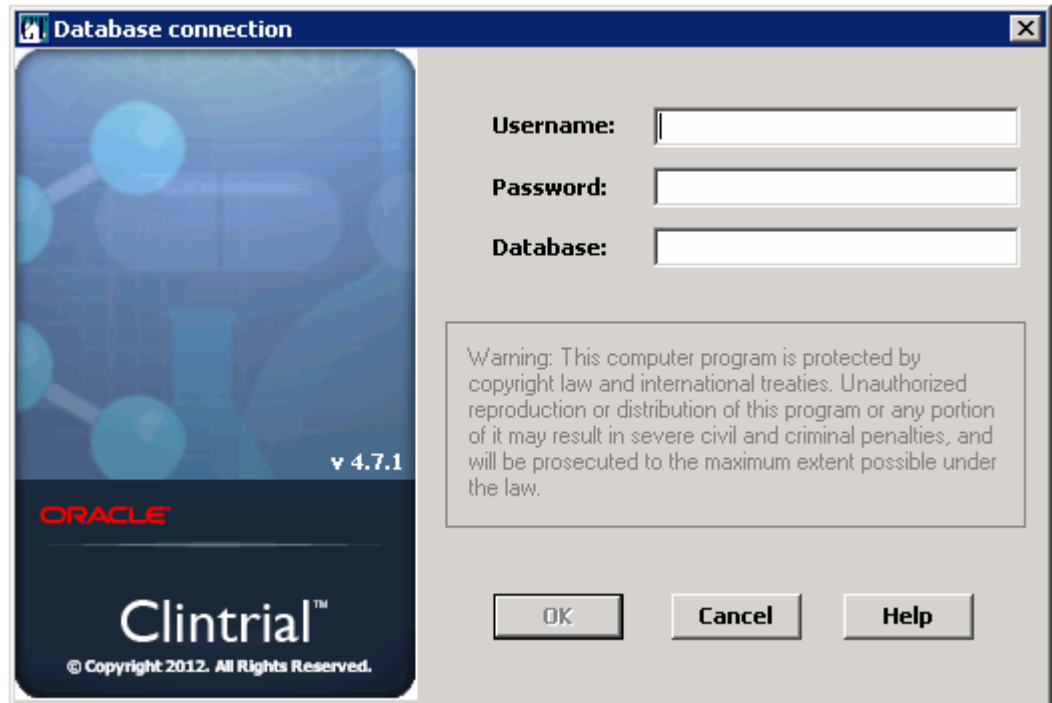


10 Click **Finish**.

Starting a Clintrial module

- 1 Double-click the icon for the module, or, select **Start > Programs > Clintrial-group-name > Module-name**.

The **Database Connection** dialog box appears.



- 2 Complete the fields in the **Database Connection** dialog box.

Field:	Description:
User Name	Name of the user account that is provided to you by your Clintrial administrator.
Password	Password for your user account.
Database	The Oracle Net Service Name for the database. The string is in the format database-alias. Optionally, you can precede the database service name with the @ character.

The values that you enter, except for the Password, are displayed as default values for these fields the next time you start a Clintrial module.

- 3 Click **OK**.

The main window for the selected module appears.

CHAPTER 6

The Clintrial client software Windows Registry settings

In this chapter

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About the Ct4user.reg file	106
Setting up multiple users on a single client	108
About network installation	110

Overview

You do not need to set any registry entries manually. However, there are several registry entries that you might want to set.

Caution: Do not edit registry entries unless you are an experienced user. If you edit other entries, you could create a Clintrial configuration that could lead to unexpected results. Always back up your registry before making any changes. For more information, see your system administrator.

Much of the Clintrial configuration information is stored in the Clintrial database as system parameters, user preferences, and protocol parameters. However, some configuration information is specific to each computer and is stored in the Windows registry of the client. Most of this client-based information is generated automatically from the following sources:

- Control Panel setting:

For example, the Windows registry of each client uses the values in the Regional Settings Properties dialog box to define the display format of a number, such as the decimal point character, or the number of decimal places.

- Information supplied by users through the Clintrial modules.

For example:

- Database connection information that the user supplies in the Database Connection dialog box is stored in the registry for use at the next database connection attempt from that client.
- Information about site-specific menus is stored in the registry.

Note: Each new client installation uses the Windows registry settings from the previous installation, unless the settings are changed during the installation.

Editing the Windows registry

- 1 Select **Start > Run**.
- 2 Enter **Regedit** and click **OK**.
The Registry Editor window appears.
- 3 Expand the **HKEY_CURRENT_USER** folder, and navigate to the Windows registry key for the Clintrial entries:
HKEY_CURRENT_USER\Software\OracleHS\Clintrial 4.7\CT
- 4 Create a new registry entry and enter a value, or select an existing entry and modify the value as needed.

Setting registry entries manually

You may want to create and set the following registry settings:

- *ct_temp_path key* (on page 105).
- *ct_help_path key* (on page 105).
- *ct_user_help_path key* (on page 105).

Note: These keys are not created automatically during the Clintrial installation and must be created manually using the Windows Regedit program.

About the *ct_temp_path* key

When you install the Clintrial client, the *ct_path* value is set to the location of the Clintrial executables, as specified in the setup program. The default *ct_path* value is `c:\ct47`.

You should create and specify the *ct_temp_path* value if you install the Clintrial software to a folder whose name contains a space. For the *ct_temp_path* value, you must manually create a folder whose name does not contain a space and edit the Windows registry accordingly. In the Windows registry, create a new string value named *ct_temp_path* and give it the value of the temporary folder.

Note: Because the previous Oracle Utilities could not export or import to a folder whose name contains spaces, the folder you create for the *ct_temp_path* value is used when you perform imports of legacy files.

About the *ct_help_path* key

When you install the Clintrial client, the Help files are installed at the location of the Clintrial client executables, as specified in the setup program. If you change the location of Help files, you must create the *ct_help_path* value in the Windows registry and point it to that location.

About the *ct_user_help_path* key

If you create your own protocol-specific Help file, you must create and specify a *ct_user_help_path* value in the Windows registry to point to the location of the Help file.

About the Ct4user.reg file

The **Ct4user.reg** file, that is installed with all client software, creates the `ct_exe_path` key and the `ct_path` key during client installation. You must edit and rerun the `Ct4user.reg` file if you are:

- *Setting up multiple users on a single client* (on page 108).
- *Installing the Clintrial Client over a network* (on page 110).

Note: The registry settings that are established when you run the `ct4user.reg` file affect only the current Windows user. Each Windows user who wants to run the Clintrial software must run the `Ct4user.reg` file.

Contents of the Ct4user.reg file

The `Ct4user.reg` file contents are as follows:

```

REGEDIT4

;; -----
;; CT4USER.REG
;;
;; Clintrial 4 User Registration File
;; -----
;; Notes: This file is distributed as a template. The values
;;        used for ct_path and ct_exe_path are default values
;;        and may not reflect the location to which the software
;;        was installed. The values may be modified according to
;;        the following:
;;
;; "ct_exe_path" Points to the directory where the Clintrial4
;;        client software was installed.
;;
;; "ct_path" Points to a user specific directory. By default
;;        it is set to the same directory as ct_exe_path,
;;        but may be modified to reference a user specific
;;        location. This may be desirable in the case of
;;        multiple users running the software on a single
;;        workstation, or in the case of a shared network
;;        installation. Clintrial uses this location to
;;        write log files and other user specific data.
;;
;; "language_id" Refers to the language selected during
installation.

[HKEY_CURRENT_USER\Software\OracleHS\Clintrial 4.7\CT]
"ct_path"="C:\\Program Files\\OracleHS\\Clintrial 4.7"
"ct_exe_path"="C:\\Program Files\\OracleHS\\Clintrial 4.7"
"ct_temp_path"="C:\\temp"
"language_id"="1"

```

Note: The `Ct4user.reg` file is delivered with the default values shown (C:\CT47) for `ct_path` and `ct_exe_path`. The `Ct4user.reg` file will contain the new values even if the destination folder is changed.

Running the Ct4user.reg file

Note: Before you run the Ct4user.reg file, modify the values of ct_path and ct_exe_path in the ct4user.reg file. Then, when you run the file, the ct_path and ct_exe_path are set according to the modifications you made.

- Double-click the ct4user.reg file.

The ct_path and ct_exe_path are set in the current Windows user's registry on the client.

Verifying registry settings

Run Switchboard.

If ct_path and ct_exe_path are set correctly, the bitmaps for all installed client modules appear in the **Switchboard** window.

If the module bitmaps do not appear, there is a problem with the registry settings.

For more information, see *When a system administrator installs the Clintrial software* (on page 109).

Setting up multiple users on a single client

Note: To avoid possible conflicts in files that are stored on the client and are used by the Clintrial software, different users of a single client (that is, users who log on to the same client with different Windows user names) must run the Ct4user.reg file and set the ct_path and ct_exe_path.

For each user of a single client:

- Set the ct_exe_path to the folder where the Clintrial software is installed.
- Set the ct_path to a unique folder for each Windows user name.

Caution: If the ct_path is not set to a different folder for each Windows user, conflicts can occur in log files and import/export files.

If multiple Clintrial users log on to a single client, each user must:

- 1 Create a different folder, separate from the folder that contains the Clintrial client software.
- 2 Edit the Ct4user.reg file:
 - Setting ct_path to the folder created in Step 1.
 - Setting ct_exe_path to the folder where the Clintrial software is installed.
- 3 Run the Ct4user.reg file.

For more information, see *Running the Ct4user.reg file* (on page 107).

Example

Dr. Smith and Dr. Jones want to use the Clintrial software on the same client.

Dr. Smith must:

- 1 Log on to the client using his client user account.
- 2 Create a folder for the files.
- 3 Edit the Ct4user.reg file to reflect the locations of the ct_path and ct_exe_path folders.

For example:

```
ct_path:c:\CT47_Dr_Smith
ct_exe_path:c:\CT47
```

- 4 Run the Ct4user.reg file.

Dr. Jones must:

- 1 Log on to the client using the client user account.
- 2 Create a folder for the files, different from Dr. Smith's folder.
- 3 Edit the Ct4user.reg file to reflect the locations of the ct_path and ct_exe_path folders.

For example:

```
ct_path:c:\CT47_Dr_Jones
```


`ct_exe_path:c:\CT47`

- 4 Run the Ct4user.reg file.

When a system administrator installs the Clintrial software

Depending on your procedures, a system administrator may log on to your client and install the Clintrial software. When you use the Clintrial software, you will probably log on to the client under a different user account than the administrator.

Caution: In this situation, the registry entries for your client user account are not set, and you cannot use the Clintrial software.

- 1 Log on to the client using your own client user account.
- 2 Edit the Ct4user.reg file:
 - Set `ct_path` to the folder where you will store the Clintrial software-related files.
 - Set `ct_exe_path` to the folder where the system administrator installed the Clintrial software.
- 3 Run the ct4user.reg file.

For more information, see *Running the Ct4user.reg file* (on page 107).

About network installation

If you setup a network installation, you must modify the `ct_path` and `ct_exe_path` keys and run the `Ct4user.reg` file on each client using the network installation. For more information, see *Running the Ct4user.reg file* (on page 107).

Caution: Oracle does not recommend network installations of the Clintrial client software because performance is typically degraded in such configurations.

Note: Setting up clients with a network installation does not automatically create desktop shortcuts to the Clintrial software. You must manually create shortcuts to network applications.

Modifying the `ct_path` and the `ct_exe_path` keys

For the `ct_path` key:

- On each client, in `ct4user.re` file, change the `ct_path` key so that it points to a location on the client to store log files.

For example:

`ct_path:d:\CT47_Dr_Jones`

This location is also used as the default folder when importing and exporting protocols, and when batch loading data.

Caution: Do not point the `ct_path` to a shared location on the network.

For the `ct_exe_path` key:

- On each client, in `ct4user.re` file, change the `ct_path` key so that it points to the location of the shared Clintrial installation on the network.

For example:

`ct_exe_path:G:\ct47_network_installation`

CHAPTER 7

Exporting, importing, and setting up codelists and protocols

In this chapter

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Exporting and importing codelists and protocols

There are two methods of exporting and importing codelists and protocols supported in Clintrial 4.7.1.

The recommended method utilizes Oracle's Data Pump Export and Import utilities (named **expdp** and **impdp** by Oracle). These utilities support all Oracle 10.2 features except for XML schemas and XML schema-based tables. The design of these utilities results in greatly enhanced data movement performance over the original Export and Import utilities. They are available as **Export** and **Import** in the **Design** module.

Note: If you are exporting then importing a non-unicode database to an Oracle 10.2 or 11.2 installation, you are required to use the **expdp** and **impdp** utilities.

The second method supported for export and import utilizes the original Oracle utilities (named **exp** and **imp** by Oracle). These are the same utilities supported in Clintrial 4.6, and are now called **Legacy Export** and **Legacy Import**, and are available in **Design**.

For more information, see Chapter 20 in the Clintrial *Admin and Design* document.

Note: When importing a protocol from Clintrial 4.6, there may be Oracle errors generated in the associated logs with error ORA-39152. Despite these error messages, the protocol has been successfully imported. These error messages may be safely ignored.

Run the import/export directory creation script

To use the Clintrial software to import/export protocols or codelists using Oracle's Data Pump Export (**expdp**) and Import (**impdp**) utilities, you must create at least one Oracle directory on the Clintrial server to hold the files.

Oracle provides a script (**ctdirect.sql**) to assist in this process. The script creates two directories; one for data (**CT_DATAPUMP_DIR**) and one for log files (**CT_DATAPUMP_LOG**) and grants rights to the Design users.

Caution: At any of the prompts for an account password, the installation aborts if you enter the incorrect password.

- 1 Start SQL*Plus from the appropriate installation directory and log on to the database instance.
- 2 Run the **ctdirect.sql** script:

```
SQL> @ctdirect
```

You are prompted to enter a connection string.
- 3 Enter the **@** symbol followed by the instance (or service) name to connect to.

You are prompted to enter the Clintrial CTPROC Account Password.
- 4 Enter the CTPROC Account Password.

You are prompted to enter the full path for the directory files for the Clintrial Import/Export.
- 5 Enter the full path for the files.

The script creates or replaces the directory on the core server.

It grants required read and write privileges on the directory.

In addition, Design users are not given direct access to the dump files outside of the Oracle database unless they have the appropriate operating system privileges. This is true for any operating system. This must be in addition to running the above script. If these privileges are not granted, then an error similar to the following will be encountered when running the Oracle **expdp** and **impdp** utilities:



Similarly, the Oracle database requires permission from the operating system to read and write files in the directories.

Alternatively, if different users require different access privileges, data pump directories can be created, one for each group of users.

For more details on the Oracle Data Pump utility, consult your Oracle database documentation.

Issue associated with protocols and codelists imported from Oracle 9i

In some cases, when you try to import a protocol or codelist from Clintrial 4.5, you may encounter an **ORA12899: Value too large for column** error. This is caused because a column that should be imported as a CHAR was imported as a BYTE.

To correct this condition, you must edit the codelist or protocol DMP file using a binary file editor.

- 1 Open the dump file in a binary editor.
- 2 Search for BYTE...INTERPRETED.
- 3 Change BYTE to CHAR.
- 4 Save and close the file.

When you import the DMP file again, the columns should reflect the correct data type.

Note: Using a non-binary editor will corrupt the DMP file.

Set up protocols for added functionality

- **CTL_REFERENCE**—Protocol that adds to Lab Loader functionality.
- **CTRESOLVEREF**—Protocol that stores discrepancy configuration information in the Resolve module.
- **CT_MEDDRA**—Thesaurus protocol that you can use to hold MedDRA dictionary data for use with the Manage module.
- **CTG_MEDDRA**—Extended thesaurus protocol that you can use to hold MedDRA dictionary data for use with the Classify module.
- **CTG_WHODD**—Extended thesaurus protocol that you can use to hold your WHO-DD data for use with the Classify module.

To set up these protocols, you must use a Clintrial client on which the following components have been installed:

- The Oracle Import utility.
- The Design module.

The Clintrial DMP files must be copied to the server in an accessible directory, for example:

CT_DATAPUMP_DIR

Note: The required DMP files are also included with the `ct47_smp.tar` file and the respective server TAR files.

For more information about setting up the protocols distributed with the Clintrial software, see *Medika Sample Studies* (on page 117).

Setting up the CTL_REFERENCE protocol

To complete the setup of the Lab Loader module, you must import the CTL_REFERENCE protocol, and then run the script to install the CTL_FUNC package.

- 1 Install the client software, as described in *Installing, upgrading, and maintaining the client software* (on page 93).
- 2 Start the Design module with the user name CTSYS, for which the default password is CTSYS.
- 3 Import the following protocol export DMP file:

`ctl_re_md.dmp`

Note: You must name the protocol that you are importing CTL_REFERENCE.

- 4 From the Lab Loader installation directory, run the `ctlinstfunc.sql` script:

`SQL> @ctlinstfunc`

Setting up the CTRESOLVEREF protocol

Importing the CTRESOLVEREF protocol

To complete the Resolve installation, you must import the CTRESOLVEREF protocol.

- 1 Install the client software, as described in *Installing, upgrading, and maintaining the client software* (on page 93).
- 2 Start the Design module with the user name CTSYS.
- 3 Import the following protocol export DMP file, which is located in the ct47\resolve directory on the client and in the ct47_smp.tar file:

ct_reso_md.dmp

You must name the new protocol that you are importing CTRESOLVEREF.

For more information about setting up the Medika Clinical Sample Study, see *Medika Sample Studies* (on page 117).

For more information about importing protocols, see the Design section in the *Admin and Design* guide and the Design Help.

Setting up the CT_MEDDRA thesaurus protocol

If you plan to use the MedDRA dictionary with the Manage module, you must:

- 1 Import the CT_MEDDRA protocol, including creating the tables.

The DMP file for this protocol is:

ct_med_m.dmp

- 2 Optionally, log on to the CTPROC account in SQL*Plus and execute the functions in the ct_meddra_util.create_meddra_indexes and ct_meddra_util.create_meddra_functions packages, as follows:

```
SQL> EXECUTE ct_meddra_util.create_meddra_indexes('CT_MEDDRA')
```

```
SQL> EXECUTE ct_meddra_util.create_meddra_functions('CT_MEDDRA');
```

For more information, see:

- The description of the CT_MEDDRA thesaurus protocol in the Design section in the *Admin and Design* guide.
- The description of the MedDRA-related functions in the *Clintrial Reference Guide*.

- 3 Batch load MedDRA data into this protocol.

For more information about importing protocols, thesaurus protocols, and protocol parameters, see the *Admin and Design* guide and the Design online Help.

Setting up the GCT_MEDDRA thesaurus protocol

The GCT_MEDDRA protocol is delivered with the Clintrial software. This is an extended thesaurus protocol to hold MedDRA data for use with the Classify module. If you plan to use MedDRA with the Classify module, you must set up this protocol, including setting its associated extended thesaurus protocol parameter.

- 1 Import the GCT_MEDDRA protocol.

The metadata DMP file for this protocol is:

gct_meddra_m.dmp

- 2 In the Design module, in the Protocol Browser, select the GCT_MEDDRA protocol.

Select **Protocol > Parameters**.

The Modify Protocol Parameters dialog box appears.

- 3 From the drop-down list next to the CTG_THES_TYPE parameter, select MEDDRA.
- 4 If the name of the column holding the lower level term text in the LOW_LEVEL_TERM table has been changed from LLT_NAME, enter the correct name in the CTG_MEDDRA_TERM_COL parameter.
- 5 Click **OK**.
- 6 Batch load MedDRA data into the protocol.

For more information about importing protocols, thesaurus protocols, and protocol parameters, see the *Admin and Design* guide and the Design Help.

For more information about using thesaurus protocols with the Classify module, see the *Manage, Classify, & Lab Loader* guide and the Classify online Help.

Setting up the GCT_WHODD thesaurus protocol

The GCT_WHODD thesaurus protocol is delivered with the Clintrial software. This is an extended thesaurus protocol to hold WHO-DD data for use with the Classify module. If you plan to use the WHO-DD with the Classify module, you must set up this protocol, including setting its associated extended thesaurus protocol parameter.

- 1 Import the GCT_WHODD protocol.

The metadata and data DMP file for this protocol is:

gct_whodd_md.dmp

- 2 In the Design module, in the Protocol Browser, select the GCT_WHODD protocol.

Select **Protocol > Parameters**.

The Modify Protocol Parameters dialog box appears.

- 3 From the drop-down list next to the CTG_THES_TYPE parameter, select the value WHODD.

Click **OK**.

For more information about importing protocols, thesaurus protocols, and protocol parameters, see the *Admin and Design* guide and the Design online Help.

For more information about using thesaurus protocols with the Classify module, see the *Manage, Classify, and Labloader* guide and the Classify online Help.

Setting up the Mini Medika Sample Study

The Mini Medika Sample Study is a simple clinical data protocol that you can import immediately after installation without any additional setup. Use it to test protocol import and see an example of a Clintrial study book.

- 1 Install the Oracle and the Clintrial software on the server.
- 2 Install the Oracle and the Clintrial software on the client computers.
- 3 Using the Design module, import ct_mini_md.dmp to create the MINI_MEDIKA clinical data protocol.

For more information, see the Design section in the *Admin and Design* guide.

Setting up the Medika or CDISC Medika Clinical Sample Studies

For details about each step in setting up the Medika Sample Studies, see the following sections:

<input checked="" type="checkbox"/> Workflow Steps	References
<input type="checkbox"/> Install: <ul style="list-style-type: none"> • The Oracle and the Clintrial software. • The Resolve module (optional). 	Step 1 (on page 119)
Install the Oracle and Clintrial 4.7 software on the client computers (including, optionally, the Resolve module).	Step 2 (on page 119)
<input type="checkbox"/> Using the Design module, import the following optional protocols: <ul style="list-style-type: none"> • CTRESOLVEREF protocol—Optional, for use with the Resolve module. • CTL_REFERENCE protocol—Optional, for use with the Lab Loader module. • LAB_NORMALS protocol—Optional, for use with the Lab Loader module only in the sample study. 	Step 3 (on page 120)

☑ Workflow Steps	References
<p>Using the Design module, import the following coding thesaurus protocols:</p> <ul style="list-style-type: none"> ☐ • ART_THESAURUS protocol—Sample thesaurus protocol used to code adverse events in MEDIKA_CLINICAL. • DRUG_THESAURUS protocol—Sample thesaurus protocol used to code drugs in MEDIKA_CLINICAL. • CT_MEDDRA protocol—Optional, for coding with MedDRA. • GCT_MEDDRA protocol—Optional, for use with the Classify module. • GCT_WHODD protocol—Optional, for use with the Classify module. 	Step 4 (on page 121)
☐ Using the Design module, import the VIEW_CODELISTS sample view codelists protocol.	Step 5 (on page 124)
☐ Using the Design module, import the sample codelists.	Step 6 (on page 124)
☐ Using the Design module, create flags that are used by the Resolve module.	Step 7 (on page 124)
☐ Using the Design module, import the MEDIKA_CLINICAL sample clinical data protocol or the CDISC_MEDIKA sample clinical data protocol.	Step 8 (on page 124)
☐ Create an Oracle account to store site-specific PL/SQL functions.	Step 9 (on page 125)
☐ Using the Admin module, set the Design system parameter PROC_SITE_ACCOUNT to CTSITEPROC.	Step 10 (on page 126)
<p>☐ If you are targeting the CDISC_MEDIKA sample clinical data protocol, run <code>\\client-dir\sample\CDISC\CDISC Medika\setup_CDISC.sql</code>.</p> <p>After running the setup file, complete steps 13 through 15.</p>	Step 11 (on page 126)
☐ If you are targeting the MEDIKA_CLINICAL sample clinical data protocol, compile the CT_SAMPLE package and grant EXECUTE privileges.	Step 12 (on page 127)
☐ Compile the DEPROCS package and grant EXECUTE privileges.	Step 13 (on page 127)
☐ Using the Resolve module, set up the sample clinical data protocol for the Resolve module (optional).	Step 14 (on page 127)
☐ Compile the customized CT_RESOLVE_USER package (optional).	Step 15 (on page 128)

Sample protocol-specific help

The Medika Sample Study provides protocol-specific Help for entering or editing data in the MEDIKA study book of the MEDIKA_CLINICAL protocol. In addition, the sample study provides an example of metadata help for one of the study pages.

When the Clintrial client is installed, the protocol-specific Help is also installed. No further setup is required.

You can write similar Help for your own protocols. You can also write Help to describe your internal business practices and system requirements. You can provide step-by-step instructions for processes and procedures and include conceptual information where applicable.

Step 1: Install the Oracle and the Clintrial software on the server

To install the Oracle and Clintrial software on the server, follow the instructions in *Preparing to install or upgrade to the Clintrial 4.7 Server* (on page 23) and *Performing a new installation of the Clintrial 4.7 software* (on page 41).

You can use the Medika Sample Study with or without the Resolve module. If you plan to use the Resolve module with the sample study, you must install the Resolve module on the server. To install the Resolve module, run the ctvinst.sql script as described in *Performing a new installation of the Clintrial 4.7 software* (on page 41). You do not yet need to import the CTRESOLVEREF protocol or set up a protocol for the Resolve module.

For more information, see *Step 3* (on page 120) and *Step 14* (on page 127).

Step 2: Install the Oracle software and the Clintrial software on the client

To install the Oracle and the Clintrial software on the clients, install the client software for all the Clintrial modules that you will use and follow the client installation instructions in *Installing or upgrading the Clintrial 4.7 client software* (on page 96). On at least one client, install the following software, which you will need to set up the Medika Sample Study:

- Oracle utilities, as described in *Installing or upgrading the Clintrial 4.7 client software* (on page 93).
- A third-party tool that allows you to write, compile, and work with PL/SQL.

If you use the Resolve module, install the Resolve client software, which you will use to set up the MEDIKA_CLINICAL protocol for the Resolve module in *Step 14* (on page 127). To install the Resolve client software:

- 1 Select the **Custom** option from the client installation wizard.
- 2 Select **Extended Modules** and **Sample Study**.

This installs all extended modules and all of the Medika Sample Studies.

You choose the study to work with by opening the proper protocol after installation.

If you do not want to install all extended modules, click **Change**, and check the specific extended modules to install.

Step 3: Import the Resolve and Lab Loader protocols

This section describes the protocols that you can optionally import if you plan to use the Medika or CDISC Medika Clinical Sample Study with the Resolve and Lab Loader extended modules.

Note: Some of the DMP files and other files described in this section are not specific to either Sample Study, but can be used to create protocols that can be used with your data. Files that are not specific to the Medika Sample Study are extracted to additional directory locations.

Importing the CTRESOLVEREF protocol

The Resolve module uses the CTRESOLVEREF protocol to store panels, statuses, and state transitions.

Note: CTRESOLVEREF is used by the Resolve module with all of your data and is not specific to the Medika Sample Study.

If you installed the Resolve module, but have not imported the CTRESOLVEREF protocol:

- 1 In the Design module, import metadata and data to the CTRESOLVEREF protocol, using the `ctreso_md.dmp` file.

At the Resolve module server installation, these files are extracted to the specified server directory.

At client installation, when you select the **Custom** option, and select **Extended Modules** and **Sample Study**, the Clintrial software places the DMP files in the Resolve client directory and in the `Sample\Protocols` subdirectory, (or `sample\CDISC\CDISC_MEDIKA`), each of which is below the directory that you specified for the client installation.

Note: When you select **Extended Modules**, the default is to select all extended modules, as well as the Resolve and Lab Loader protocols. Click **Change** to modify the default selections.

- 2 Remain logged on to the Design module.

For more information about using CTRESOLVEREF, see the Resolve section in the *Enter, Resolve, and Retrieve* guide.

For more information about protocol import, see the Design section in the *Admin and Design* guide.

Importing the CTL_REFERENCE and LAB_NORMALS protocols

The Clintrial software supplies the following protocols for use with the Lab Loader module:

- The CTL_REFERENCE thesaurus protocol contains lab normal ranges and SI unit conversion factors.
- The LAB_NORMALS Lab Loader source protocol contains clinical data to be prepared and then transferred into the destination protocol MEDIKA_CLINICAL.

Note: You can use the CTL_REFERENCE protocol as imported from the metadata DMP file to batch load your own lab normals data. The CTL_REFERENCE data DMP file and the LAB_NORMALS DMP files are for use only with the Medika Sample Study.

If you installed the Lab Loader module and you have not imported the CTL_REFERENCE and

LAB_NORMALS protocols:

- 1 In the Design module, import metadata and data to protocols named CTL_REFERENCE and LAB_NORMALS, using:

- **ctl_re_md.dmp**—Metadata and data DMP file for CTL_REFERENCE
- **lab_normals_md.dmp**—Metadata and data DMP file for LAB_NORMALS

At the Lab Loader server installation, `ctl_re_md.dmp`, and the batch load control files `ctl_unit_conversion.ctl` and `ctl_normal_range.ctl`, are extracted to the specified server directory.

During the Clintrial server installation, the `ctl_re_md.dmp` was placed in the `LabLoader-server-dir`. At client installation, when you select the **Custom** option, and select **Extended Modules** and **Sample**, the Clintrial software places the `ctl_re_md.dmp` in the Lab Loader client directory, which is below the directory that you specified for the client installation.

The `lab_normals_md.dmp` file was placed in the in the `LabLoader-server-dir\LabNormals` subdirectory.

Note: When you select **Extended Modules**, the default is to select all extended modules, as well as the **Resolve** and **Lab Loader** protocols. You can modify the default selections by clicking **Change**.

- 2 Remain logged on to the Design module.

Step 4: Import the thesaurus protocols

This section describes how to import:

- **ART_THESAURUS** and **DRUG_THESAURUS**—The coding thesaurus protocols that are used by the CDISC Medika Clinical Sample Study.

Note: If you are going to use the coding feature in the **CDISC MEDIKA Sample Study**, you must import the **ART_THESAURUS** protocol.

- **CT_MEDDRA**—The coding thesaurus protocol that is used to code against the MedDRA dictionary, whether or not you use the Medika Sample Study.
- **GCT_MEDDRA** and **WHO-DD**—The optional coding thesaurus protocols that are used to code against the MEDDRA dictionary with the Classify module, whether or not you use the Medika Sample Study.

Note: Oracle supports the standard drug dictionary metadata **WHO-DD** format **B2**. A custom dictionary may be created to support any format.

Importing the ART_THESAURUS and DRUG_THESAURUS protocols

In the Design module, import the sample coding thesaurus protocols. Items in the ADV panel of the `MEDIKA_CLINICAL` protocol refer to the coding thesaurus protocol `ART_THESAURUS`. Items in `PRVMED` and `CONMED` panels refer to the coding thesaurus protocol `DRUG_THESAURUS`. If you use a different name for the new coding thesaurus protocol, you must change the **Thesaurus** attribute for coding items in the `MEDIKA_CLINICAL` clinical data protocol.

- 1 In the Design module, as the user `CTSYS`, import metadata and thesaurus data to a protocol named `ART_THESAURUS`, using the `ct_art_thes_md.dmp` file.

Note: If you plan to use the coding feature in the CDISC_MEDIKA sample study, you must import the ART_THESAURUS protocol.

- In the Design module, as the user CTSYS, import metadata and thesaurus data to a protocol named DRUG_THESAURUS, using `ct_drug_thes_md.dmp` file.

Importing the CT_MEDDRA thesaurus protocol

The Clintrial software supplies the CT_MEDDRA protocol for use with coding to the MedDRA dictionary. CT_MEDDRA contains the panels, panel keys, and views to receive and use batch-loaded data from the MedDRA dictionary.

Note: You can use CT_MEDDRA to code your own data to the MedDRA dictionary and with the Medika Sample Study. You must purchase and load the MedDRA dictionary data to use CT_MEDDRA.

Note: The MEDIKA_CLINICAL sample clinical data protocol codes against the ADV (Adverse Events) panel using the ART_THESAURUS protocol. However, you can substitute the ADVLLT or the ADVPT page sections (based on panels of the same name) on the ADV page template. The ADVLLT and ADVPT panels contain coding targets to code against CT_MEDDRA.

- In the Design module, import metadata and data to a protocol named CT_MEDDRA, using:
 - `ct_med_m.dmp`—Metadata DMP file for CT_MEDDRA.
 - `*.ctl`—control files you can use to create batch load files for the MedDRA data, which you then batch load into CT_MEDDRA.

At the Clintrial core server software installation, the DMP file and control files are extracted to the core server installation directory.

- Optionally, log on to the CTPROC account in SQL*Plus and execute the functions in the `ct_meddra_util.create_meddra_indexes` and `ct_meddra_util.create_meddra_functions` packages, as follows:

```
SQL> EXECUTE ct_meddra_util.create_meddra_indexes('CT_MEDDRA');
```

```
SQL> EXECUTE ct_meddra_util.create_meddra_functions('CT_MEDDRA');
```

- Remain logged on to the Design module.

For more information about the `ct_meddra_util` functions, see:

- The description of the CT_MEDDRA protocol in the Design section in the *Admin and Design* guide.
- The description of the MedDRA-related functions in the *Clintrial Reference Guide*.

For more information about protocol import, see the Design section in the *Admin and Design* guide.

Importing the GCT_MEDDRA protocol and GCT_WHODD protocol

The Clintrial software supplies the following thesaurus protocols for use with the Classify module:

- **The GCT_MEDDRA thesaurus protocol**—holds data from the MedDRA dictionary for use with the Classify module.
- **The GCT_WHODD thesaurus protocol**—holds data from the WHO-DD for use with the Classify module.

GCT_MEDDRA and GCT_WHODD each contain the panels, panel keys, views, and sample algorithms to use the extended thesaurus protocol functionality provided by the Classify module.

Note: GCT_MEDDRA and GCT_WHODD are used by the Classify module with your data and are not specific to the Medika Sample Study.

You must purchase and load the MedDRA dictionary data to use the GCT_MEDDRA protocol. The Clintrial software supplies the WHO-DD data for the GCT_WHODD protocol.

If you have installed the Classify module and you have not yet imported the GCT_MEDDRA protocol and GCT_WHODD protocol:

- 1 In the Design module, import metadata and data to the GCT_MEDDRA and GCT_WHODD protocols, using the following protocol DMP files:
 - **gct_meddra_m.dmp**—The metadata DMP file for GCT_MEDDRA.

Note: No data is supplied for GCT_MEDDRA. You must purchase and load the MedDRA data dictionary. You must create batch load files for the MedDRA data, then batch load the data to GCT_MEDDRA.

- **gct_whodd_md.dmp**—Metadata and data DMP file for GCT_WHODD.

During the Classify server installation, these files are extracted to the specified server directory.

At client installation, when you select the **Custom** option, and select **Extended Modules** and **Sample Study**, the Clintrial software places the DMP files in the sample subdirectory, which is below the directory that you specified for the client installation.

Note: When you select Extended Modules, the default is to select all extended modules, as well as the Resolve and Lab Loader protocols. You can modify the default selections by clicking Change.

- 2 Set the CTG_THES_TYPE protocol parameter for the GCT_MEDDRA protocol to MEDDRA, and the parameter for the GCT_WHODD protocol to WHODD.
- 3 Set the CTG_MEDDRA_TERM_COL protocol parameter to specify the name of the column holding the low-level term text in the LOW_LEVEL_TERM table.

If you do not specify a value for the CTG_MEDDRA_TERM_COL parameter, the software will use the default value LLT_NAME as the name of the low-level term column.

Note: The default name of the low-level term column in the standard GCT_MEDDRA protocol is LLT_NAME_ENGLISH. If you change this name in the GCT_MEDDRA protocol, enter the new name in the CTG_MEDDRA_TERM_COL protocol parameter field.

- 4 Remain logged on to the Design module.

For more information about the Classify extended thesaurus protocol functionality, see the *Manage, Classify, and Labloader* guide.

For more information about protocol import, see the Design section in the *Admin and Design* guide.

Step 5: Import the sample view codelists protocol

In the Design module, as the user CTSYS, import the VIEW_CODELISTS protocol that contains panels upon which the view codelists are based:

- **M_INVESTIGATOR view codelists**—Contains investigator information.

Note: You should import the VIEW_CODELISTS protocol before you import the codelists, so that the panels are available for the view codelists using ct_viewcode_md.dmp file.

Step 6: Import the sample codelists

Before importing the MEDIKA_CLINICAL protocol, import the sample codelists. In the Design module, as the user CTSYS, import the ct_medika_c.dmp codelists import file.

Step 7: Create sample flags

Before you import the sample clinical data protocol, create the following flags in the Design module:

Category	Flag Name
GENERAL (supplied by the Clintrial software) Description: General flags.	DELTA_BP Description: Blood pressure varies by > 10% from previous visit.
DISCREPANCY_P1 Description: Priority 1 (high) discrepancies.	COMMENT_FIRST Description: Inconsistency noted in the first review. INCOMPLETE Description: Field on the CRF is not complete.
DISCREPANCY_P2 Description: Priority 2 (medium) discrepancies.	DATA_ILLEGIBLE Description: Data for this field is illegible on the CRF.

The first flag is used to check data in the VITAL panel of the MEDIKA_CLINICAL protocol. The other two are used by data that is related to the Resolve module.

Note: Create all three flags whether or not you use the Resolve module.

Step 8: Import the CDISC_MEDIKA sample clinical data protocol

In the Design module, as the user CTSYS, import the sample clinical data protocol.

If you are importing the CDISC_MEDIKA sample clinical data protocol, import metadata and clinical data to the CDISC_MEDIKA protocol, using the CDISC_MEDIKA_md.dmp file in the

\\client-dir\samples\CDISC\CDISC MEDIKA subdirectory.

The dictionary protocol (CDISC_SDTM_31) contains panel definitions that are based on the SDTM v3.1. It may be used as a reference library by users when building SDTM-compliant study protocols.

To import this reference library, use the protocol CDISC_SDTM_311_m.dmp file in the \client-dir\samples\CDISC\CDISC STDM 31 subdirectory.

Note: If you are not also importing the MEDIKA_CLINICAL sample study, proceed to steps 13 and 14.

If you are importing the MEDIKA_CLINICAL clinical data protocol, import metadata and clinical data to a protocol named MEDIKA_CLINICAL, using the following protocol ct_med_clin_md.dmp file in the \client-dir\samples\Protocols subdirectory.

Step 9: Create an account for site-specific PL/SQL

Oracle recommends that you create an Oracle account to store site-specific and protocol-specific PL/SQL packages, procedures, and functions used by the Clintrial derivations, rules, and data-entry processing procedures. The sample study includes the grnt.sql script to create this account.

Start SQL*Plus from the module's installation directory and log on to the database instance.

The server module software and verification scripts are placed in directories called one of the following:

\$HOME/ct4server/ct47/ct47_<Clintrial_module>

\$HOME/local/ct4server/ct47/ct47_<Clintrial_module>

Where

\$HOME is the **\$ORACLE_HOME** directory

<Clintrial_module> is one of the following:

- **srv**—core server
- **ctc**—Multisite Distribution server
- **ctx**—Multisite Replication server
- **ctg**—Classify server
- **ctl**—Lab Loader server
- **ctv**—Resolve server
- **ctqa**—Ad Hoc Query (the Retrieve module)

For example, on a Windows system, the path name and directory name for the core server installation directory could be:

- 1 **C:\oracle\ct4server\ct47\ct47_srv**
- 2 Run the grnt.sql script from the \\ct47_smp\Packages directory:

SQL> @grnt

Here are the names of scripts you may run:

- ctpost—core server
- ctcpst—Multisite Distribution server
- ctxpst—Multisite Replication server
- ctgpst—Classify server
- ctlpst—Lab Loader server
- ctvpst—Resolve server
- ctqpst—Retrieve server

You are prompted to enter the name for the log file.

- 3 Press **Enter** to accept the default, or enter the log file name.

You are prompted to enter a connection string.

- 4 Enter the @ symbol followed by the instance (or service) name to connect to.

You are prompted to enter the SYSTEM Account Password.

- 5 Enter the SYSTEM Account Password.

You are prompted to enter the Clintrial CTPROC Account Password.

- 6 Enter the Clintrial CTPROC Account Password.

You are prompted to enter the CTSITEPROC Account Password to use for the CTSITEPROC account.

- 7 Enter the CTSITEPROC Account Password.

You are prompted for default tablespace to use for the CTSITEPROC user.

Note: This cannot be the SYSTEM tablespace.

- 8 Press **Enter** to accept the default, or enter the CTSITEPROC default tablespace.

You are prompted to enter the temporary tablespace for the CTSITEPROC user.

Note: This tablespace must have temporary storage (contents must be TEMPORARY). Also, this cannot be the SYSTEM tablespace.

Step 10: Set PROC_SITE_ACCOUNT

- After creating the CTSITEPROC account, start the Admin module and set the Design system parameter PROC_SITE_ACCOUNT to CTSITEPROC.

Step 11: Run setup_CDISC.sql if you are targeting CDISC_MEDIKA

- 1 Log on as CTSITEPROC.
- 2 Run the setup_CDISC.sql script (assuming that C:\ct48\sampleCDISC\CDISC Medika is the location of the file and the SQL command is run from that folder):

```
SQL> connect ctsiteproc/ctsiteproc@instance-name;
```

```
SQL> @setup_CDISC.sql;
```

The setup_CDISC script calls the deprocs_CDISC.sql and ctsample.sql packages.

- 3 Complete steps 13 through 15.

Step 12: Compile CT_SAMPLE and grant EXECUTE if you are targeting the MEDIKA_CLINICAL

The ctsample.sql script:

- Compiles the CT_SAMPLE package, which contains stored functions for use by sample study rules and derivations.
 - Includes statements that drop and add a public synonym for the CT_SAMPLE package.
- 1 Log on as CTSITEPROC, and run the script (assuming that C:\ct47\samples\Packages is the location of the file and the SQL command is run from that folder).
 - 2 Grant EXECUTE privileges on CT_SAMPLE to CTSITEPROC, using the GRANT_EXECUTE_PRIVS command in the CT_PROC_ACCOUNT package:

```
SQL> connect ctsiteproc/ctsiteproc@instance-name;
```

```
SQL> @ctsample.sql;
```

```
SQL> execute ct_proc_account.grant_execute_privs('CT_SAMPLE');
```

Step 13: Compile DEPROCS and grant EXECUTE.

The deprocs.sql file:

- Compiles the DEPROCS package, which contains data-entry processing procedures that are used by the sample study.
- Includes statements that drop and add a public synonym for deprocs.

While logged in as CTSITEPROC, run the deprocs.sql file as follows (assuming that C:\ct47\samples\Packages is the location of the file and the SQL command is run from that folder):

```
SQL> connect ctsiteproc/ctsiteproc@instance-name;
```

```
SQL> @deprocs.sql;
```

Step 14: Set clinical data protocol for the Resolve module

If you plan to use the Resolve module with a Medika Sample Study, you must set up the MEDIKA_CLINICAL or CDISC_MEDIKA protocol for the Resolve module, as follows:

- 1 Start the Resolve module as a user who has the Full access level for the non-protocol access right Admin System.

Access levels and rights are set and appear in the Admin module.

For example, you can start the Resolve modules as the user CTSYS.

- 2 Set the protocol to MEDIKA_CLINICAL or CDISC_MEDIKA.
- 3 Select **Setup > Setup for Resolve**.

Step 15: Compile the CT_RESOLVE_USER package

If you use the Resolve module, you may want to customize it so that the investigator number and name from the INVESTIGATORS panel determines the list of investigators in several Resolve dialog boxes for the protocol. To do so, you create a customized version of the CT_RESOLVE_USER package that is delivered with the Clintrial software. The Clintrial software includes the following files that allow you to customize the Resolve module for the sample study:

- **sm_ruser.sqh**—Package specification for the customized CT_RESOLVE_USER package.
- **sm_ruser.sql**—Package body for the customized CT_RESOLVE_USER package.

This has been customized for MEDIKA_CLINICAL.

You can add changes for your own protocols.

- **before.sql**—Grants access to the CTSITEPROC account for the INVESTIGATORS_DATA table and INVESTIGATORS_UPDATE table in the MEDIKA_CLINICAL protocol, as required by the CT_RESOLVE_USER package.
- **af_ruser.sql**—Grants access to the CTSITEPROC account for the INVESTIGATOR_UPDATE table in the CTRESOLVEREF protocol, as required by the CT_RESOLVE_USER package.

To use the customized CT_RESOLVE_USER package:

- 1 After setting appropriate permissions on the before.sql and af_ruser.sql scripts, if you gave the imported MEDIKA_CLINICAL or CDISC_MEDIKA protocol another name, set the appropriate permission on the sm_ruser.sql file and edit it to refer to that name.
- 2 Log on to the CTSITEPROC account (assuming that C:\ct47\samples\Packages is the location of the file and you run the SQL command from that folder).
- 3 Enter the following command:

```
SQL> @before.sql;
```

Note: Because this file logs on to the CTPROC account, when it has finished running, you must log back in to the CTSITEPROC account.

- 4 Log on to the CTSITEPROC account and enter the following commands:

```
SQL> @sm_ruser.sqh;
```

```
SQL> @sm_ruser.sql;
```

If you find errors in sm_ruser.sql, correct them in your editor and run the file again.

- 5 Change the public synonym for the CT_RESOLVE_USER package and grant access to it:

```
SQL> drop public synonym ct_resolve_user;
```

```
SQL> create public synonym ct_resolve_user for ctsiteproc.ct_resolve_user;
```

```
SQL> grant execute on ct_resolve_user to ct_user;
```

- 6 Be sure that the CTSITEPROC account can correctly run all the functions in the CT_RESOLVE_USER package, run the modified copy of af_ruser.sql.

For example:

```
SQL> @af_ruser.sql;
```

Sample study protocols and files

The following table lists the protocol DMP files, codelists DMP files, and other files that you can use to create the Medika Sample Studies in your Clintrial database instance. When you select the **Custom** option, and select **Sample Study**, the Clintrial software places these files in the directories listed in the table.

Note: Some of the DMP files and other files are not specific to the Medika Sample Studies, but can be used to create protocols that can be used with your data. Files that are not specific to a sample study are extracted to additional directory locations, as described in the table. The files are listed in the recommended order of use when setting up the Medika Sample Studies.

Files	Use	Directory location	Description
ct_mini_md.dmp	MINI_MEDIKA clinical data protocol	\client-dir\samples\ \Protocols	A simple clinical data protocol that you can import immediately after installation, with no additional setup.
ct_medika_c.dmp	Codelists	\client-dir\samples\ \Protocols	All codelists that are used by the sample study.
ct_med_clin_md.dmp	MEDIKA_CLINICAL protocol	\client-dir\samples\ \Protocols	A clinical data protocol that contains the ENROLL study book (for enrollment data), the MEDIKA study book (for clinical data), and the LAB_NORMS study book (for a Type 0 panel).
CDISC_MEDIKA_CRF.doc	CDISC_MEDIKA Clinical data protocol	client-dir\samples\ CDISC	MS Word file, example CRFs for the CDISC_MEDIKA Clinical data protocol.
CDISC_MEDIKA_c.dmp CDISC_MEDIKA_md.dmp	CDISC_MEDIKA Clinical data protocol	client-dir\samples\ CDISC\ CDISC Medika	Codelist file, example clinical data file and metadata file for the CDISC_MEDIKA Clinical data protocol.
setup_CDISC.sql	CDISC_MEDIKA Clinical data protocol	client-dir\samples\ CDISC\ CDISC Medika	Setup file for the CDISC_MEDIKA Clinical data protocol.
ctsample.sql	CDISC_MEDIKA protocol	client-dir\samples\ CDISC\ CDISC Medika	Example PL/SQL Package for CDISC_MEDIKA.

Files	Use	Directory location	Description
deprocs_CDISC.sql	CDISC_MEDIK A protocol	client-dir\ samples\ CDISC\CDISC Medika	Example PL/SQL DEPPS Package for CDISC_MEDIKA.
grnt.sql	CDISC_MEDIK A protocol	client-dir\samples\ CDISC\CDISC Medika	Used to create the CTSITPROC account for CDISC_MEDIKA.
CDISC_STDM_31_m.dmp	CDISC STDM 3.1 protocol	client-dir\samples\ CDISC\CDISC STDM 31	STDM 3.1 Compliant protocol.
ct_reso_md.dmp	CTRESOLVERE F protocol	\Resolve-server-dir \client-dir\Resolve \client-dir\ Samples\Protocols	A clinical data protocol used by the Resolve module.
ctl_re_md.dmp	CTL_REFEREN CE protocol	\LabLoader-server- dir (both .dmp files) \client-dir\Lab Loader (ctl_re_md.dmp only)	A Lab Loader thesaurus protocol that contains lab normal ranges and SI unit conversion factors, and sample data for use with MEDIKA_CLINICAL. (Optionally, you can batch load your own data using the ctl_unit_conversion.ctl and ctl_normal_range.ctl control files.)
ctl_unit_conversion.ctl ctl_normal_range.ctl	CTL_REFEREN CE protocol	\LabLoader-server- dir \client-dir\Lab Loader	Control files that are used to create batch load files from which you can batch load your own data to the CTL_REFERENCE protocol. (Optionally, you can use the sample data provided in the ctl_re_d.dmp file.)
lab_normals_md.dmp	LAB_NORMALS	\LabLoader-server- dir\ LabNormals	A Lab Loader source protocol that contains clinical data to be prepared and then transferred into the destination protocol MEDIKA_CLINICAL.

Files	Use	Directory location	Description
ct_art_thes_md.dmp	ART_THESAUR US protocol	\client-dir\samples\ Dictionaries	A coding thesaurus protocol that contains sample ART codes that you can use to code medical events or conditions in the sample study. This ART code information is intended for use as an example only.
ct_drug_thes_md.dmp	DRUG_THESAU RUS protocol	\client-dir\samples\ Dictionaries	<p>A coding thesaurus protocol that contains the following:</p> <ul style="list-style-type: none"> • Sample WHO drug industry information that you can use to code medications in the sample study. • MEDIKA company drug code information. <p>This drug code information is intended for use as an example only.</p> <p>Note: Oracle supports the standard drug dictionary metadata WHO-DD format B2. You can create a custom dictionary to support any format.</p>

Files	Use	Directory location	Description
ct_med_m.dmp	CT_MEDDDRA protocol	\core-server\client-dir\samples\ Dictionaries\Meddra	A thesaurus protocol into which you can batch load MedDRA dictionary data for coding with your data or with the Medika Sample Study. Note: The sample study does not code using this thesaurus protocol, but provides sample Adverse Event panels with the correct coding targets if you load MedDRA data. You can substitute a MedDRA-specific panel for the Adverse Event panel used in the sample. The sample study codes against sample ART codes. For more information, see <i>Setting up the Medika or CDISC Medika Clinical Sample Studies</i> (on page 117).
spec_pref_comp.ctl spec_cat.ctl soc_term.ctl soc_intl_order.ctl soc_hlgt_comp.ctl pref_term.ctl md_hierarchy.ctl low_level_term.ctl hlt_pref_term.ctl hlt_pref_comp.ctl hlgt_pref_term.ctl hlgt_hlt_comp.ctl ct_med_m.dmp	CT_MEDDDRA protocol	\core-server \client-dir\samples\ Dictionaries\Meddra	Control files that are used to batch load the MedDRA dictionary data into CT_MEDDDRA protocol.
gct_meddra_m.dmp	GCT_MEDDDRA protocol	\Classify-server-dir \client-dir\samples\ Dictionaries	A thesaurus protocol into which you can batch load MedDRA dictionary data for use with the Classify module.
gct_whodd_md.dmp	GCT_WHODD protocol	\Classify-server-dir \client-dir\samples\ Dictionaries	A thesaurus protocol for WHO-DD data for use with the Classify module.

Files	Use	Directory location	Description
ct_viewcode_md.dmp	VIEW_CODELISTS protocol	\client-dir\samples\Dictionaries	A clinical data protocol that contains information that is used by view codelists in MEDIKA_CLINICAL for the following: <ul style="list-style-type: none"> Investigator information. Signature meaning codes.
grnt.sql		\client-dir\samples\Packages	Used to create the CTSITEPROC account.
ctsample.sql	CT_SAMPLE package	\client-dir\samples\Packages	Used to set up the CT_SAMPLE package.
deprocs.sql	DEPROCS package	\client-dir\samples\Packages	Used to set up the DEPROCS data entry processing procedure package.
before.sql af_ruser.sql sm_ruser.sql sm_ruser.sql	CT_RESOLVE_USER package	\client-dir\samples\Packages	Used to customize the CT_RESOLVE_USER package.
compile.sql	All protocols	client-dir\samples\Packages	
medika.hlp medika.cnt metadata.hlp metadata.cnt tracegloss.hlp tracegloss.cnt	Protocol-specific help in MEDIKA_CLINICAL		Used to illustrate company-specific context-sensitive Help for use in study books in the Enter module.

Examples of the Clintrial functionality in the Medika Clinical Sample Study

In the Design module, use the **Reports** menu to select reports that describe the metadata for the protocol that you are running.

Type of functionality	Name	Where in MEDIKA_CLINICAL
Checklist	<ul style="list-style-type: none"> • M_LABS_UNITS_CHM • M_LABS_UNITS_HEM • M_VAL_MULTI 	Panel/Item: <ul style="list-style-type: none"> • LAB/TEST_UNITS_CHEM • LAB/TEST_UNITS_HEM • LAB/URNGUIDE Study page: <ul style="list-style-type: none"> • Laboratory Tests
Coding targets	Code 1 item: <ul style="list-style-type: none"> • CODE1_ART • DRGCODE • CODE1_ART • INDCODE1, DRGCODE 	Panels: <ul style="list-style-type: none"> • MEDHIST • PRVMED • ADV • CONMED Study pages: <ul style="list-style-type: none"> • Medical Hx/Prev Meds • Concomitant Meds • Adverse Events

Type of functionality	Name	Where in MEDIKA_CLINICAL
Derivations and rules	<p>Set up for error item appears in the Resolve module, with error logic in derivation, and derived message:</p> <ul style="list-style-type: none"> CHECK_AGE derivation and rule (DMG panel) <p>Set up for error item appears in the Resolve module, with error logic and message in rule:</p> <ul style="list-style-type: none"> CHECK_PULSE derivation and rule (VITAL panel) <p>Set up to call user-defined PL/SQL package:</p> <ul style="list-style-type: none"> COMPDT calls CT_SAMPLE (CONMED panel) <p>Many derivations and rules call the CT_SAMPLE package in ctsample.sql.</p>	<p>Panels:</p> <ul style="list-style-type: none"> DMG VITAL CONMED <p>Study pages:</p> <ul style="list-style-type: none"> Demographic/Investigator Vital/Neuro Exam Concomitant Meds
Data-Entry Processing Procedures (DEPPs)	<p>Value Changed Procedure DEPP (cursor movement):</p> <ul style="list-style-type: none"> DEPROCS.ITEMFOCUS <p>Value Changed Procedure DEPP (calculate new value or check a value):</p> <ul style="list-style-type: none"> DEPROCS.CONVERT-TEMP DEPROCS.CHK_PREV-_BP_SYS <p>Page Opened, Page Saved, and Initializing Page Section DEPP:</p> <ul style="list-style-type: none"> DEPROCS.LOCKSUBJECT <p>All DEPPs call the DEPROCS PL/SQL package in deprocs.sql.</p>	<p>Page section (for cursor movement or new value):</p> <ul style="list-style-type: none"> DMG VITAL <p>Page template: (for Page Opened and Page Saved):</p> <ul style="list-style-type: none"> ADV <p>Page template/page section (for Initializing Page Section):</p> <ul style="list-style-type: none"> ADV/CONTEXT <p>Study pages:</p> <ul style="list-style-type: none"> Demographic/Investigator Vital Signs/Neuro Exam Adverse Events

Type of functionality	Name	Where in MEDIKA_CLINICAL
Master-detail panels	Panels with cross-panel master-detail relationship: <ul style="list-style-type: none"> • VITAL and NEUROL Panels with within-panel master-detail relationship: <ul style="list-style-type: none"> • MEDHIST • PRVMED • CONMED • ADV 	Study pages: <ul style="list-style-type: none"> • Vital Signs/Neuro Exam • Medical Hx/Prev Meds • Concomitant Meds • Adverse Events
Page sections based on a single panel, but displaying different items	<ul style="list-style-type: none"> • BOTDISP • DRGCMP • BOTRET • BOTRETFINAL 	Panel: <ul style="list-style-type: none"> • DRGCMP Study pages: <ul style="list-style-type: none"> • First Bottle Dispensed • Drug Administration • Bottle Returned and Dispensed • Last Bottle Returned
Sequences		Page Sections/Items: <ul style="list-style-type: none"> • PHYEXM/EXAM • LABCHM/TEST_NAME • LABHEM/TEST_NAME • LABURN/TEST_NAME Study pages: <ul style="list-style-type: none"> • Physical Examination • Laboratory Tests
Subset codelists	Subsets of M_LABS_UNITS: <ul style="list-style-type: none"> • M_LABS_UNITS_CHM • M_LAB_UNITS_HEM 	Panel/Items: <ul style="list-style-type: none"> • LAB/TEST_UNITS_CHM • LAB/TEST_UNITS_HEM Study page: <ul style="list-style-type: none"> • Laboratory Tests

Examples of the Clintrial functionality in the CDISC Medika Clinical Sample Study

In the Design module, use the **Reports** menu to select reports that describe the metadata for the protocol that you are running.

Type of functionality	Name	Where in CDISC_MEDIKA
Coding targets	Code 1 item:	Panel:
	<ul style="list-style-type: none"> • AEDECOD 	<ul style="list-style-type: none"> • AE Study Pages: <ul style="list-style-type: none"> • Adverse Events
Derivations and rules	<ul style="list-style-type: none"> • DIABP_RNG - Diastolic blood pressure range check. Set up for error item display in Resolve, with error logic in derivation, and derived message 	Panel: <ul style="list-style-type: none"> • VS Study Page: <ul style="list-style-type: none"> • Vital Signs
	<ul style="list-style-type: none"> • PARTIALDATES - concatenating partial date elements 	Panel: <ul style="list-style-type: none"> • AE Study Page: <ul style="list-style-type: none"> • Adverse Events
	<ul style="list-style-type: none"> • DOMAIN_INSERTING: Inserts the domain abbreviation for every panel 	All Panels
	<ul style="list-style-type: none"> • DATECOLLECTION: Transfers the collectdate to the date field for the related date field (CDISC domain specific) 	All Panels
	Derivations to build the subject number and transfer the site ID	Panel: <ul style="list-style-type: none"> • ENROLL
<p>Note: Many derivations and rules call the CT_SAMPLE package in ctsample.sql.</p>		
Data Entry Processing Procedures (DEPPs)	<ul style="list-style-type: none"> • Value changed procedure DEPP (cursor movement) - NMDEPROCS.ITEMFOCUS 	Page Section: <ul style="list-style-type: none"> • DM01
	<ul style="list-style-type: none"> • Page Opened, Page Saved and Initializing Page Section DEPP - NMDEPROCS.LOCKSUBJECT 	Page Template: <ul style="list-style-type: none"> • VITAL

Type of functionality	Name	Where in CDISC_MEDIKA
	Note: All DEPPs call the NMDEPROCS PL/SQL package in nmdeprocs.sql	
Page sections based on a single panel, but displaying different items	<ul style="list-style-type: none"> • LB01 • LB02 	Panel: <ul style="list-style-type: none"> • LB Page Template
Sequences		Page Sections/ Items: <ul style="list-style-type: none"> • IE01 / IETESTCD, IECAT, IETEST • QS01 / QSCAT, QSTESTCD, QSTEST Study Pages: <ul style="list-style-type: none"> • JNTASS01, IE_INC01

Troubleshooting

Deleting and reimporting for use with the Resolve module

If you deleted the MEDIKA_CLINICAL or the CDISC_MEDIKA sample study and are reimporting it for use with the Resolve module, you must perform the following steps:

- 1 Rerun the before.sql script, as described in *Step 14* (on page 127).
- 2 Log on to the CTSITEPROC account and recompile the CT_RESOLVE_USER package as follows:

```
SQL> alter package ctsiteproc.ct_resolve_user compile body;
```

- 3 In the Resolve module, run **Setup for Resolve**.

CHAPTER 8

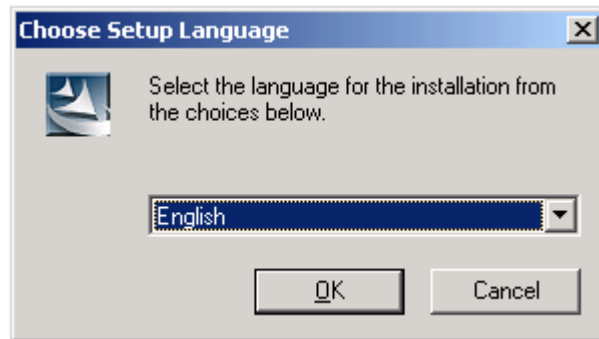
Deinstalling the Clintrial software

In this chapter

Running the deinstallation wizard for the Clintrial core software	140
Modifying, repairing, or removing the Clintrial 4.7 client software.....	150

Running the deinstallation wizard for the Clintrial core software

- 1 Navigate to the location of the installation files and double-click **CTServerInstaller.exe**.
The **Choose Setup Language** window appears.

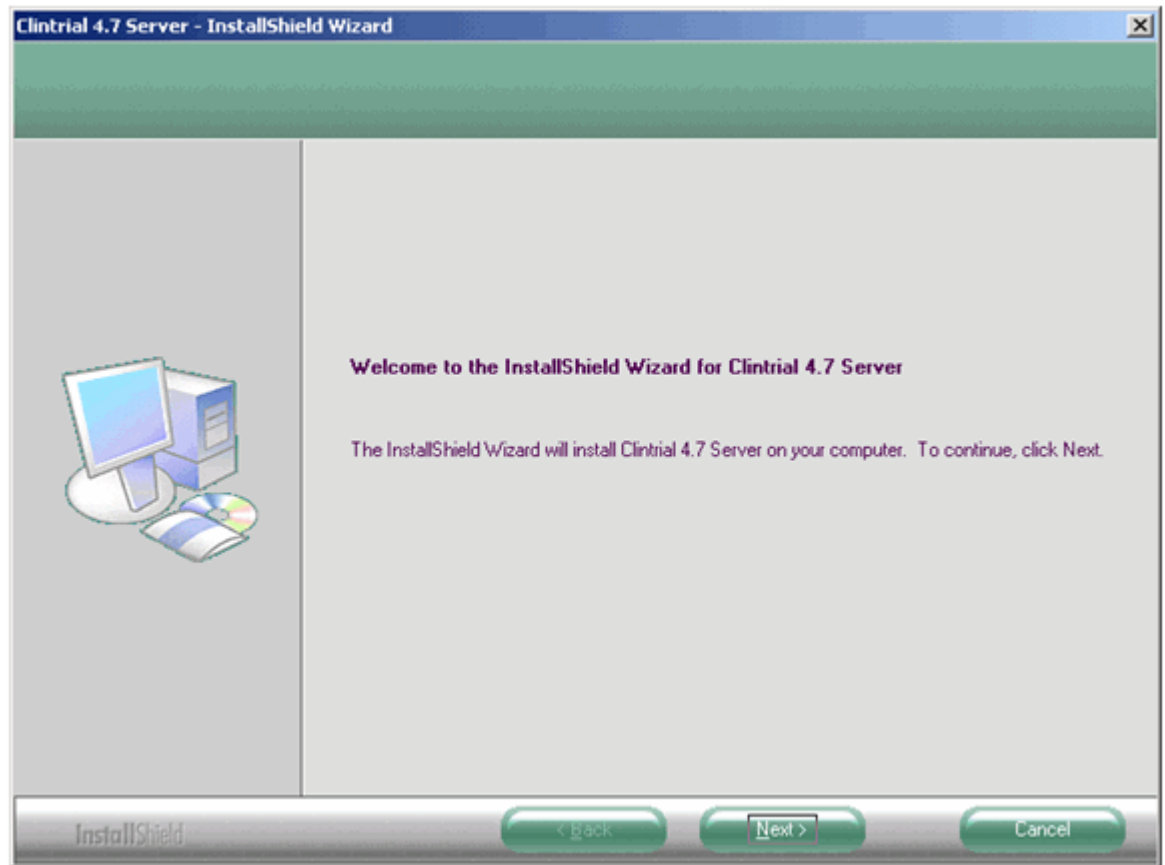


If you want to choose a language other than English on an English operating system, the proper language pack must be installed and the Windows default language must be changed. For example, if you want to conduct the installation in Japanese, the Asian language pack must be installed and the default language must be changed to Japanese.

For more information, see your Windows documentation.

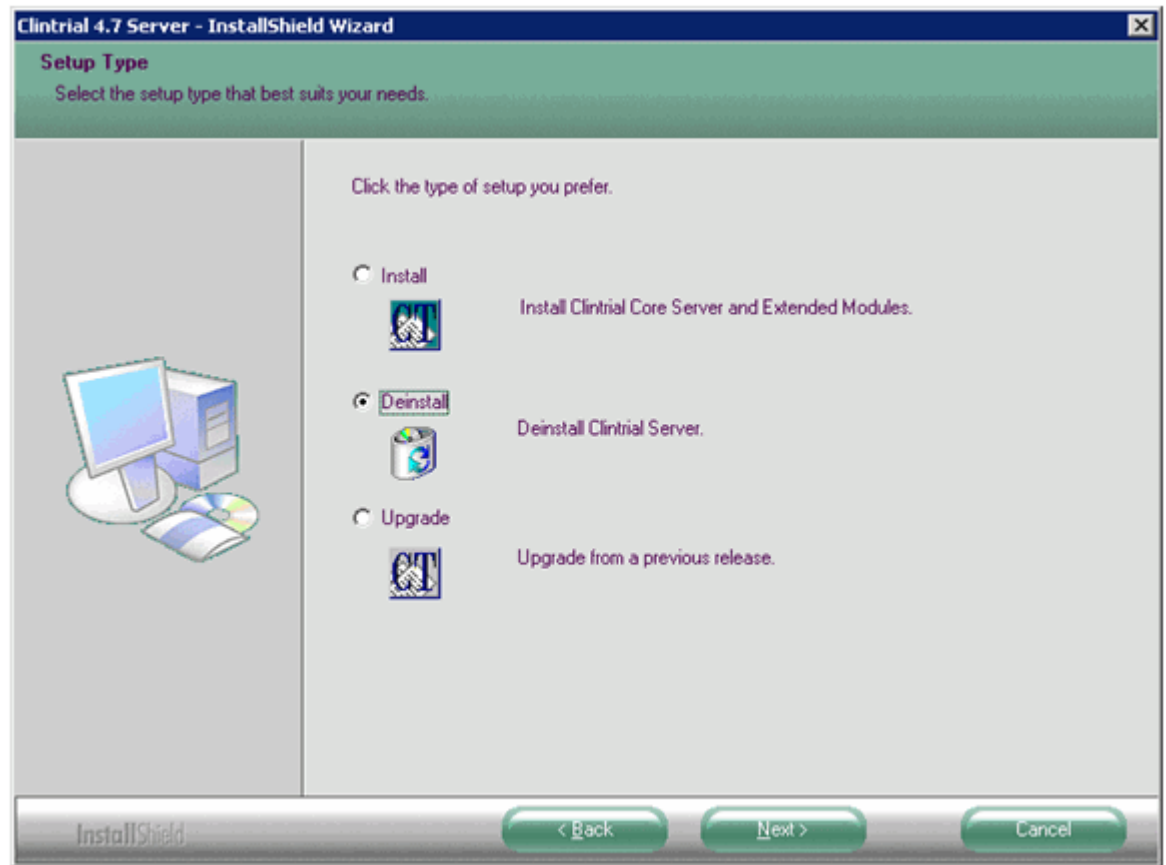
- 2 Select the language you want the wizard to use during setup. This also the language that will be used for the labels and descriptions for codelists and tags.
- 3 Click **Next**.

The **Welcome** window appears.



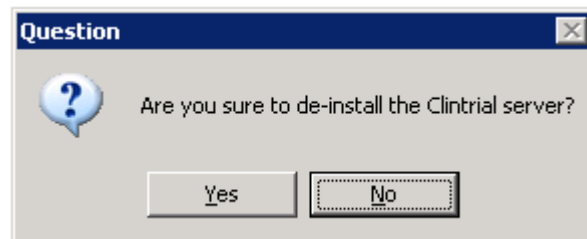
- 4 Click **Next**.

The **Setup type** window appears.



- 5 To deinstall the server and/or the extended modules, select the **Deinstall** button.
- 6 Click **Next**.

A small **Question** dialog will display, asking you if you are sure you want to deinstall the Clintrial software.



- 7 Click **Yes**.

The first **Edit data** window, which asks for information on the Oracle database, appears.

Clintrial 4.7 Server - InstallShield Wizard

Edit Data
Enter requested data.

Please enter the following information.

Database Connection String: (Oracle database name defined in tnsnames.ora.)

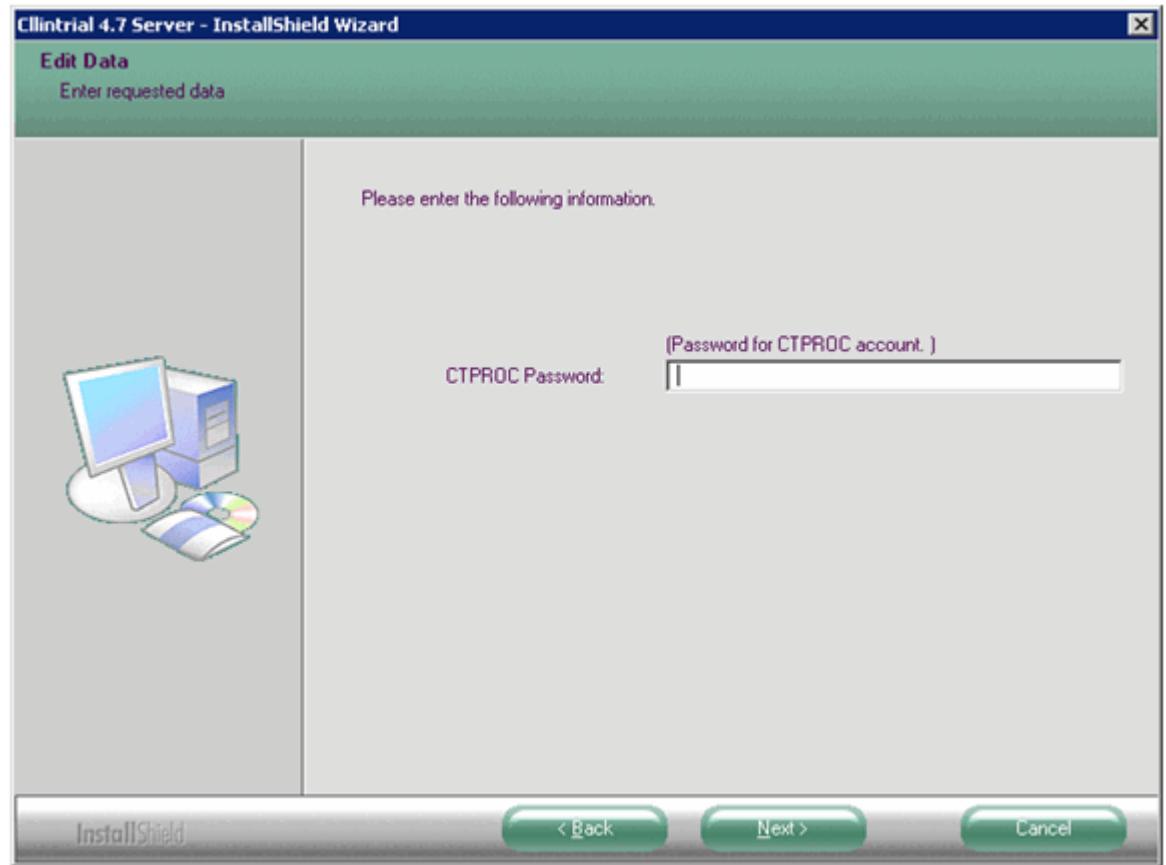
Oracle SYS account:

Oracle SYSTEM account:

Password: Confirm Password:

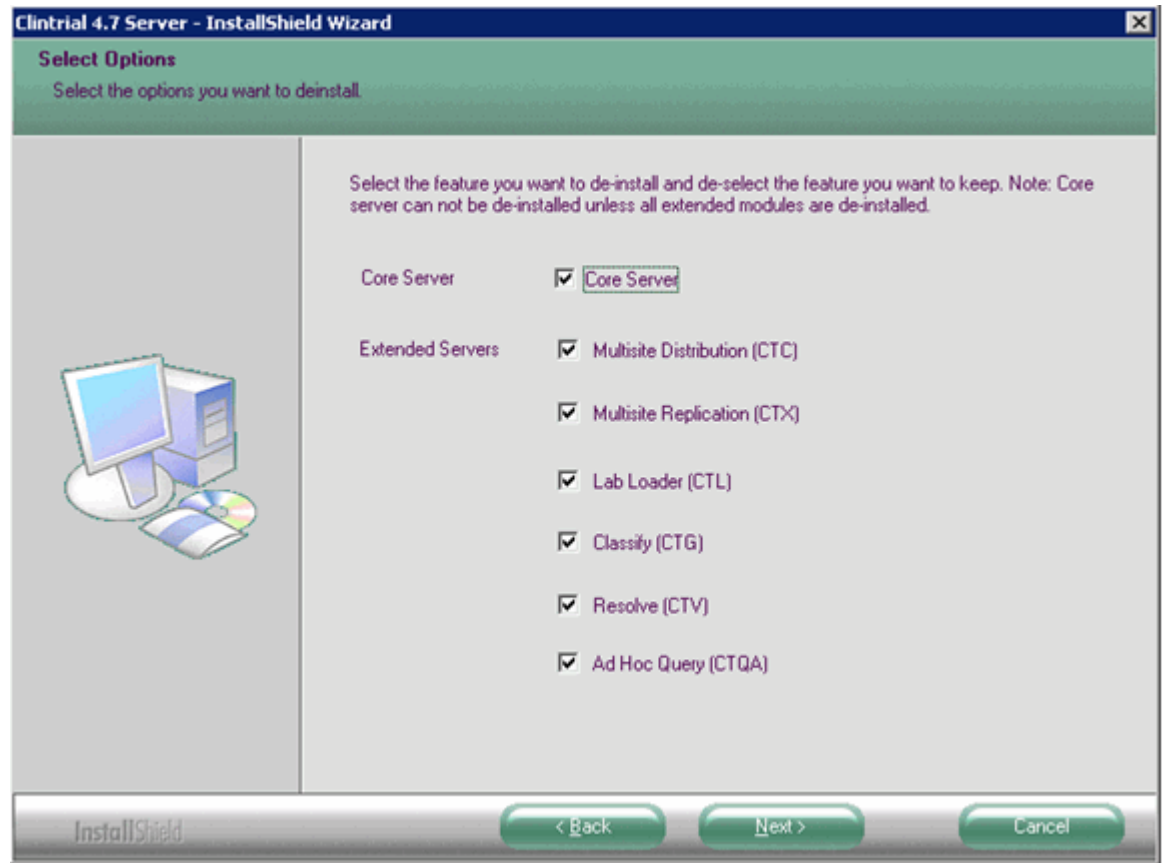
InstallShield < Back Next > Cancel

- 8 Enter the following information:
 - **Database Connection String** as it is defined in the **tnsnames.ora** file.
 - Enter and confirm the following Oracle database passwords:
 - Oracle **SYS** password.
 - Oracle **SYSTEM** password.
- 9 Click **Next**.
- 10 The **Edit Data** window for the CTPROC Password displays.



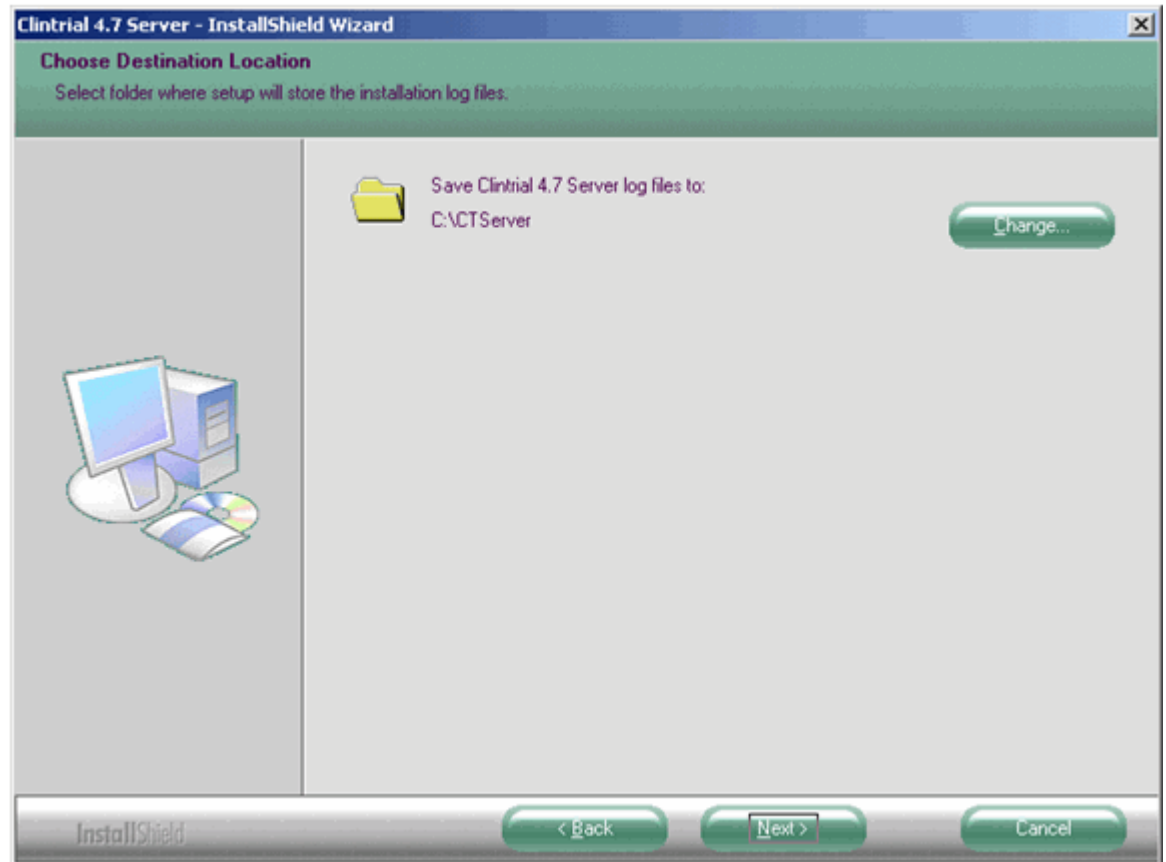
- 11 Enter the password for the **CTPROC** account.
- 12 Click **Next**.

The **Select Options** screen will display.



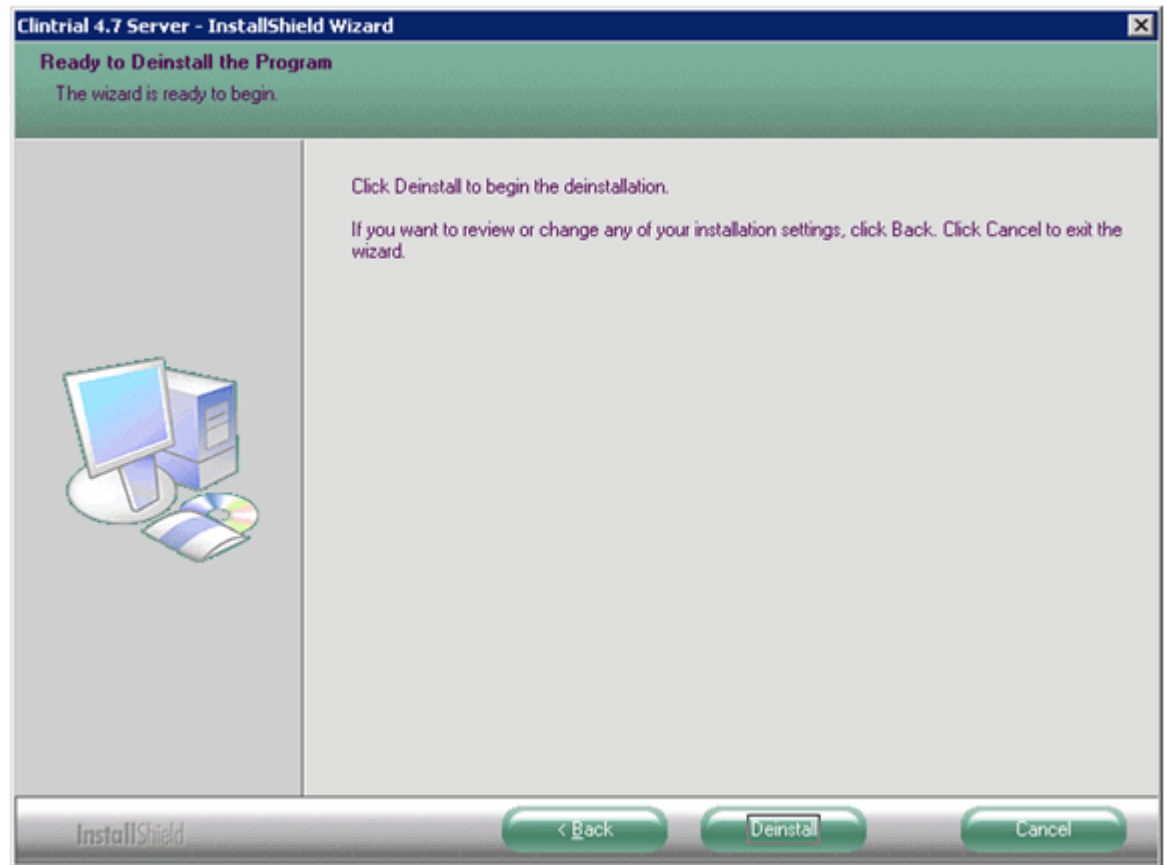
- 13 The features installed will be selected automatically for the deinstallation process.
- 14 Clear the boxes for any features you do not want to deinstall.
- 15 Click **Next**.

The **Choose Destination Location** screen will display. The specified location will store the deinstallation log files.



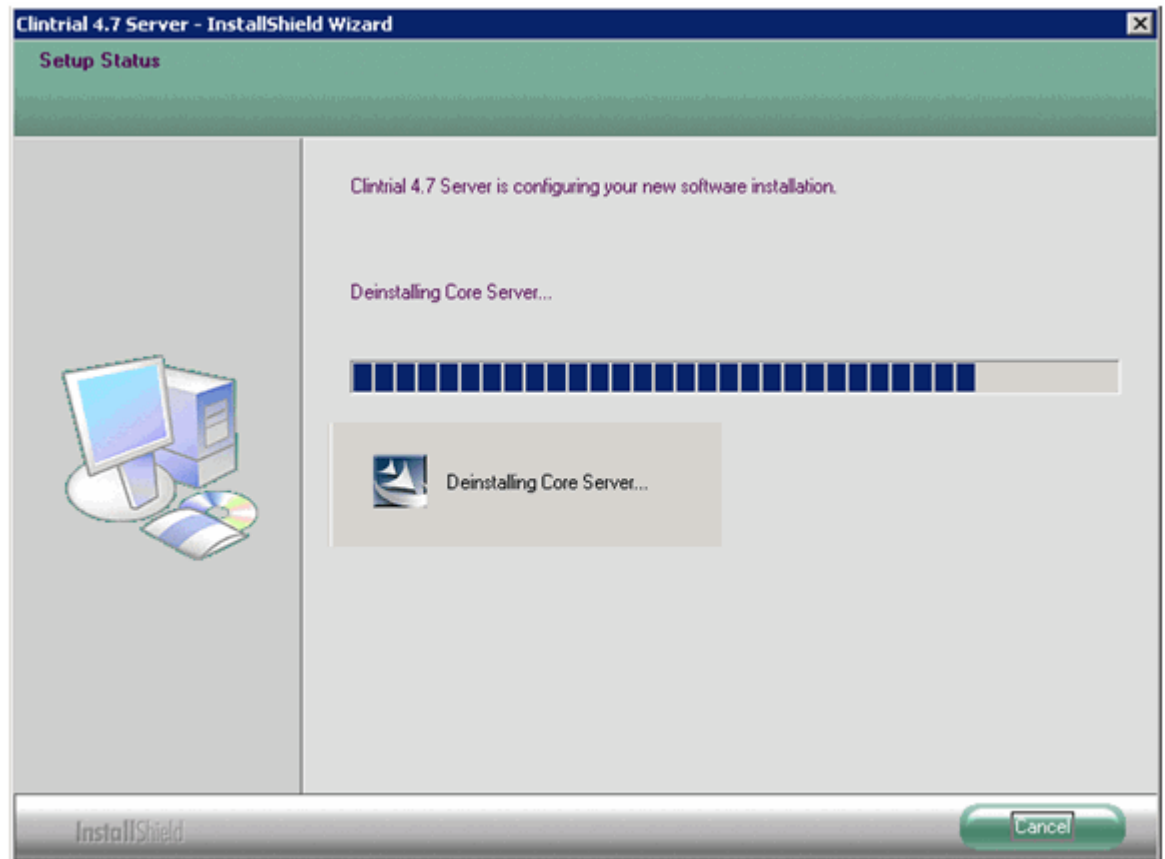
- 16 Accept the default location (which is where the Clintrial server is currently installed), or choose a new location.
- 17 Click **Next**.

The **Ready to Deinstall** window appears.



- 18 Click on **Deinstall** to begin the deinstallation. Otherwise, click on **Back** to modify the selections.

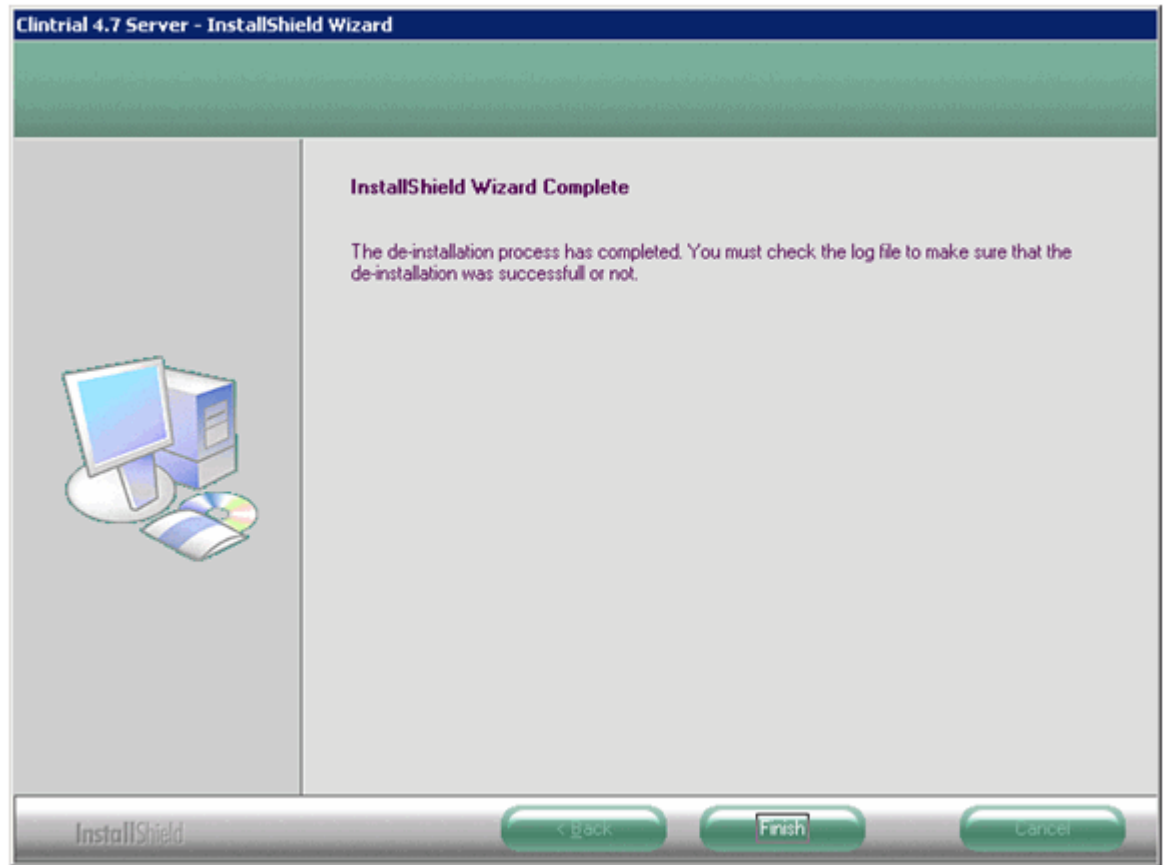
After clicking on **Deinstall**, the **Setup Status** screen will display the deinstallation status.



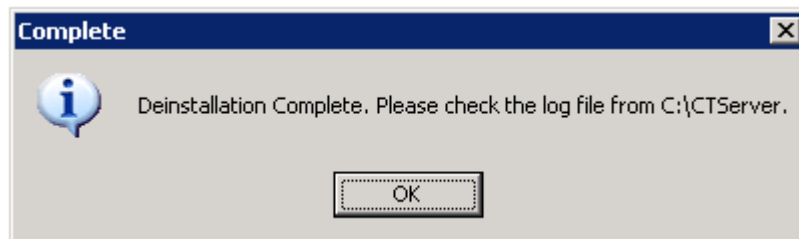
At the same time, a DOS status dialog will also display, indicating the processes for each module.

```
D:\oracle\ora10\bin\sqlplus.exe
De-Install Started 03:15:57 PM Wed Jan 28, 2009
Verifying Connection To Oracle SYSTEM.
Connected.
Verifying No Clintrial Extended Modules Or Clintrace Installed.
You Are About To De-Install Your Clintrial Server On Site CI47G.
Verifying Clintrial users do not own objects
Verifying no Clintrial users are connected to the database...
Dropping The Protocol Accounts.
Dropping The Protocol_DATATRANS Accounts.
Dropping The User Accounts.
Dropping The Clintrial System Accounts.
```


After the process is finished, the **InstallShield Wizard Complete** window appears.



- 19 Click **Finish** and a small **Complete** dialog will display, reminding you where the log files were written.



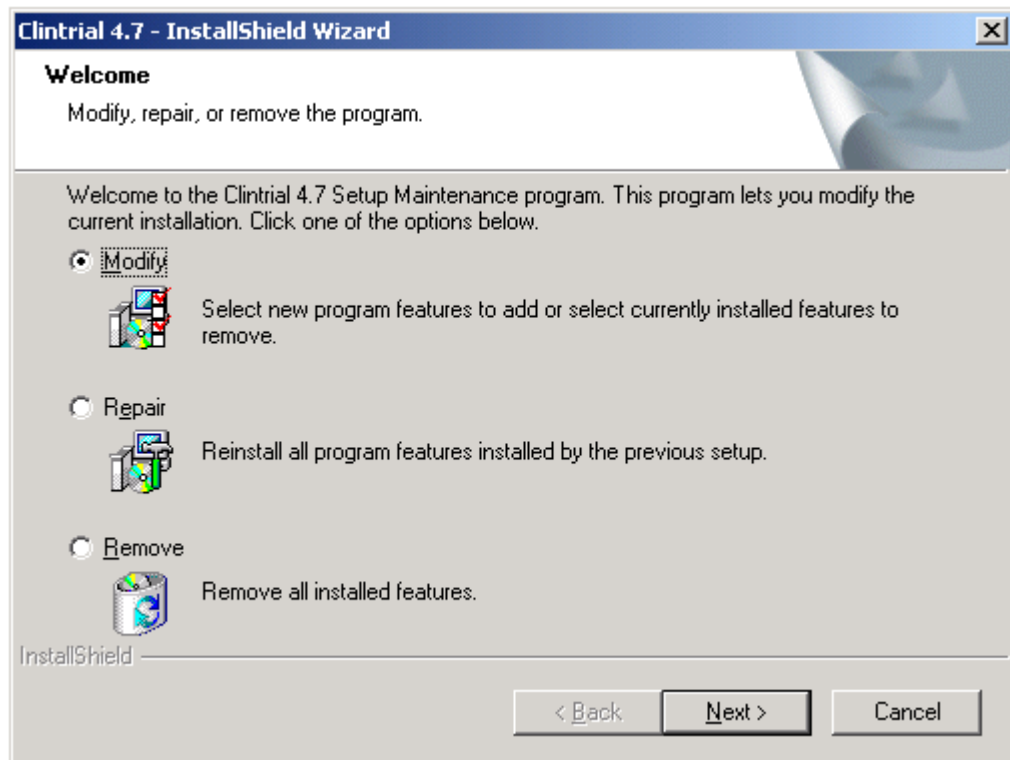
- 20 Click **OK**.
- 21 Check the log files to make sure all the deinstallation was successful.

Modifying, repairing, or removing the Clintrial 4.7 client software

- 1 Navigate to the location of the installation files and double-click **CT4Setup.exe**.

The **Choose Setup Language** window will not display, since this is not the first time the software has been installed.

The **Welcome** window for the Clintrial setup program appears.



- 2 Choose **Modify** if the first installation used **Custom**, and you want to change the features installed.

Choose **Repair** if you just want to reinstall Clintrial 4.7.

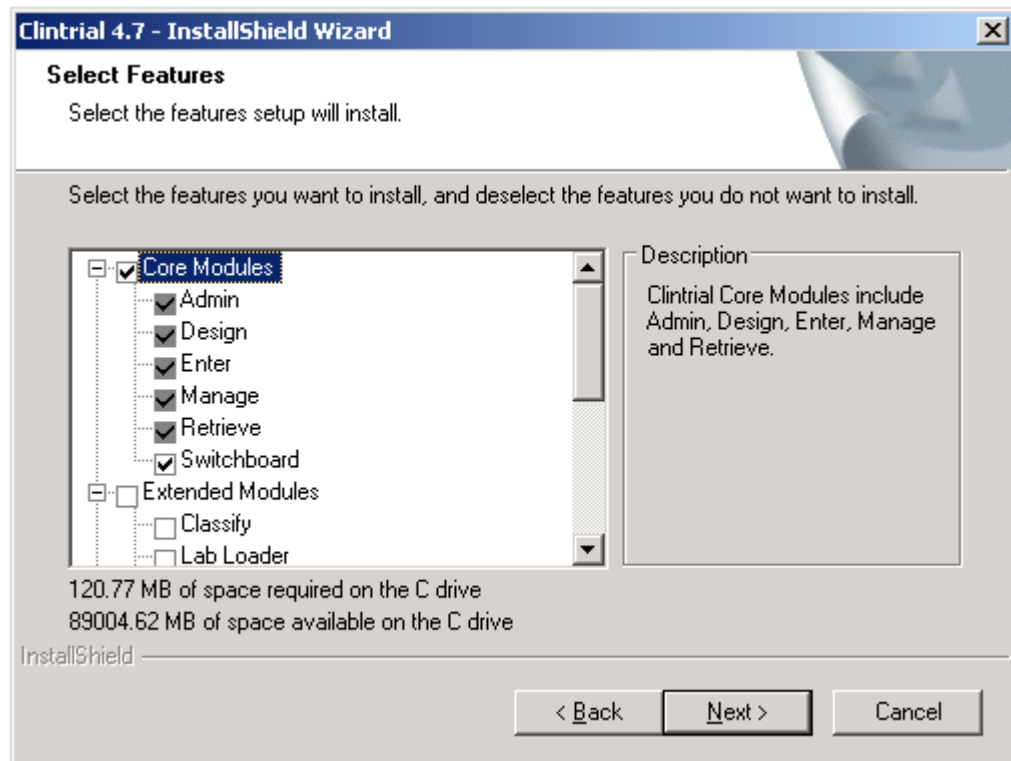
Choose **Remove** if you want to remove the previous Clintrial 4.7 client installation.

When something is wrong for the previous client installation, it is recommended to use **Remove** to remove the previous client installation and then run the installation again.

Note: There is no upgrade per se for the client to go from Clintrial 4.5 or 4.6 to 4.7. You may leave older clients undisturbed on your computer if desired, or remove them using the Windows Control Panel. You can then install the Clintrial 4.7 Client, using the instructions in Installing or upgrading the Clintrial 4.7 client software.

- 3 Click **Next**

The **Select Features** window will display if you chose **Modify**.

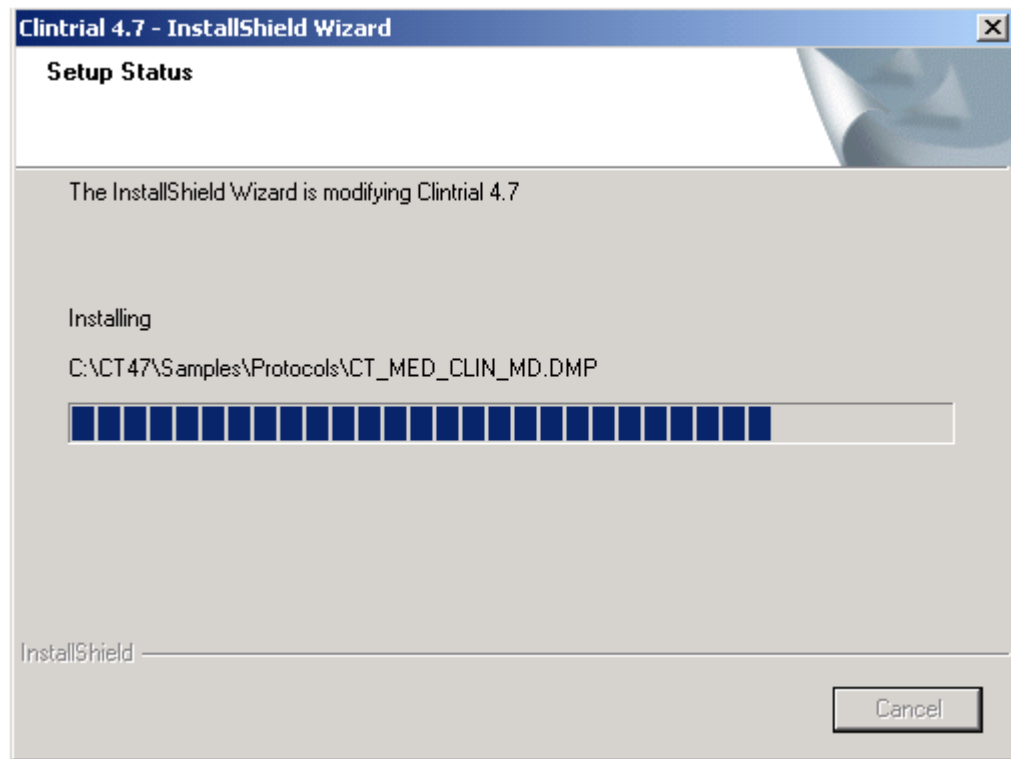


- 4 Select the components to install.

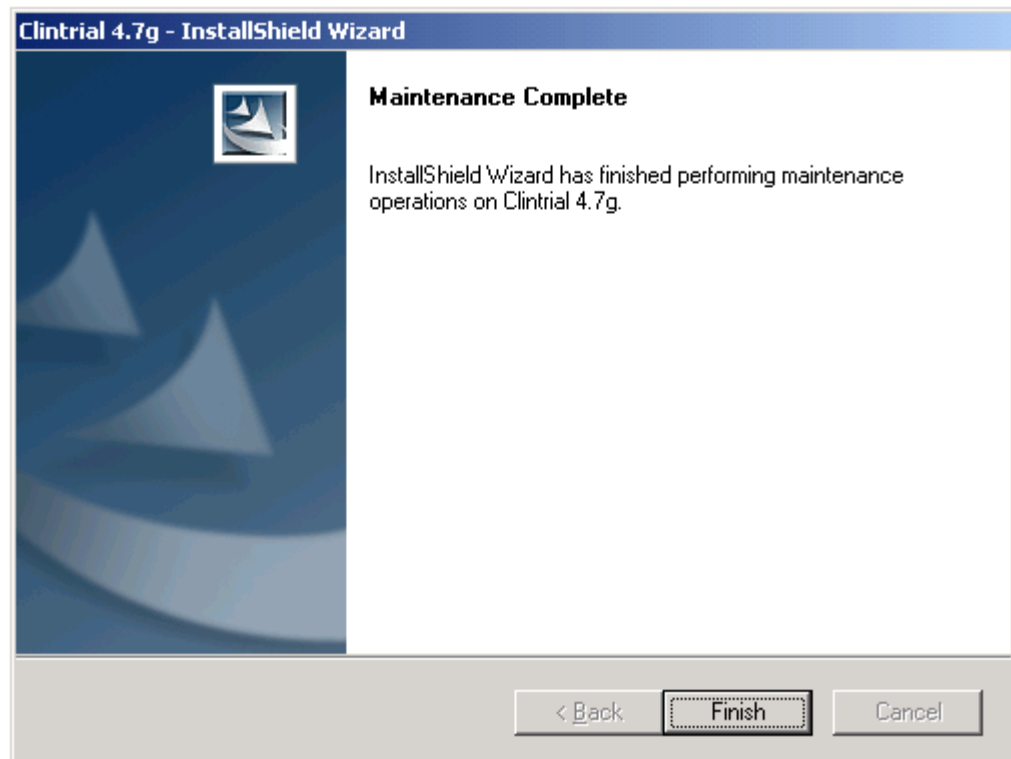
Note: the **Select Features** window is the same as the one seen in the initial installation wizard.

- 5 When you have completed selecting the features, click **Next**.

The Setup Status window appears.



- 6 After the maintenance operation is finished, the **InstallShield Wizard Complete** window appears.



- 7 Click **Finish**.

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