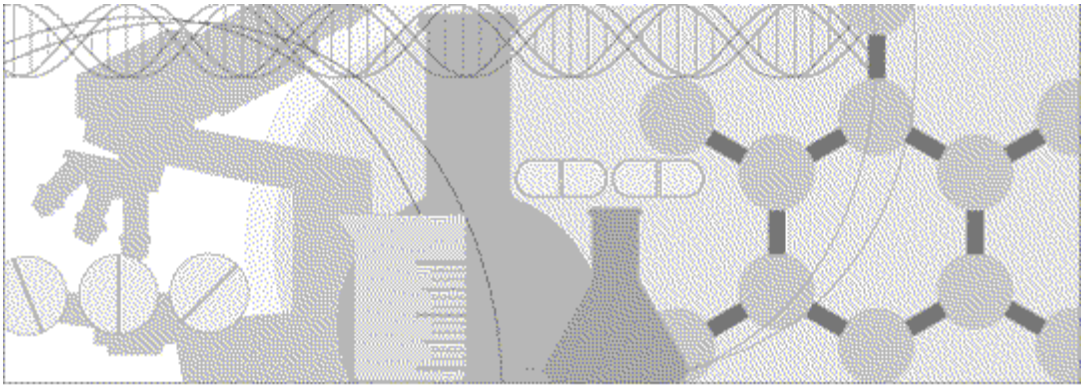
CIS Administrator Guide

Clintrial Integration Solution
Release 4.6 SP0



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Contents

About this guide

In this preface

Overview of this guide

The *CIS Administrator Guide* describes:

- How to use the CIS Administration application to manage adapters, load balanced machines, and synchronization connections.
- How to troubleshoot synchronization problems and how to recover in case of a system failure.
- Data transfer and storage in an integrated study.
- Key database tables.

Audience

This guide is for:

- CIS administrators
- Database administrators
- System engineers

Related information

Documentation

In addition to the CIS documentation listed in the following table, the documentation for the following applications provides information about the software products used in a CIS environment:

- Clintrial software
- InForm software
- InForm Adapter software
- Central Designer software

Title	Description	Format
CIS Release Notes	• New features, fixed issues, hardware and software requirements, and upgrade considerations.	PDF. Available from the Phase Forward Download Center.
CIS Known Issues	• Known problems and workarounds (if available).	PDF. Available from the Phase Forward Download Center.
CIS Administrator Guide	• How to use the CIS administration tool (CIS Administration) to manage adapters, load-balanced machines, CIS protocols, and synchronization connections. • Troubleshooting, data transfer and storage, and key database tables.	PDF and HTML. Available from the CIS Administration user interface, the documentation CD, and the Phase Forward Download Center.
CIS Designer Guide	• Integrated study design considerations.	PDF. Available from the documentation CD and the Phase Forward Download Center.
CIS Installation Guide	• Hardware and software requirements. • Product interoperability considerations. • Procedures for installing, configuring, and upgrading the CIS Administration application.	PDF. Available from the documentation CD and the Phase Forward Download Center.
CIS online Help	• Application field definitions. • Procedures for using each page of the CIS Administration application.	HTML. Available from the CIS Administration user interface.

Training

In addition to the CIS training courses listed in the following table, the training courses for the

following applications provide information about the software products used in a CIS environment:

- Clintrial software
- InForm software
- Central Designer software

For information about the following training offerings for CIS, contact Phase Forward.

Title	Description	Format
Clintrial Integration Solution Training	Teaches clinical study specialists to create and manage integrated and hybrid studies using CIS, the Clintrial software, and the InForm software.	Instructor-led training.
Hosting CIS Integrated Studies	Teaches database, network, and web professionals to set up and manage integrated studies, as well as perform general troubleshooting.	Instructor-led training.

If you need assistance

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

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

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http://www.phaseforward.com/support
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In the event that our toll-free telephone service is interrupted, please use either of the following methods to contact the Global Support Center:

- Email

  customer.support@phaseforward.com

- Telephone

In the US:	781-902-4900
Outside of the US:	+44 (0) 1628 640794

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

CHAPTER 1

CIS Overview

In this chapter

Integrating InForm and Clintrial software

The Clintrial Integration Solution (CIS) software is an application that allows users to integrate the features of the InForm software and the Clintrial software in a complete environment for study development and execution.

About the InForm software

The InForm™ software is an integrated study management system that comprises:

- The InForm software, a web-based electronic data capture (EDC) tool for entering, monitoring, and cleaning data in an ongoing clinical study.
- InForm Reporting and Analysis, a reporting application, developed by Cognos Corporation, which has been customized and integrated into InForm software by Phase Forward.

With the InForm software, you can:

- Enter data remotely into study databases over the Internet.
- Clean and monitor study data.
- Review management and clinical data reports to track the progress of your studies and obtain previews of clinical data trends.
- Produce standard and ad hoc reports on clinical and study management data.

Benefits of integration

The CIS software enables the integration between the InForm and Clintrial systems. Using the CIS software, you can combine the benefits of both products into a single system for data entry, data management, and study archiving.

Study design and deployment

In a CIS environment, you can design a study using the Central Designer software.

As a result, you can:

- Reuse components in existing studies that were created using the Central Designer software, that are currently deployed with the InForm software.
- Deploy a completed study definition as:
  - A paper-based protocol in the Clintrial software.
  - An EDC study in the InForm software.
  - A study with both paper-based and EDC sites.

Data entry and validation

The CIS software enables you to:

- Transfer EDC clinical data from an InForm study database to tables in a Clintrial protocol database. Users enter data through a web browser by using the InForm software.
- Maintain both paper-based and EDC sites for the same study. Users enter data using either the InForm software (for EDC sites) or the Clintrial Enter module (for a paper-based workflow), and the CIS software transfers the EDC data to the Clintrial database.
- Validate EDC data by using rules created either with the InForm or with the Clintrial software. Users resolve EDC data queries in the InForm software, whether they originated from InForm or Clintrial rules.

Data coding

You can code data using the Central Coding application or the Clintrial Manage and Classify modules. In an integrated study environment with the CIS software, you can use the Clintrial modules with EDC data originating from the InForm software as well as with data originating from the Clintrial software.

Data loading

Both the Clintrial software and the InForm software provide tools for loading batch data such as lab results. In a CIS integrated study environment, you can batch load EDC data in either system (and batch load paper-based data only with the Clintrial tools).

In the Clintrial software, you can:

- Use the batch loading capabilities of the Manage module or the Lab Loader module to load EDC data into the Clintrial database and validate it.
- Resolve discrepancies on batch-loaded EDC data with the Resolve module.

If you prefer to use the InForm Data Import utility, you can:

- Use the InForm Data Import utility to load EDC data into the InForm study database.
- Validate the data by using the InForm user interface.
- Transfer the data to the Clintrial database.

Data storage and analysis

With the CIS software, you can use the extensive data retrieval and reporting features of the Clintrial software for both paper-based and EDC data.

About the Clintrial software

The Clintrial software is a clinical data management system. The Clintrial software consists of a set of integrated modules that can be installed as needed. This modular approach enables you to design study protocols and then collect and manage clinical data according to the needs of your company's processes. The Clintrial software includes the following core modules.

Module	Purpose
Admin	System administration.
Design	Design and creation of the Clintrial database and the study books that you need to enter clinical data.
Enter	Interactive data entry.
Manage	Data management.
Retrieve	Clinical data access and extraction.

In addition to the Clintrial core modules, the following Clintrial extended modules add to the basic functionality of the core modules.

Module	Purpose
Classify	Resolution of omissions (coding failures).
Lab Loader	Batch loading of data with screening features not available in the Manage module.
Resolve	Resolution of discrepancies raised when rules run against clinical data fail. **Note:** The Resolve module contains functions that are required in an integrated study with the CIS software.
Multisite	Distribution of clinical data among multiple remote locations.

About integrated studies

Studies that are performed using the InForm, Clintrial, and CIS software are integrated studies. Integrated studies are either EDC-only studies or hybrid studies.

About integrated EDC-only studies

In an integrated EDC-only study, users enter data using the EDC capability of the InForm software. Users log on to a study URL using a browser. Data is stored in an InForm study database on a remote server in the same way as in a nonintegrated study.

Users enter data through the InForm user interface defined in the study URL. Data stored in the study database then transfers, through a process called *synchronization,* to a Clintrial protocol database, where it is available for processing and analysis with Clintrial modules.

You can design an integrated EDC-only study to support data validation with:

- InForm rules, query processing, and resolution.
- Clintrial rules and InForm query processing and resolution.
- A combination of the validation processing from both systems.

About hybrid studies

A hybrid study supports data entry from both the InForm (EDC) and Clintrial (paper-based) environments. In a hybrid study:

- Data entered through EDC is stored in an InForm study database and then transferred to a Clintrial protocol database in the same way as in an EDC-only study.
- Data entered through the Clintrial software is stored only in the Clintrial protocol database.

You can design a hybrid study to support data validation with the following scenarios:

- Paper-based data is validated by Clintrial validation processing, and EDC data is validated with InForm validation processing.
- Paper-based data is validated by Clintrial validation processing, and EDC data is validated by both InForm and Clintrial validation processing.

Note: You cannot integrate a study in which data entry is all paper-based. (You cannot transfer data entered with the Clintrial Enter module into an InForm study database for visibility through the InForm user interface.) However, you can convert an all-paper-based study into a hybrid study and introduce the capability to enter data with either the InForm software or the Enter module.

Integration architecture

This section describes the system components of a CIS integrated environment. In a CIS integrated environment, you deploy integrated clinical studies on production servers that gather clinical data through the InForm EDC interface and store the data in a Clintrial protocol database. The CIS software performs the following integration tasks between the Clintrial and InForm software:

- Transfers study metadata and translates metadata definitions between Clintrial and InForm.
- Transfers clinical data.
- Transfers data validation information.

For clarity, the Clintrial, CIS, and InForm components are described as residing on separate computers in the discussions that follow. Actual configurations can vary, depending on study size and organizational priorities. For example, in a design environment, it is possible to install all components on the same physical computer. In a production environment, it is possible to install each product component on multiple computers to maximize processing efficiency and take advantage of the load balancing capability of the CIS software.

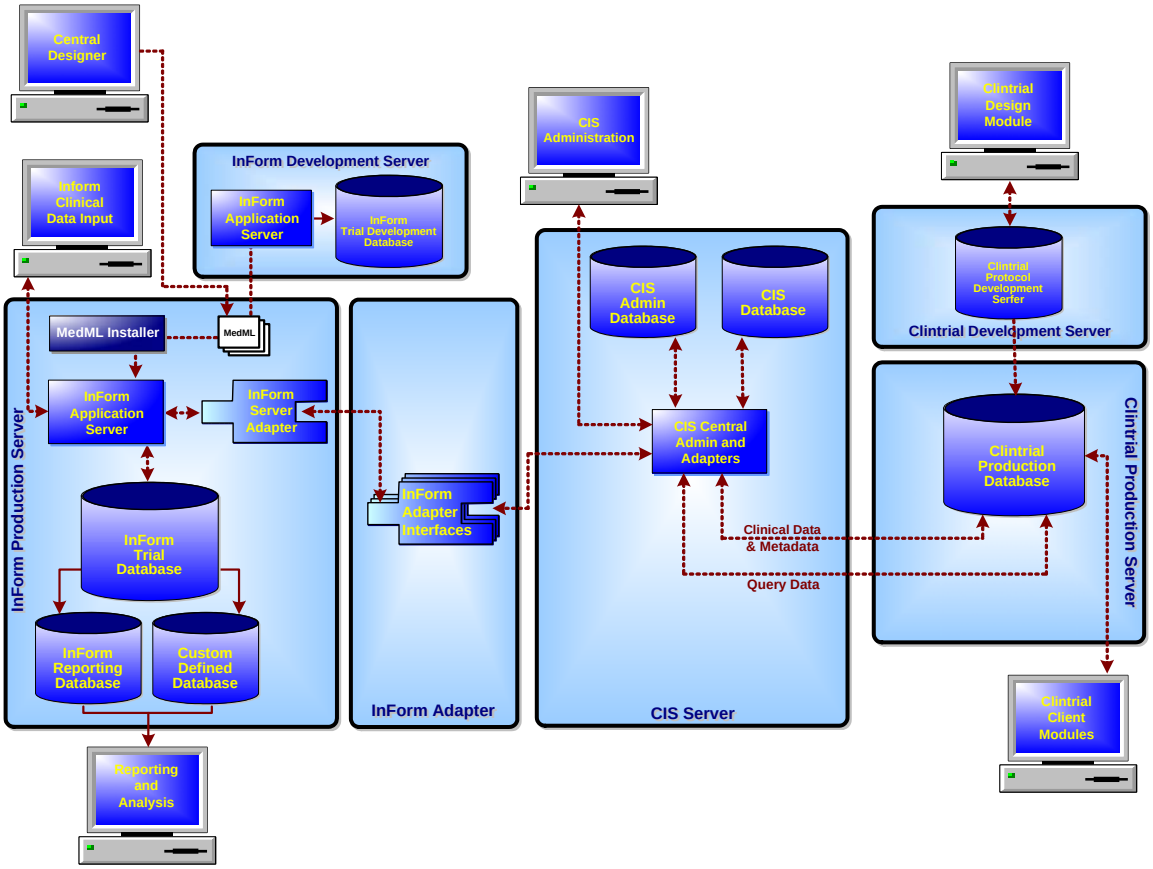
Overview of CIS architecture

The CIS architecture consists of the following components:

Purpose	InForm software	CIS	Clintrial software	InForm Adapter
Study design and implementation	• The Central Designer software.	n/a	Clintrial Design module	n/a
Run-time data entry and data management	• The InForm software. • InForm Reporting and Analysis.	n/a	Clintrial client modules: Classify, Enter, Lab Loader, Manage, Multisite Distribution, Resolve	n/a
Database management (Oracle databases)	• InForm study database (development and production). • InForm reporting database. • Customer-defined database.	• CIS Admin database • CIS database	Clintrial study database (development and production)	The InForm Adapter database.
Data transfer administration	n/a	CIS Administration	n/a	n/a

Purpose	InForm software	CIS	Clintrial software	InForm Adapter
Data transfer	n/a	n/a	n/a	The InForm Adapter software

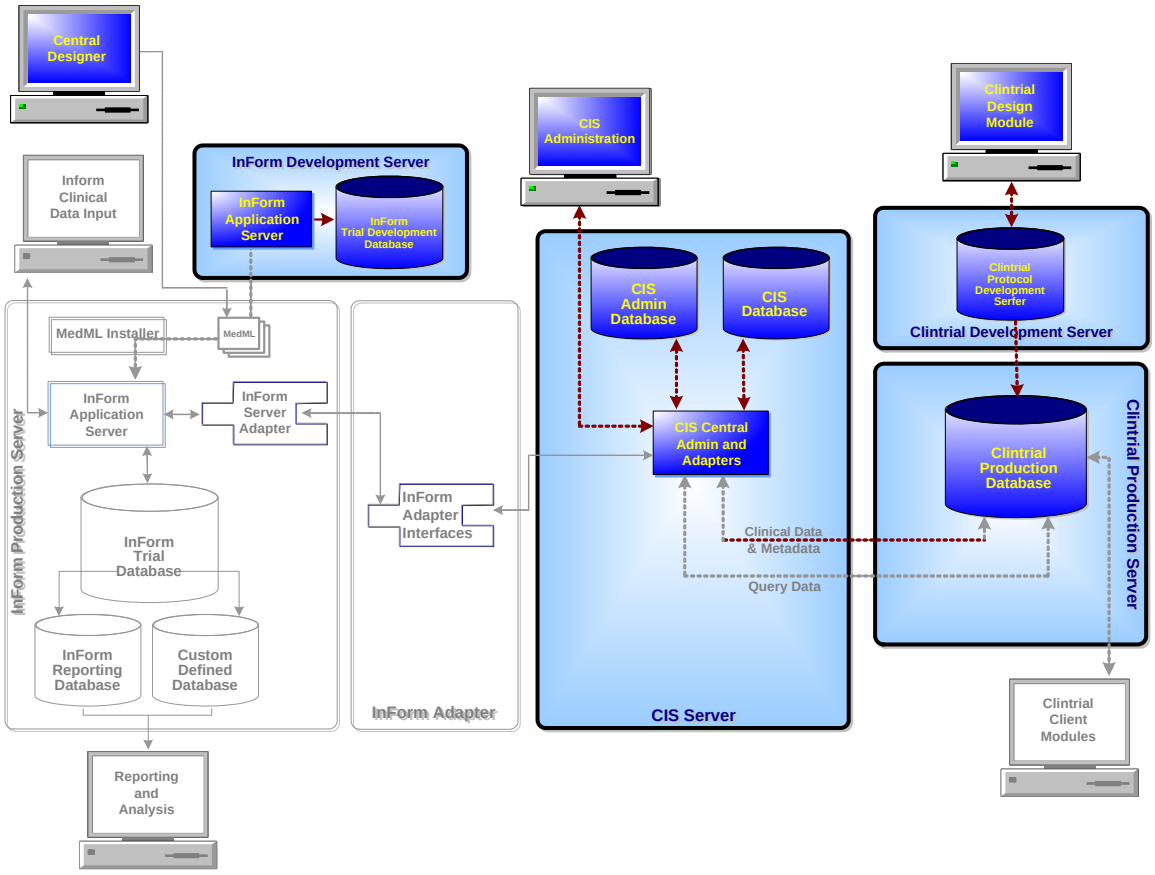
All administration tasks are performed using the CIS Administration application with the Internet Explorer Web browser. The following diagram illustrates the components in the CIS environment.



Design environment

The CIS integrated design environment enables you to create metadata definitions of study components. The CIS synchronization functionality enables the transfer of study metadata and clinical data between the CIS servers and the InForm servers.

The following diagram illustrates the components of the CIS design environment.



Component	Purpose
Central Designer software	Design InForm study components and data mappings and send the Central Designer deployment package to an InForm study database.
InForm application server	Execute all InForm study activities.
InForm study development database	Store study metadata and clinical data for an InForm study that is being developed.
CIS Administration application	Configure the CIS environment and monitor synchronized protocol connections.
CIS Admin database	Store CIS administrative data.
CIS database	Retrieve, translate, and store Clintrial protocol metadata in MedML format.

Component	Purpose
CIS Central Admin and adapters	Perform CIS administrative activities and process transactions between the Clintrial software and the InForm software.
Clintrial Design module	Design a Clintrial protocol.
Clintrial protocol development database	Store and test new Clintrial protocol components.
Clintrial production database	Store protocol components, EDC study data, and paper-based study data for studies that are integrated with the InForm software.

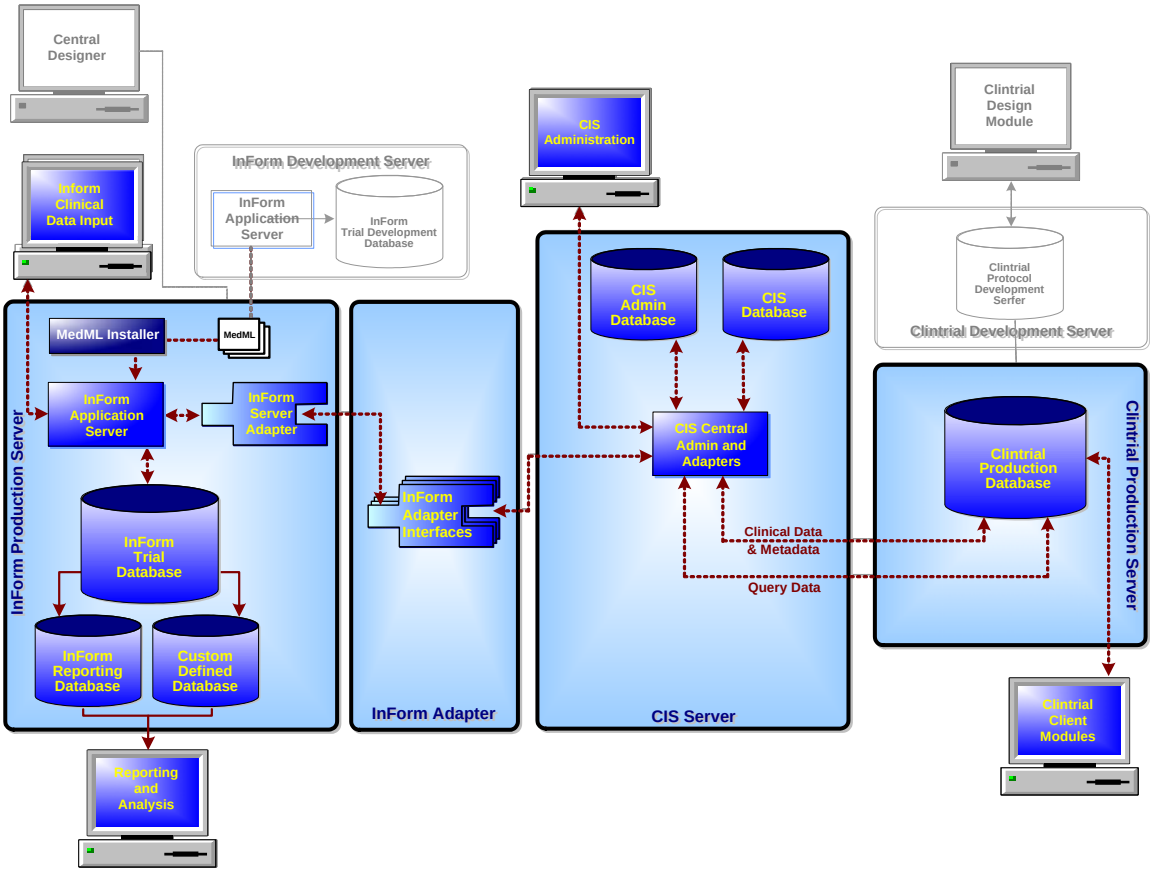
Production environment

When study design and development are complete, use the CIS integrated production environment to:

- Test the flow of metadata and clinical data between the product components.
- Run a live integrated study.

In an integrated production environment, the CIS synchronization functionality enables the transfer of study metadata and clinical data between the CIS server and the InForm server. Study metadata and clinical data transfer between the CIS server and the Clintrial software server over an OLEDB connection.

The following diagram illustrates the components of the CIS production environment.



Component	Purpose
InForm clinical data input	Enter, update, and monitor clinical study data in the InForm software.
Central Designer software	Create a study deployment package and deploy it to the InForm database.
InForm application server	Execute all InForm study activities.

Component	Purpose
InForm Server Adapter	Provide a secure web service interface for interactions between the InForm Adapter interfaces and the InForm application server.
InForm study database	Store study metadata and clinical data for an InForm study
InForm reporting database	Store study management and clinical data for reporting on an InForm study.
Customer-defined database	Store clinical data in a custom format.
InForm Reporting and Analysis	Design and execute custom and predefined reports on InForm clinical and administrative data.
InForm Adapter interfaces: • InForm Adapter Service • InForm Adapter Central Administration • InForm Adapter Transaction interface	Pass requests between CIS and the InForm Server Adapter.
CIS Administration application	Configure the CIS environment and monitor synchronized protocol connections.
CIS Admin database	Store CIS administrative data.
CIS Central Admin and adapters	Perform CIS administrative activities and process transactions between the Clintrial software and the InForm software.
Clintrial client modules	Manage and analyze integrated study data.
Clintrial production database	Store protocol components, EDC study data, and paper-based study data.

Load balancing

Load balancing allows multiple machines to share the work load of a CIS synchronization and achieves the following:

- Improves performance when multiple synchronizations are defined.
- Provides redundancy by moving the synchronization process to another machine if the initial processing machine fails.

When the CIS software processes a scheduled or manually run synchronization, it selects a load-balance machine to process the synchronization. If a machine is processing a synchronization and stops responding, the machine is automatically taken offline and the synchronization process is assigned to another machine.

Note: Each synchronization is processed by only one machine. Therefore, load balancing cannot improve the performance of a single synchronization but only the performance of multiple synchronizations.

A load-balancing environment is set up by installing the CIS software on multiple machines and having them all store information as the same CIS database user.

For more information, see the *CIS Installation Guide* and ***Monitoring and managing load balancing*** (on page 121) in this guide.

Integrated study workflows

Design environment workflow

The CIS integrated design environment enables you to create study component metadata definitions by using the Central Designer software.

Designing with the Central Designer software

The following steps illustrate a typical integrated design scenario in which the Central Designer software is the primary design tool.

1 Using the Central Designer software, develop a study.

2 Using the Central Designer software, create a deployment package for the study.

3 Deploy the package to the InForm study database.

The deployment process installs the MedML metadata definitions and the CIS mapping definitions in the InForm study database.

4 Using CIS Administration, create a synchronization connection between the InForm study database and the Clintrial clinical database, and transfer the protocol component definitions to the Clintrial database through the synchronization process.

5 Using the Clintrial Design module, refine the protocol component definitions as needed to accommodate paper-based data entry.

For more information, see:

- ***Working with data mappings*** in the *CIS Designer Guide*.
- Central Designer documentation.

Production environment workflow

When study design and development are complete, use the CIS integrated production environment to:

- Test the flow of metadata and clinical data between the product components.
- Run a live integrated study.

The following steps illustrate a typical integrated production environment workflow:

1 Deploy the package to an InForm study database.

2 Create a synchronization connection between the InForm study database and the Clintrial clinical database, and transfer the protocol component definitions to the Clintrial database through the synchronization process.

3 Enter clinical data through the InForm software (storing EDC data in the InForm database) and through the Clintrial Enter module (storing the paper-based data in the Clintrial database).

4 Through a synchronization connection, and using data mapping definitions, transfer the study metadata and the EDC clinical data from the InForm study database to the Clintrial database.

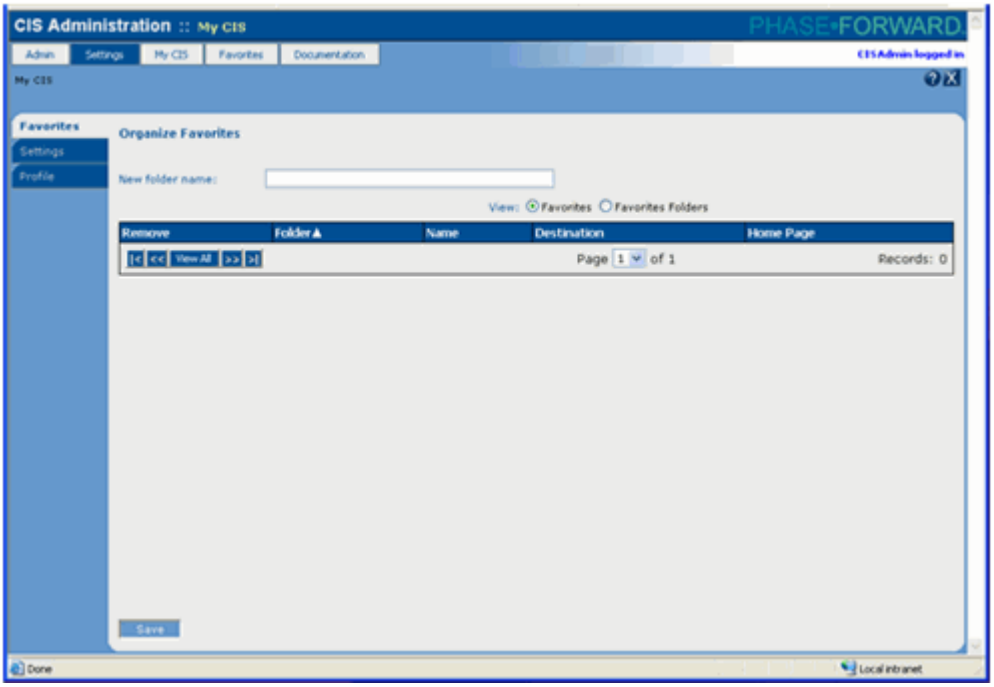
5 Validate entered data by running Clintrial or InForm rules:

- Resolve EDC data queries in the InForm software, whether they originate from rules within the InForm database or the Clintrial database.
- Resolve paper-based data discrepancies by using the Clintrial data validation modules.

6 Archive and manage study data in the Clintrial clinical data management system.

CIS Administration application

The CIS Administration application enables administrative users of the CIS software to manage synchronization connections, CIS users, and load-balancing machines.



CHAPTER 2

CIS Administration

In this chapter

Overview of CIS Administration

The CIS Administration application enables you to administer your CIS environment from a central application. Use CIS Administration to:

- Manage synchronization connections. A synchronization connection defines a communication path between an InForm study database and a Clintrial database. By using the CIS synchronization features of CIS Administration, you can:
  - Define synchronization connections and standard synchronization schedules.
  - Initiate synchronization and monitor synchronization status and history.
  - Create study books for a protocol.
  - Enable notifications in the case of a synchronization error.
  - Edit failed transactions from InForm software to the Clintrial software to enable processing to continue.
- Manage CIS user rights and roles.
- Define and update the CIS environment, including:
  - Database instances for the CIS synchronization.
  - Adapter components of CIS.
  - Load-balanced computers.
  - Environment configuration settings.
  - Favorites (frequently visited folders and pages).
- Recover data after a database restoration
- Reset a protocol.

Logging on to the CIS Administration application

To start the CIS Administration application, you use the Clintrial Integration Solution logon page. Before you can log on, obtain the URL for the logon page.

1 Type the URL for the CIS Administration application into your browser.

2 Type your user name and password.

The CIS Administration home page appears.

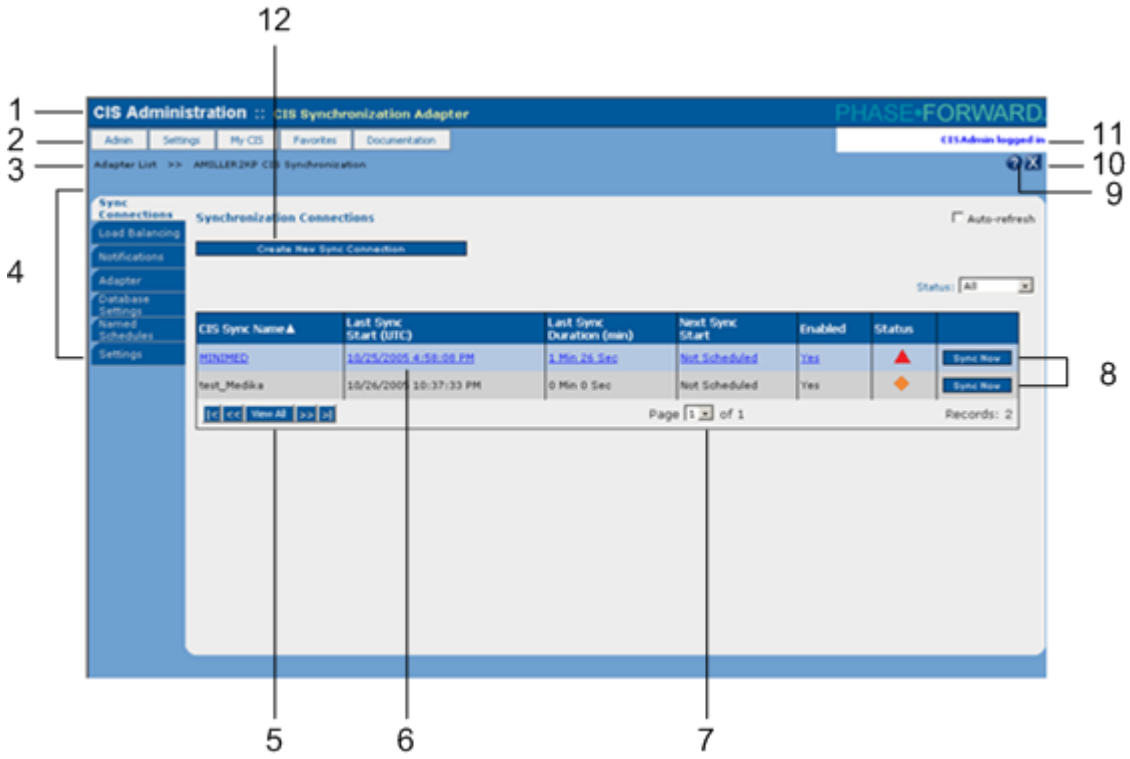
Note: The CIS product provides an initial logon with CISAdmin as the user name and password. Use these logon credentials for the initial logon. You should change your password after you initially log on.

CIS system administrators can change a user password and can set an interval after which a user password expires. If your password has been changed by an administrator or has expired, you must change the password the next time you log on to the CIS Administration application.

For more information, see ***Changing your user password*** (on page 30).

Common features of CIS Administration pages

The pages of CIS Administration include common information and navigation features.



1—Title bar indicates the area of CIS Administration in which you are currently working.

2—Click a menu button and select a command to move to other areas of CIS Administration.

3—Navigation path displays the last pages you have visited. Click a page name to return to that page.

4—Select a tab to work with the features that are available in the area of CIS Administration that the title bar identifies.

5—Click to navigate through the pages of a multiple-page display.

6—Click a link in a row of a grid to display information about a specific object in the grid.

7—Select a page number to move to a specific page.

8,12—Click a command button to initiate an action.

9—Click the button with a question mark to display help on the current page of CIS Administration.

10—Click the button with an X to log off from CIS Administration.

11—Indicates the user ID of the user currently logged on to CIS Administration.

CIS Administration pages

The CIS Administration application consists of pages that you use to monitor and manage the CIS environment. The pages available to users depend on the views defined for the application and the security rights and privileges assigned to the users. From the following top-level pages, you can access additional pages.

CIS Administration page	Purpose
CIS Synchronization Adapter	Monitor and manage synchronization connections, email notifications, load balancing, schedules, and global settings for synchronization connections.
Clintrial Admin Adapter	Monitor and manage Clintrial Adapters.
InForm Admin Adapter	Monitor and manage InForm Adapters.
Register Adapters	Register InForm Adapters.
Configuration	Set general and security information for the CIS Administration environment.
Plugin List	Monitor and mange plugins (pages) for servers and adapters.
Security Administration	Monitor and manage users, roles, and domains for security.
My CIS	View and customize the CIS Administration environment.
Add Favorites	Add links for frequently used pages.
Documentation List	Access online Help pages.

Menus

The menu options that appear in the CIS Administration application vary depending on the roles and rights assigned to the user account.

Menu option	Purpose
Admin	Access administrative pages for synchronizations and adapters. This menu can include the following options: • **CIS Sync**—Access the synchronization pages. • **Clintrial**—Access pages for Clintrial Adapters. • **InForm**—Access pages for InForm Adapters. • **Register Adapters**—Access pages for registering adapters and load-balance machines.

Menu option	Purpose
Settings	Access pages for setting general global values for your CIS environment and authentication values for user logons. This menu can include the following options: • **Configuration**—Access pages for specifying global settings and authentication settings. • **Plugins**—Access pages to view and manage the plugins (pages) of the CIS Administration application. • **Security**—Access pages for defining users, roles, and rights for the CIS environment.
My CIS	Access tabs of the My CIS page for customizing the CIS Administration interface. Initially, My CIS is the first page that appears when you start the CIS Administration application. From this page, you can define: • **Favorites**—View and organize favorites and favorite folders. • **Settings**—Customize the interval (auto-refresh rate) that CIS Administration uses to refresh the application pages used for monitoring and managing. • **Profile**—Manage your profile including changing the password.
Favorites	Organize and add pages. This menu can include the following options: • **Organize**—Add favorite pages and folders to your CIS Administration view. • **Add Favorite**—Specify new favorite pages and folders that you want to add to your CIS Administration view. • List of the favorite pages you added.
Documentation	Access online Help pages.

Database users and System users in the CIS environment

The CIS environment has users that support different kinds of activities and tasks.

Type of User	Description
Oracle	Users that provides access to Oracle databases. Three Oracle users are created when you install the CIS software: • **CIS Administration Database—**Owns all of the CIS administration database objects. • **CIS Database User—**Owns all the CIS database objects. For more information, see the *CIS Installation Guide*. • **CISUser**—Used to connect to the Clintrial database. The CISUser is a default user that cannot be changed. You can change the password for this user. CISUser is one of the five default user accounts that you can manage through the CIS interface.
Windows	Windows **Run as** user that has access to domains. This user is required in a design environment.
CIS	**Sync**—System user used to connect to the adapters (web services) within CIS Administration. The initial name and password for this user is Service. For more information, see ***Viewing and changing global synchronization connection settings*** (on page 94).

User accounts provided with the CIS software

In the CIS environment, security is managed by assigning rights to roles, and associating one or more roles to each user account.

The CIS software provides five default user accounts. Each account is assigned default roles.

User Name	Display Name	Assigned roles
CAAdmin	CA Administrator	Administrator (role) System User Role Adapter user Role Security Admin Role Configuration Admin Role
CISAdmin	CISAdmin	Administrator (role) System User Role Security Admin Role Configuration Admin Role

User Name	Display Name	Assigned roles
CISPower	CISPower	Power User (role) System User Role Adapter User Role
CISUser	CISUser	User (role) System User Role Adapter User Role
Service	CA Service User	Adapter User Role System User Role Configuration Admin Role

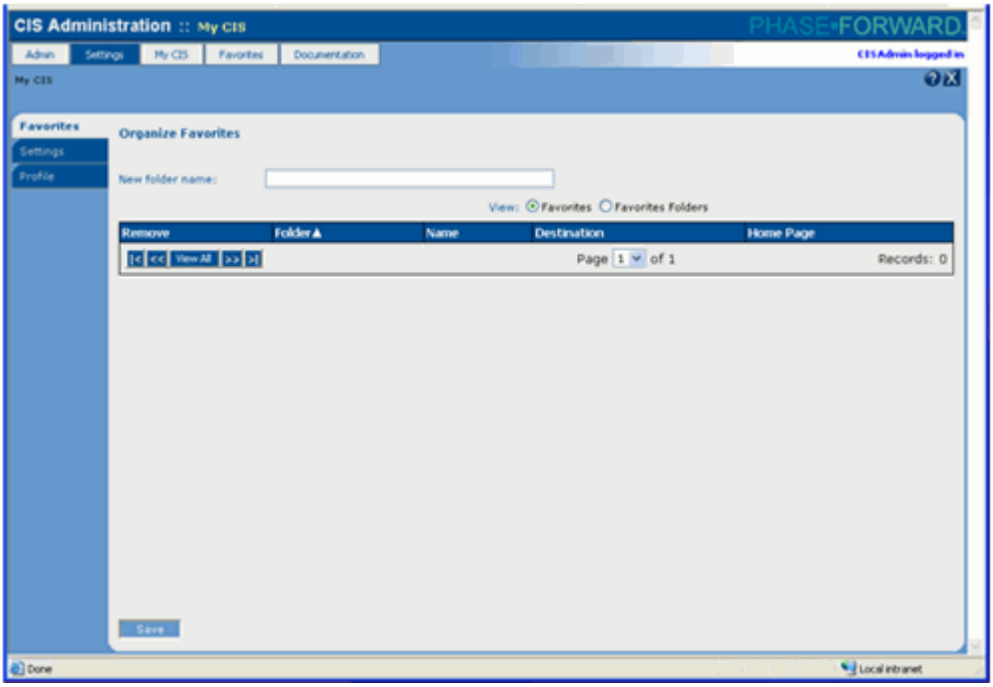
For information about the rights assigned to the Administrator role, Power User role, and User role, see ***CIS synchronization page rights and assignments to default roles*** (on page 50).

For information about the Configuration Admin Role, the Security Admin role, and the Adapter User Role, see ***CIS central administration page rights and assignments to default roles*** (on page 52).

Customizing the CIS Administration application

Overview of customizing the CIS Administration

CIS Administration enables you to customize views of the CIS Administration application. You customize a view using the My CIS page.



The My CIS page has the following tabs:

- **Favorites**—View and organize favorite pages and folders.
- **Settings**—Specify the initial logon page for your home page and customize the interval (auto-refresh rate) that CIS Administration uses to refresh the application pages used for monitoring and management.
- **Profile**—Manage your profile including changing passwords.

In addition to using these tabs to customize views, you can use the Favorites option on the main menu to ***add and organize bookmarks*** (on page 27) for favorite pages.

From the My CIS page, you can:

- ***View and add folders*** (on page 26).
- ***Rename a folder*** (on page 26).
- ***Remove a folder*** (on page 27).
- ***View favorites*** (on page 27).
- ***Remove favorites*** (on page 27).
- ***Rename a favorite*** (on page 28).
- ***Change the folder of a favorite*** (on page 28).
- ***Manage My CIS user settings*** (on page 29).
- ***Change user profiles*** (on page 30).

Viewing and adding folders for favorite pages

You can view existing folders and add new folders to help organize pages for easy navigation.

1 Select **My CIS**.

The Favorites tab of the My CIS page appears and displays a list of favorites.

2 Click **Favorite Folders**.

A list of current folders appears.

3 In the **New folder** name field, type the name of a folder in which to store favorites.

4 Click **Save**.

Changing the name of a favorite folder

Usually, folder names identify the type of pages stored in them. If the type of pages stored in a folder changes, you can change the name of the folder.

1 Select **My CIS**.

The Favorites tab of the My CIS page appears and displays a list of favorites.

2 Click **Favorite Folders**.

A list of current folders appears.

3 In the **Name** column, type a new name for the folder you want to rename.

4 Click **Save**.

Removing a favorites folder

When you no longer use a folder, you can remove it.

1 Select **My CIS**.

The Favorites tab of the My CIS page appears and displays a list of favorites.

2 Click **Favorite Folders**.

A list of folders appears.

3 In the **Remove** column for each folder you want to remove, select the checkbox.

4 Click **Save**.

Adding a favorite page

You can add pages that you use frequently to a folder for convenient access. Use the Add Favorite window to add a favorite.

1 Navigate to the page you want to add to your favorites.

2 Select **Favorites** > **Add Favorite**.

The Add Favorite window appears.

3 Click **Save**.

Viewing favorites

You can view a list of favorites from the Favorites tab of the My CIS page.

1 Select **My CIS**.

The Favorites tab of the My CIS page appears and displays a list of favorites.

2 If there are multiple pages, use the **View All** and other navigation buttons to move through the pages.

Removing a favorite

When you no longer use a favorite page, you can remove the page.

1 Select **My CIS**.

The Favorites tab of the My CIS page appears and displays a list of favorites.

2 In the **Remove** column for each favorite you want to remove, select the checkbox.

3 Click **Save**.

Renaming a favorite

You can rename a favorite page from the Favorites tab of the My CIS page.

1 Select **My CIS**.

The Favorites tab of the My CIS page appears and displays a list of favorites.

2 In the **Name** column, type the new name of the favorite you want to rename.

3 Click **Save**.

Changing the folder of a favorite

You can change the folder where a favorite is stored from the Favorites tab of the My CIS page.

1 Select **My CIS**.

The Favorites tab of the My CIS page appears and displays a list of favorites.

2 In the **Folder** column for the favorite you want to move, select the new folder from the drop-down list.

3 Click **Save**.

Viewing your user profile

1 Select **My CIS**.

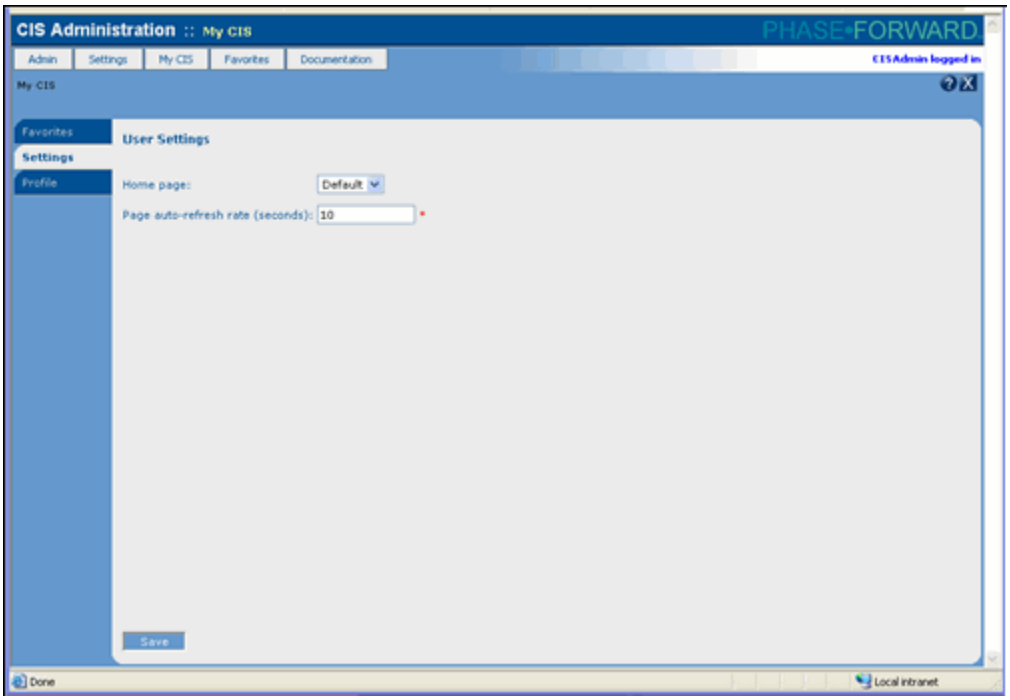
The Favorites tab of the My CIS page appears and displays a list of favorites.

2 Select **Profile**.

Managing My CIS user settings

Overview of managing My CIS user settings

You use the Settings tab of the My CIS page to ***set a home page and refresh rate for your application pages*** (on page 29).



Note: To set your home page, the system must be set to allow all users to change their home page. For more information, see ***Managing configuration settings*** (on page 46).

Setting a home page and auto-refresh rate

Before setting your home page and auto-refresh rate, add the page that you want as your CIS Administration home page to the Favorites tab of the My CIS page.

1 On the **Settings** tab of the **My CIS** page, select the page that you want as your home page from the **Home page** drop-down list. This list contains the pages you defined as favorites and the default page. The home page is the first page that appears after you log on to CIS Administration.

Note: If CIS Administration is configured not to allow users to specify individual home pages, or if you do not have any favorite pages, the only value available is Default.

2 In the **Page auto-refresh rate (seconds)** field, type the number of seconds that you want CIS Administration to wait before automatically refreshing pages that contain dynamic information.

3 Click **Save**.

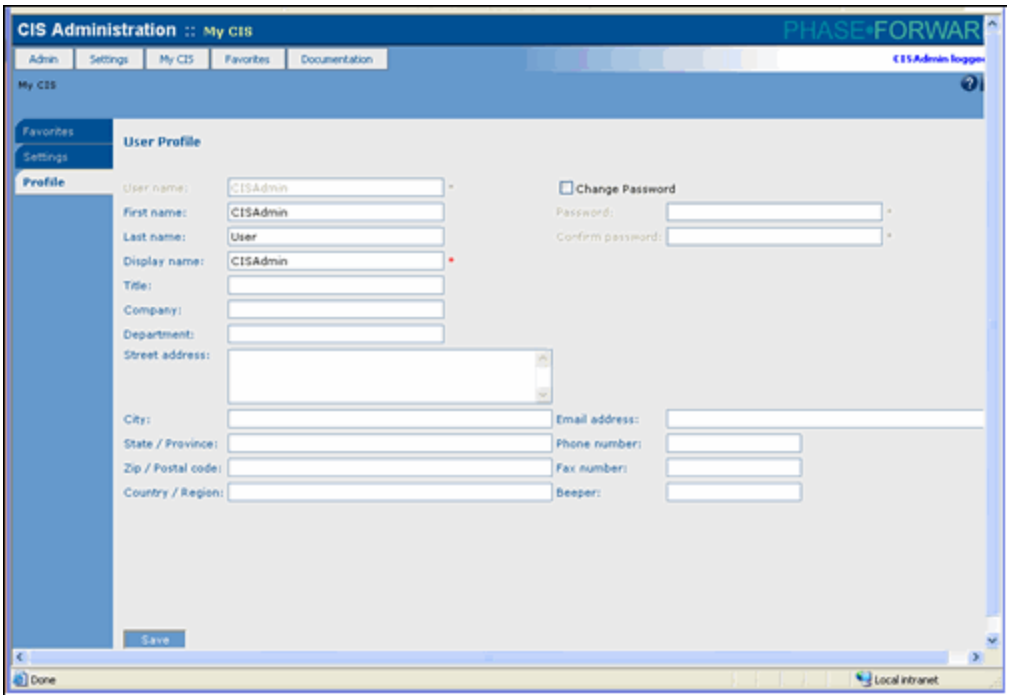
For more information, see:

- ***Overview of customizing views*** (on page 25).
- ***Adding a favorite page*** (on page 27).

Managing your user profile

Overview of managing your user profile

User profiles provide detailed information about users. To manage your user profile, use the Profile tab of My CIS page.



From the Profile tab of the My CIS page, you can:

- ***View or edit your profile*** (on page 30).
- ***Change your password*** (on page 30).

Viewing or editing a My CIS user profile

You can change your user profile to provide detailed user information.

1 Select **My CIS** from the menu.

The Favorites tab of the My CIS page appears and displays a list of favorites.

2 Select **Profile**.

The Profile tab appears.

3 Type your profile information in the appropriate fields. Only the **Display name** field is required.

4 Click **Save**.

Changing your user password

Security requirements for a location often require that passwords be changed at specified intervals. You might also want or need to change your password for other reasons.

1 Select **My CIS**.

The Favorites tab of the My CIS page appears and displays a list of favorites.

2 Select **Profile**.

The Profile tab appears.

3 Select the **Change Password** checkbox.

4 In the **Password** field, type the new password. Passwords must meet the requirements and the rules for your specific location.

Allowed characters in passwords are upper and lowercase letters, digits, underscore (_), pound sign (#), and dollar sign ($).

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

6 Click **Save**.

Registering InForm Adapters

Overview of registering an InForm Adapter

After installing the InForm Adapter, you must:

1 Make sure that the InForm Adapter security configuration reflects the level of security you intend to use in CIS:

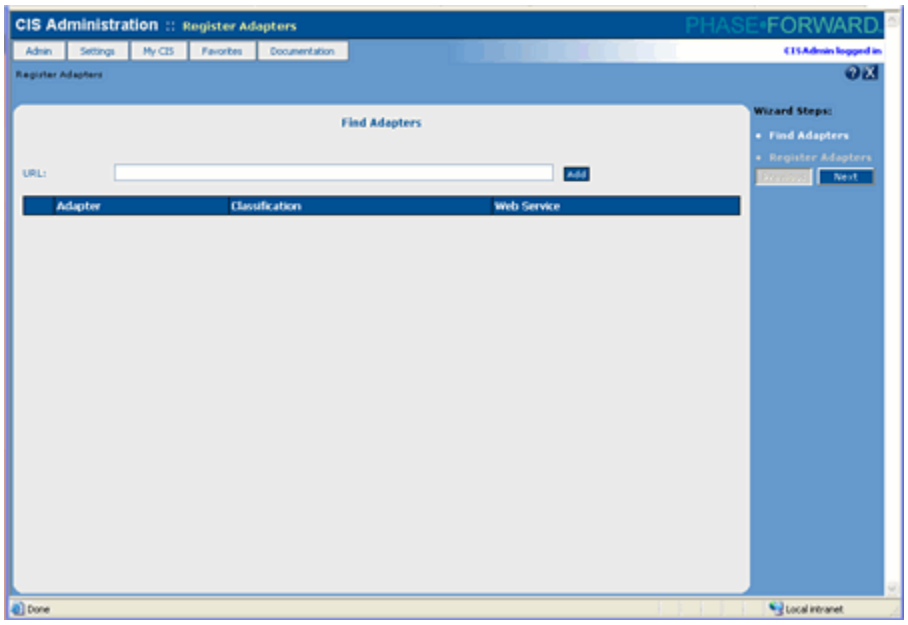
- If you are using Authentication Only (default) security, you do not need to configure the InForm Adapter before registering it.
- If you are using Authentication, Signing, and Encryption security, you *must* configure the InForm Adapter before registering it. The InForm Adapter software must use FullPolicy for the service interfaces used by CIS.

  If you do not perform this configuration, the InForm Adapter might fail to register.

For more information, see the *InForm Adapter Installation Guide*.

2 Register the InForm Adapter for use in the CIS environment. You register an InForm Adapter by providing the URL for the adapter. Use the Find Adapter page of the Register Adapters Wizard.

Note: If you use a hardware load-balancing machine to distribute transaction processing to different InForm Adapters, you must also register the load balancing machine. To register the load-balancing machine, you enter the URL for that machine.



From Find Adapter page of the Register Adapters Wizard, you can ***register an InForm Adapter*** (on page 32).

Registering an InForm Adapter

1 Select **Admin** > **Register Adapters**.

The Find Adapter view of the CIS Administration Register Adapters page appears.

2 Type the **URL** that identifies the location of the adapter. Specify the URL using the following string:

```
http://MACHINE/informadapter/centraladmin/informcai.asmx
```

where *MACHINE* is the name of the computer on which the adapter is installed.

3 Click **Add**.

The adapter appears in the table. Repeat these steps for each adapter that you want to register. If you do not want to register an adapter, use the **Remove** button to remove the adapter.

4 After adding all the adapters you want to register, click **Next**.

The Register Adapters view of the CIS Administration Register Adapters page appears. This page displays details about the adapters you want to register.

5 Review the list of adapters to verify that the information is correct for each adapter. You can use the **Previous** button to return to the **Find Adapter** page to make corrections.

6 Click **Finish**.

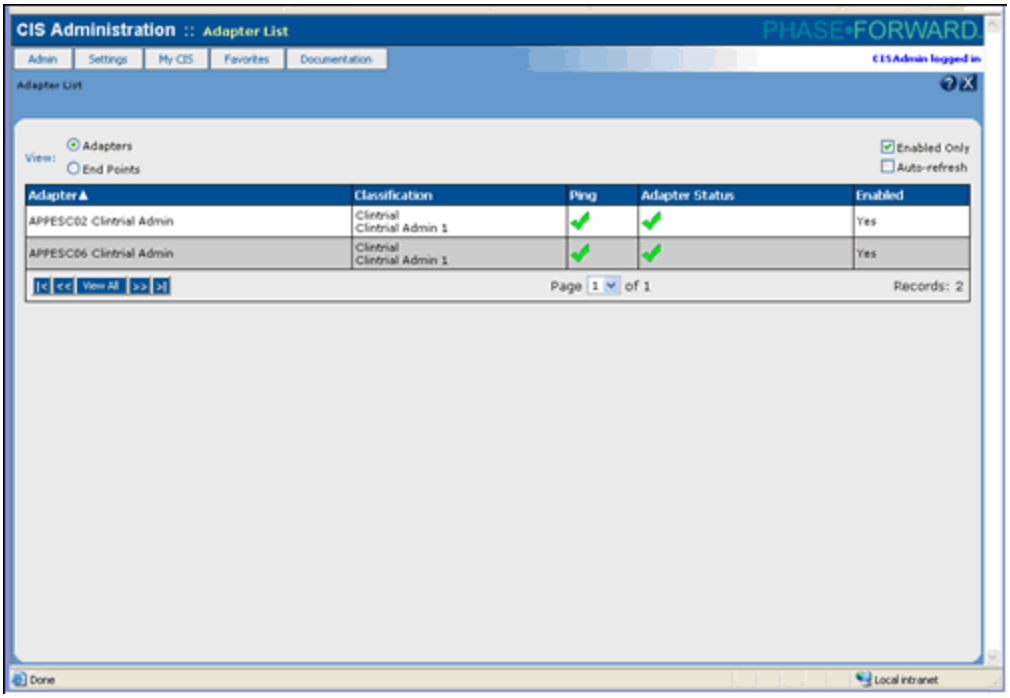
The adapters are registered, and details about each adapter appear in the Register Adapters view of the CIS Administration Register Adapters page.

Managing adapters

Overview of managing adapters

You can view adapter information from CIS central administration. When only a single adapter of a specific type is registered, the Admin Adapter page for that specific adapter appears initially. When multiple adapters of the same type are configured and registered, information about these adapters in your CIS environment appear in the Adapter List page. From Adapter List page, you can change the view between a list of Adapters or End Points, view only enabled adapters, and change the refresh rate for the page. You can also access other pages to view and manage adapters. The Adapter List page provides summary information for each adapter. From this page, you click a row to view details about that specific adapter.

For more information, see ***Adapter List page - Fields*** (on page 36).



From the Adapter List page, you can:

- ***Filter and sort the adapter list*** (on page 34).
- ***Enable and disable auto-refresh for this page*** (on page 35).
- ***Manage InForm Adapters and end points*** (on page 37).
- ***Manage Clintrial Adapters*** (on page 40).
- ***Manage CIS Synchronization Adapters*** (on page 63).

Filtering and sorting adapters in the adapter list

From the Adapter List page, you can filter the adapters that appear in the list and sort the adapter list

by column.

- To view just enabled adapters, select **Enabled Only**.

  Only enabled adapters appear in the list.

- To view all registered adapters, deselect **Enabled Only**.

  All adapters registered appear in the list.

- To sort the columns in a table, click on the specific column.

Enabling and disabling Auto-refresh

You can control whether the information in the Adapter List page refreshes automatically or manually.

1 To automatically refresh the page at the configured rate, select **Auto-refresh**. For more information, see ***Setting a home page and auto-refresh rate*** (on page 29).

2 To specify that the page refreshes only manually, deselect **Auto-refresh** (the default).

Viewing a list of InForm Adapters

You view a list of InForm Adapters from the Adapter List page.

1 Select **Admin** > **InForm**.

  If more than one InForm Adapter is installed, the Adapter List page appears and displays a list of InForm Adapters. If only one InForm Adapter is installed, the InForm Admin Adapter page appears.

2 To view a list of end points, click **End Points**.

  The view changes to a list of end points for enabled adapters and displays the following information:

  - **Adapter**—Name of the InForm Adapter for the InForm end point (trial).
  - **URL**—Location where the adapter is installed.
  - **End Point**—InForm trial for the adapter.
  - **Status**—Displays a green check mark if the end point status is OK or a red X if the end point status is Error.

Viewing a list of Clintrial Adapters

You view a list of Clintrial Adapters from the Adapter List page.

- Select **Admin** > **Clintrial**.

  If more than one Clintrial Adapter is installed, the Adapter List page appears and displays a list of Clintrial Adapters. If only one Clintrial Adapter is installed, the Clintrial Admin Adapter page appears.

Adapter List page—Fields

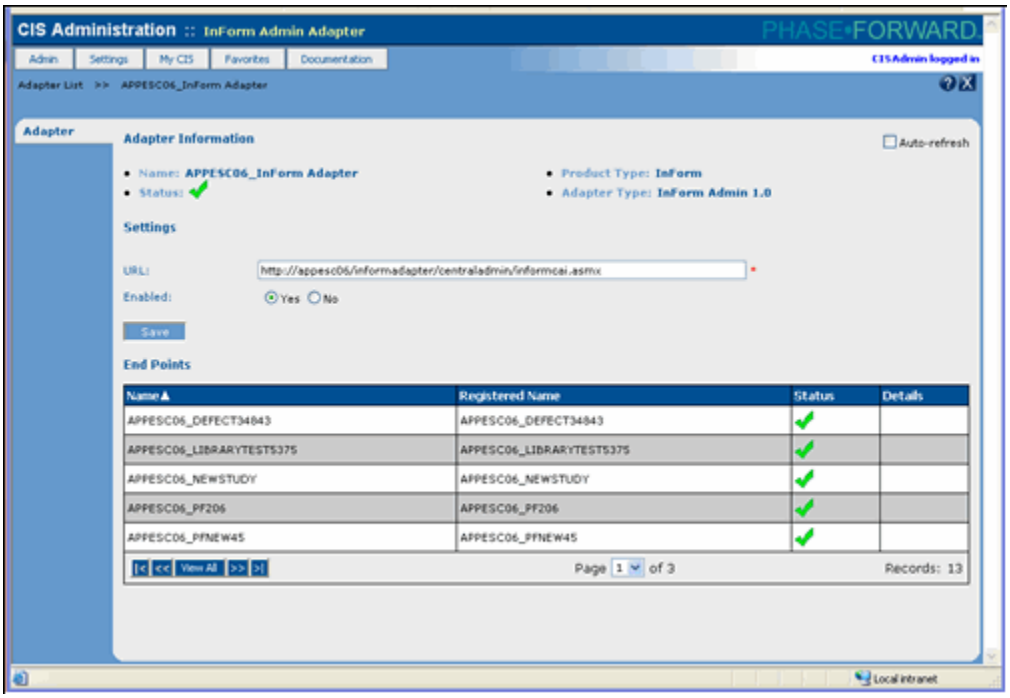
Field	Description
View	• **Adapters**—The page displays a list of adapters. • **End Points**—The page displays the list of InForm trials that are associated with an InForm Adapter.
Enabled Only	• **If selected**—The list of adapters shows only adapters for which the status is Enabled. • **If not selected**—The list of adapters shows all registered adapters.
Auto-refresh	• **If selected**—The page refreshes automatically at the interval specified on the Settings tab of the My CIS page. • **If not selected**—The page does not refresh automatically.
Adapter	Name of the adapter.
Classification	Information about the product type, the adapter type, and the adapter version.
Ping status	• **Green check mark**—CIS Administration can communicate with the adapter. • **Red X**—CIS Administration cannot communicate with the adapter.
Adapter status	• **Green check mark**—Adapter status is OK. • **Red X**—Adapter status is Error. • **Gray circle with a line**—Adapter is disabled.
Enabled status	• **Yes**—Adapter is enabled. • **No**—Adapter is disabled.

Managing InForm Adapters and end points

Overview of managing InForm Adapters and end points

You view and manage information about a specific InForm Adapter and its end points from the Adapter tab of the InForm Admin Adapter page.

For more information, see ***Adapter tab of the Admin Adapter page - Fields*** (on page 38).



From the InForm Admin Adapter page, you can perform the following tasks:

- ***Enable and disable auto-refresh*** (on page 37).
- ***View and change the URL for the adapter*** (on page 38).
- ***Enable and disable the adapter*** (on page 38).

Enabling or disabling auto-refresh for an InForm Adapter

You can enable or disable the auto-refresh option for adapters. If you enable the option, the page automatically refreshes based on the value entered for the auto-refresh rate.

Note: Depending on the auto-refresh rate and your environment, selecting Auto-refresh might impact the performance of the application.

For more information, see ***Setting a home page and auto-refresh rate*** (on page 29).

1 Select **Admin** > **InForm**.

If multiple adapters are installed, the Adapter List page appears. Click the row of the adapter you want to view and manage. The Adapter tab of the InForm Admin Adapter page appears.

or

If only one adapter is installed, the Adapter tab of the InForm Admin Adapter page appears.

2 To enable or disable auto refresh, select one of the following:

- To automatically refresh the page at the configured rate, select **Auto-refresh**.
- To specify that the page refreshes manually, deselect **Auto-refresh** (the default).

3 Click **Save**.

Viewing and changing the URL for an InForm Adapter

If an adapter is moved to a different machine, you can change the URL to point to the new location.

1 Select **Admin** > **InForm**.

If multiple adapters are installed, the Adapter List page appears. Click the row of the adapter you want to view and manage. The Adapter tab of the InForm Admin Adapter page appears.

or

If only one adapter is installed, the Adapter tab of the InForm Admin Adapter page appears.

2 In the **URL** field, type the full path of the location where the adapter is installed.

3 Click **Save**.

Changing the enabled state of an InForm Adapter

When adapters are removed from your environment or when the computer where an adapter resides is offline, you can change the enabled state of an adapter.

1 Select **Admin** > **InForm**.

If multiple adapters are installed, the Adapter List page appears. Click the row of the adapter you want to view and manage. The Adapter tab of the InForm Admin Adapter page appears.

or

If only one adapter is installed, the Adapter tab of the InForm Admin Adapter page appears.

2 In the **Enabled** group, select **Enabled** or **Disabled**.

3 Click **Save**.

Adapter tab of the Admin Adapter page—Fields

Field	Description
The top section of the page displays information about the adapter.	
Auto-refresh	• **If selected**—The page refreshes automatically at the interval specified on the Settings tab of the My CIS page. • **If not selected**—The page does not refresh automatically.

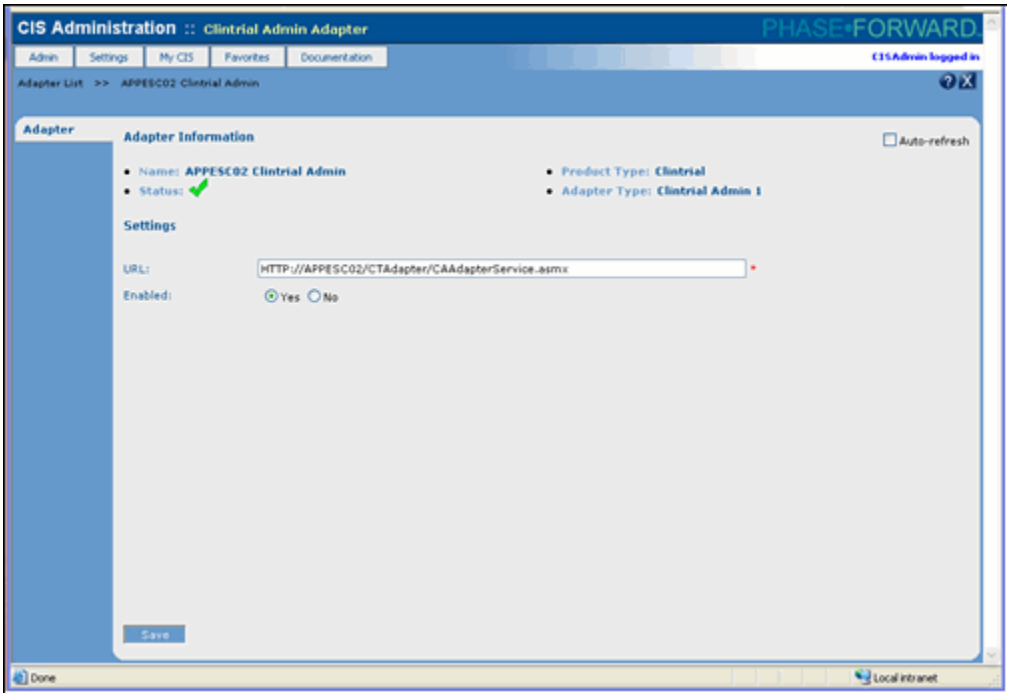
Field	Description
Name	Name of the adapter.
Status	• **Green check mark**—Adapter status is OK. • **Red X**—Adapter status is Error.
Product Type	Product with which the adapter is associated: • **CIS**—For CIS Synchronization Adapters. • **Clintrial**—For Clintrial Adapters. • **InForm**—For InForm Adapters.
Adapter Type	Type of adapter: • **CIS Synchronization**—For CIS Synchronization Adapters. • **Clintrial Admin**—For Clintrial Adapters. • **InForm Admin**—For InForm Adapters.
URL	URL for the adapter.
Enabled	• **Yes**—Adapter is enabled. • **No**—Adapter is disabled.
If the adapter is an InForm Adapter, the lower section of the page displays information about the end points (trials) for the adapter.	
Name	Name of the InForm trial.
Registered Name	Registered name of the InForm trial.
Status	• **Green check mark**—End point status is OK. • **Red X**—End point status is Error.
Details	Link to additional information about an end point with an Error status.

Managing Clintrial Adapters

Overview of managing a Clintrial Adapter

You view and manage information about a specific Clintrial Adapter from the Adapter tab of the Clintrial Admin Adapter page.

For more information, see ***Adapter tab of the Admin Adapter page - Fields*** (on page 38).



From the Adapter tab, you can:

- ***Enable or disable auto refresh*** (on page 40).
- ***View and change the URL for a Clintrial Adapter*** (on page 41).
- ***View and change the enabled status for a Clintrial Adapter*** (on page 41).

Enabling or disabling auto-refresh for a Clintrial Admin Adapter

You can enable or disable the auto-refresh option for adapters. If you enable the option, the page automatically refreshes based on the value entered for the auto-refresh rate.

Note: Depending on the auto-refresh rate and your environment, selecting Auto-refresh might impact the performance of the application.

For more information, see ***Setting a home page and auto-refresh rate*** (on page 29).

1 Select **Admin** > **Clintrial**.

If multiple adapters are installed, the Adapter List page appears. Click the row of the adapter you want to view and manage. The Adapter tab of the Clintrial Admin Adapter page appears.

or

If only one adapter is installed, the Adapter tab of the Clintrial Admin Adapter page appears.

2 To enable or disable auto refresh, select one of the following:

- To automatically refresh the page at the configured rate, select **Auto-refresh**.
- To specify that the page refreshes manually, deselect **Auto-refresh** (By default, Auto-refresh is deselected).

3 Click **Save**.

Viewing and changing the URL of a Clintrial Adapter

If an adapter is moved to a different machine, you can change the URL to point to the new location.

1 Select **Admin** > **Clintrial**.

If multiple adapters are installed, the Adapter List page appears. Click the row of the adapter you want to view and manage. The Adapter tab of the Clintrial Admin Adapter page appears.

or

If only one adapter is installed, the Adapter tab of the Clintrial Admin Adapter page appears.

2 In the **URL** field, type the full path of the location where the adapter is installed.

3 Click **Save**.

Changing the enabled state of a Clintrial Adapter

When adapters are removed from your environment or when the machine the adapter resides on is offline, you can change the enabled state of an adapter.

1 Select **Admin** > **Clintrial**.

If multiple adapters are installed, the Adapter List page appears. Click the row of the adapter you want to view and manage. The Adapter tab of the Clintrial Admin Adapter page appears.

or

If only one adapter is installed, the Adapter tab of the Clintrial Admin Adapter page appears.

2 In the **Enabled** group, select **Enabled** or **Disabled**.

3 Click **Save**.

Adapter tab of the Admin Adapter page—Fields

Field	Description
The top section of the page displays information about the adapter.	

Field	Description
Auto-refresh	• **If selected**—The page refreshes automatically at the interval specified on the Settings tab of the My CIS page. • **If not selected**—The page does not refresh automatically.
Name	Name of the adapter.
Status	• **Green check mark**—Adapter status is OK. • **Red X**—Adapter status is Error.
Product Type	Product with which the adapter is associated: • **CIS**—For CIS Synchronization Adapters. • **Clintrial**—For Clintrial Adapters. • **InForm**—For InForm Adapters.
Adapter Type	Type of adapter: • **CIS Synchronization**—For CIS Synchronization Adapters. • **Clintrial Admin**—For Clintrial Adapters. • **InForm Admin**—For InForm Adapters.
URL	URL for the adapter.
Enabled	• **Yes**—Adapter is enabled. • **No**—Adapter is disabled.
If the adapter is an InForm Adapter, the lower section of the page displays information about the end points (trials) for the adapter.	
Name	Name of the InForm trial.
Registered Name	Registered name of the InForm trial.
Status	• **Green check mark**—End point status is OK. • **Red X**—End point status is Error.
Details	Link to additional information about an end point with an Error status.

Managing plugin installation information

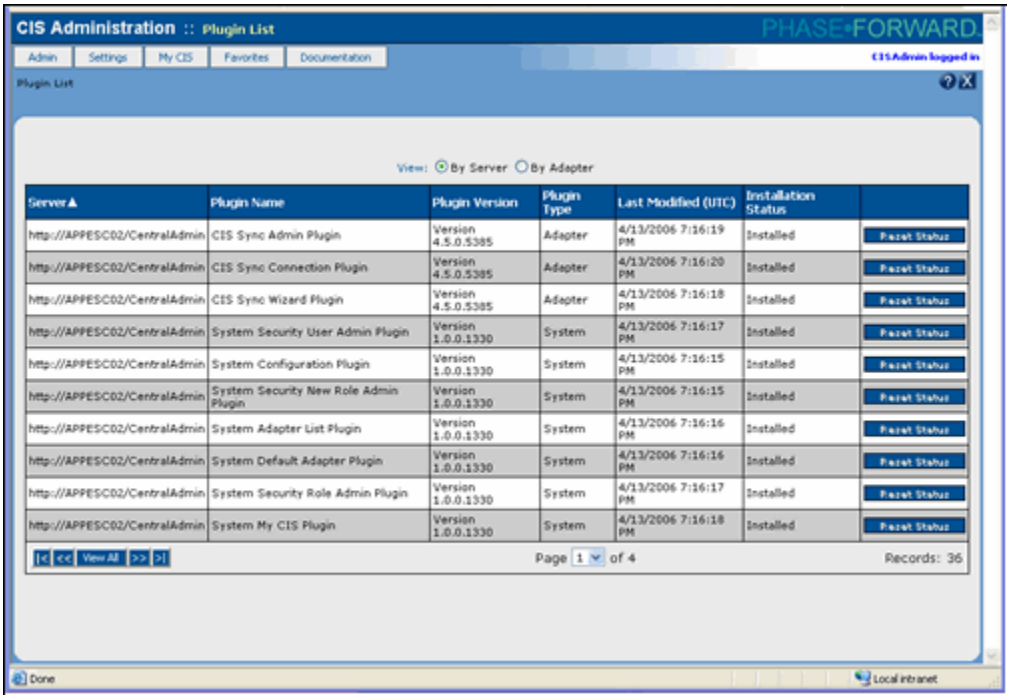
Overview of plugins

The Plugin List page displays information about the plugins (pages) in the CIS Administration environment:

- Initially, this page displays installation status information about all pages on all servers in the CIS Administration environment.
- You can also view information about the pages by adapters.

For more information, see:

- ***Plugin List page by Server - Fields*** (on page 44).
- ***Plugin List page by Adapter - Fields*** (on page 45).



From the Plugin List page, you can:

- ***View information by server*** (on page 43).
- ***View information by adapter*** (on page 44).
- ***Reset the error status of a page on a server*** (on page 44).

Viewing plugin installation information by server

The Plugin List page enables you to view details about CIS Administration pages by server or adapter. To view a list of pages by server:

- Select **Settings** > **Plugins**.

  The Plugin List page appears and initially displays installation status information for Server

pages.

For more information, see ***Plugin List page by Server - Fields*** (on page 44).

Viewing plugin installation information by adapter

The Plugin List page enables you to view details about CIS Administration pages by server or adapter. To view a list of pages by adapter:

1 Select **Settings** > **Plugins**.

The Plugin List page appears and initially displays installation status information about CIS Administration pages by server.

2 Select **By Adapter**.

For more information, see ***Plugin List page by Adapter - Fields*** (on page 45).

Resetting the error status of a page

If the installation of a page fails, the Reset Status button for the page is enabled in the by server view of the Plugin List page.

1 Select **Settings** > **Plugins**.

The Plugin List page appears and displays installation status information for CIS Administration pages by server.

2 Click **Reset Status**.

CIS Administration sets the installation status of the application page to Awaiting Install. The background service on the specified server attempts to reinstall the application page the next time it runs.

Plugin List page by Server—Fields

Field	Description
Server	URL of the CIS Administration web service for the specific CIS Admin server.
Plugin Name	Name of the plugin page.
Plugin Version	Version of the plugin page.
Plugin Type	Plugin page type.
Last Modified (UTC)	Last time (in Coordinated Universal time) the plugin page was updated.
Installation Status	Installation status of the plugin page: • Installed • Error • Awaiting Install

Plugin List page by Adapter—Fields

Field	Description
Adapter	URL of the CIS Administration web service for the specific CIS Admin server.
Plugin Name	Name of the plugin page.
Plugin Version	Version of the plugin page.
Plugin Type	Plugin page type.
Default	• **Yes**—If the plugin page is the initial page that appears for its associated adapter. • **No**—If the plugin page is not the initial page that appears for its associated adapter.

Managing configuration settings

Overview of configuration settings

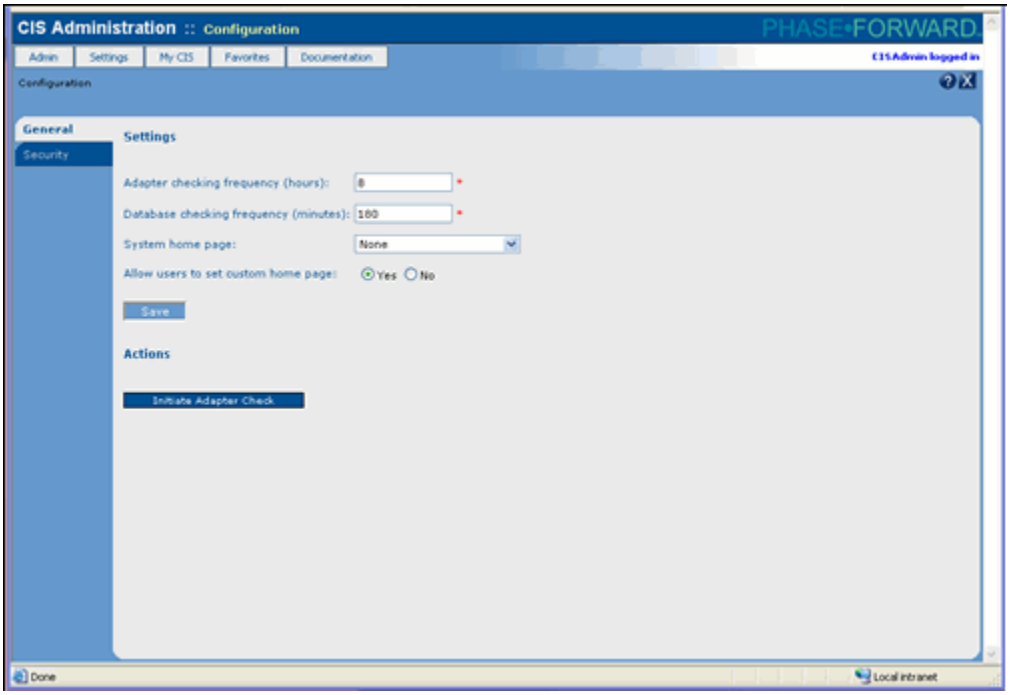
You use the Configuration page to view and manage CIS Administration configuration settings.

The Configuration page enables you to:

- Specify settings that apply globally to all components of the CIS environment.
- Set parameters that determine how CIS Administration handles user authentication.

For more information, see:

- ***General tab of the Configuration page - Fields*** (on page 48).
- ***Security tab of the Configuration page - Fields*** (on page 48).



From the Configuration page, you can:

- ***View and change general configuration settings*** (on page 46).
- ***View and change security settings*** (on page 47).
- ***Initiate checking for updates for enabled adapters*** (on page 47).

Viewing and changing general configuration settings

The General tab of the Configuration page enables you to specify settings that apply to all components of the CIS environment.

1 Select **Settings** > **Configuration**.

The Configuration page appears with the General tab selected.

2 Fill in the fields as needed, and click **Save**.

For more information, see ***General tab of the Configuration page - Fields*** (on page 48).

Viewing and changing security settings

The Security tab of the Configuration page enables you to view and change settings that determine how CIS Administration handles user authentication.

1 Select **Settings** > **Configuration**.

The Configuration page appears.

2 Select **Security**.

The Security tab of the Configuration page appears.

3 Fill in the fields as needed, and click **Save**.

For more information, see ***Security tab of the Configuration page - Fields*** (on page 48).

Checking for adapter updates

CIS Administration checks the status of all adapters at the interval specified in the Adapter checking frequency (hours) field. You can immediately initiate checks for updates for an enabled adapter from the General tab of the Configuration page.

1 Select **Settings** > **Configuration**.

The General tab of the Configuration page appears.

2 Click **Initiate Adapter Check**.

CIS Administration checks for updates for all enabled adapters in the CIS environment.

Viewing and setting the adapter checking frequency

You view and change how often CIS Administration checks for updates for an adapter from the General tab on the Configuration page.

1 Select **Settings** > **Configuration**.

The General tab of the Configuration page appears.

2 In **Adapter checking frequency (hours)**, type a value from 1 to 48 hours to determine how often CIS Administration checks for updates for enabled adapters.

3 Click **Save**.

General tab of the Configuration page—Fields

Field	Description
Adapter checking frequency (hours)	Frequency in hours for CIS Administration to check all adapters in the CIS environment to determine whether any of the adapters have changed.
Database checking frequency (minutes)	Frequency in minutes for CIS Administration to check the database for the presence of any new components that need to be placed on the local web server.
System home page	• **(Page name)**—Name of the initial CIS Administration page that appears when a user logs on. A specific page here overrides any custom home page set by a user if Allow users to set custom page is No. • **None**—The system default page (My CIS) appears.
Allow users to set custom page	• **Yes**—Users can specify the page that appears when they log on. • **No**—The home page specified in the System home page field appears when a user logs on.

Security tab of the Configuration page—Fields

Field	Description
Inactivity timeout (minutes)	Number of minutes a CIS Administration session can be inactive before it times out and CIS Administration logs a user off.
Authentication expiration (hours)	Number of hours after which a user authentication is no longer valid and the user must log on again.
Password expiration (days)	Number of days before a user password expires and the user must change the password when logging on.
Minimum password length	Minimum number of characters a user password must contain. **Note:** Allowed characters in passwords are upper and lowercase letters, digits, underscore (_), pound sign (#), and dollar sign ($).
Failed logon limit	Number of failed logon attempts a user can make before CIS Administration deactivates a user.
Audit verbosity level	• **Any**—Save all logon errors. • **Failures only**—Save errors only when a logon fails. • **Inactive failures only**—Save errors when the inactive period exceeds the value in the Security tab of the Configuration page.

Managing Security

Overview of managing security

CIS Administration enables you to define security for application users and product adapters. Defining security for a user includes the ability to define:

- Secure logons.
- Time-out periods to require authentication again.
- Users.
- Roles and rights.
- Domains that allow different roles for each adapter domain.
- Active and inactive states.

Defining security for domains includes the ability to:

- Indicate security to CIS Administration during adapter registration.
- Specify security rights for plugin pages.
- Assign security rights to users using security roles.
- Assign security domains to an adapter.

Rights and roles in the CIS environment

In a CIS environment, roles, rights, and domains are used to control the tasks that users can perform. User access to the pages (plugins) of the CIS Administration application and the tasks that a user can perform depend on the roles assigned to a user and the rights assigned to the role.

The process for providing users with specific roles and rights to perform tasks in the CIS environment includes:

- Creating and modifying roles.
- Granting rights for a specific role.
- Associating users with roles for one or more domains.
- Using domains to group roles for specific adapters.

CIS includes the following default roles for the Synchronization pages:

- **Administrator**—Allowed to perform all operations in the CIS environment.
- **Power user**—Allowed to perform most daily operations including monitoring and operations that can impact the entire system. For example, this user can add and remove a reference to a Clintrial database instance, change protocols, or set up a database connection for an adapter.
- **User**—Allowed to view the system state but cannot make changes.

CIS central administration includes the following default roles for the administration pages:

- **Security Admin**—View and modify security pages.
- **Config Admin**—View and modify adapters, pages (plugins), security configuration, and general

configuration.

- **Adapter User**—View a list of adapters and use adapters.

CIS includes the **System User Role**, a default role that gives the rights to perform any platform-based tasks. The System User Role does not provide any CIS-specific rights.

CIS synchronization page rights and assignments to default roles

CIS synchronization page rights provide access to the different pages of the CIS Administration applications and are used to control the tasks a user can perform. The rights available for a CIS user must be associated to at least one role and can be associated with many roles. If a user logon has been assigned to a specific role and rights have been granted to the role, a user can perform the task associated with a specific role. The following table defines each right and indicates the default roles with which it is associated.

Right	Action allowed	Role association		
		Admin-istrator	Power user	User
View Sync Connections	View the Synchronization Connections tab.	✓	✓	✓
View Notifications	View the Notifications tab.	✓	✓	✓
View load Balancing	View the Load Balancing tab.	✓	✓	✓
View Database Settings	View the Database Settings tab for a synchronization connection.	✓	✓	✓
View Named Schedules	View the Named Schedules tab.	✓	✓	✓
View Settings	View the Settings tab for global synchronization information.	✓	✓	✓
View Sync Info	View the General tab for a synchronization connection.	✓	✓	✓
View Sync Settings	View the Synchronization Settings tab for a synchronization connection.	✓	✓	✓
View Sync Actions	View the Synchronization Actions tab for a synchronization connection.	✓	✓	✓
View Sync Status	View the Synchronization Status tab for a synchronization connection.	✓	✓	✓
View Sync Errors	View the errors of a synchronization job.	✓	✓	✓

Right	Action allowed	Role association		
		Admin-istrator	Power user	User
Create Sync Connections	Create a new synchronization connection.	✓	✓	✓
Create Notifications	Create a new notification.	✓		
Create Clintrial Connections	Create a new Clintrial connection.	✓		
Create named Schedules	Create a new named synchronization schedule.	✓		
Edit Sync Connections	Edit an existing synchronization connection.	✓	✓	
Edit load Balance Machines	Set a load-balanced machine online or offline.	✓		
Edit Notifications	Edit an email notification.	✓		
Edit a Named Schedule	Edit a named synchronization schedule.	✓		
Edit CIS Connection	Edit CIS database connection information.	✓		
Edit Clintrial Connections	Edit a Clintrial connection.	✓		
Edit Global Settings	Edit the global synchronization settings.	✓		
Edit Transactions	Edit a failed transaction.	✓	✓	
Sync Now	Start a synchronization.	✓	✓	
Remove Sync	Delete a synchronization.	✓	✓	
Reset Protocol	Reset a protocol.	✓	✓	
Create Study Book	Auto-create a study book.	✓	✓	
Send Test Email	Send a test email from the Notifications tab.	✓	✓	
Data Recovery	Perform a data recovery.	✓	✓	
Delete Notification	Delete an email notification.	✓		
Remove Clintrial Connections	Delete a Clintrial connection.	✓		
Delete a Named Schedule	Delete a named schedule.	✓	✓	

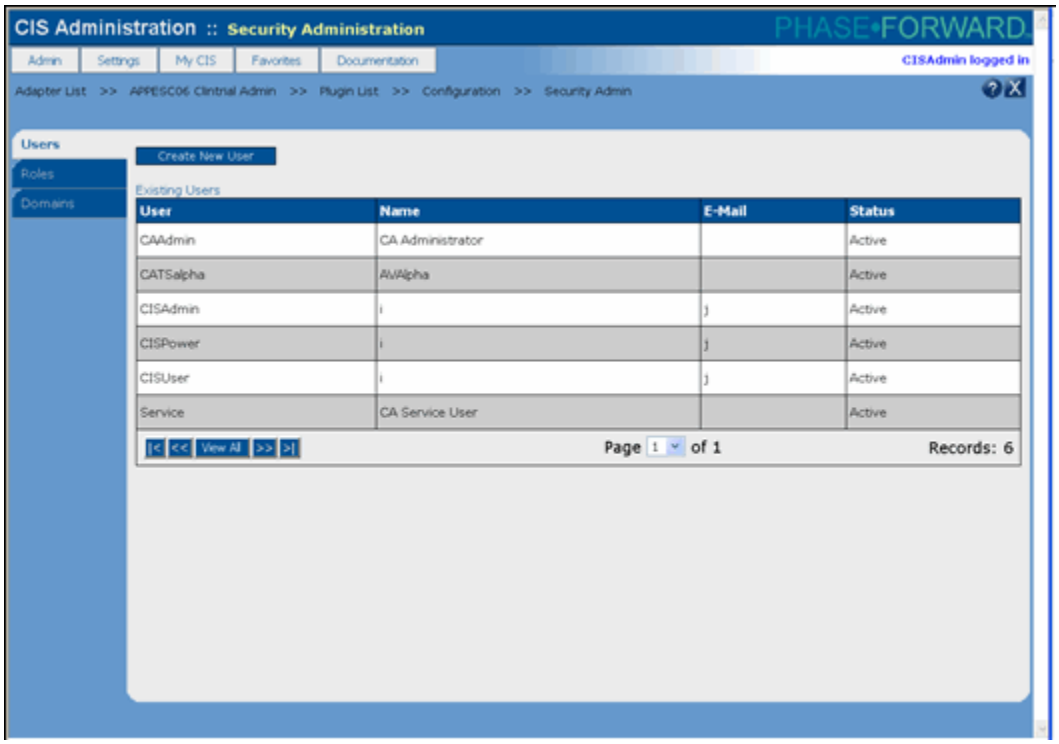
CIS central administration page rights and assignments to default roles

CIS administration rights are associated with specific administrative roles and control the central administration tasks a user can perform. The following table defines each right and indicates the default roles with which it is associated.

Right	Action allowed	Role association*		
		CA	SA	AU
Register A New Adapter With Central Administration	Register a new adapter with CIS Administration.	✓		
Modify An Adapter's General Settings	Modify the general settings for an adapter.	✓		
Use And View An Adapter	Use and view an adapter.			✓
Modify Central Administration General Configuration Setting	Modify the general configuration settings for CIS central administration.	✓		
Modify Central Administration Security Configuration Setting	Modify the security configuration settings for CIS central administration.	✓		
View And Administer Central Admin Adapter UI Plugins	View and manage interface pages (plugins) for the CIS central administration adapter.	✓		
View The Registered Adapter List	View the list of registered adapters.			✓
Administer Security For Users, Roles and Adapter Domains	Manage security for users, roles, and adapter domains.		✓	
Create A New User	Create a new user.		✓	
Edit A User's Standard Security Profile	Modify the standard security profile for a user.		✓	
Modify A User's State	Modify the state of a user.		✓	
Modify A User's Granted Roles	Modify the roles granted to a user.		✓	
Create A New Role	Create a new role.		✓	
Edit A Role's Standard Security Profile	Modify the standard security profile for a role.		✓	
Modify A Role's Granted Rights	Modify the rights granted to a role.		✓	
View and Modify An Adapter's Security Domain	View and modify the security domain of an adapter.		✓	
*** Roles:** CA=Config Admin. SA=Security Admin. AU=Adapter User.				

Security Administration page

You view and manage security from the Security Administration page.



The Security Administration page has the following tabs:

- **Users**—Displays information about all of the current users defined for the CIS environment, including their account status.
- **Roles**—Displays information about all the security roles defined for the CIS environment.
- **Domains**—Displays information about the domains assigned to adapters.

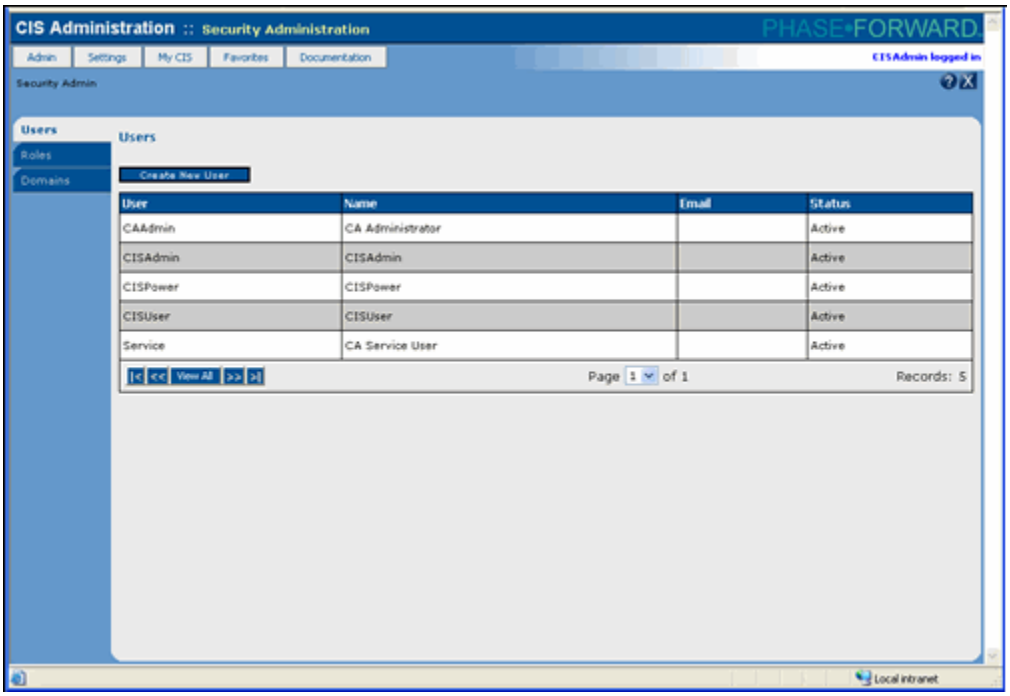
From the Security Administration page, you can view and manage:

- ***Users*** (on page 54).
- ***Roles*** (on page 57).
- ***Domains*** (on page 60).

Managing CIS users

Overview of managing CIS users

You can view and manage information about a specific user from the Users tab of the Security Administration page.



From the Users page, you can:

- ***View a list of users*** (on page 54).
- ***Create new users*** (on page 55).
- ***Edit a user profile*** (on page 55).
- ***Change an activation state*** (on page 56).
- ***View roles and associated domains*** (on page 56).
- ***Change roles and associated domains for a user*** (on page 56).

Viewing existing users

You can view a list of existing users that displays name, email address, and status for each user.

1 Select **Settings** > **Security**.

The Security Administration page appears with the Users tab selected.

2 If there are multiple pages containing information about users, you can:

- Select the specific page you want to view from the **Page** drop-down list
- Use the navigation buttons at the bottom of the page to navigate through the pages. To view the:

- **First page**—Click the single left-pointing arrow.
- **Previous page**—Click the double left-pointing arrow.
- **All rows of the table on a page that scrolls**—Click **View All**.
- **Next page**—Click the double right-pointing arrow.
- **Last page**—Click the single right-pointing arrow.

Creating a new user

You can create a new CIS Administration user to which you can assign roles and rights.

1 Select **Settings** > **Security**.

The Security Administration page appears with the Users tab selected.

2 Click **Create New User**.

The New User wizard page appears.

3 Type user profile and password information into the appropriate fields. You must provide the following information:

- User name
- Display name
- Password

  Allowed characters in passwords are upper and lowercase letters, digits, underscore (_), pound sign (#), and dollar sign ($).

- Confirm password

4 Click **Finish**.

CIS Administration displays the New User page with the information you entered and adds the user to the Users tab of the Security Administration page. The New User page includes the Edit Current User and Create New User buttons so that you can edit the user you just created or create another new user.

Editing a user profile

You can change basic user information including the user password.

1 Select **Settings** > **Security**.

The Security Administration page appears with the Users tab selected.

2 Click the link for the user you want to view.

The Edit User page appears with the Profile tab selected. From this tab, you can make changes to general information about the user.

3 To change the user password, select **Change Password**.

The Password and Confirm password fields are enabled.

4 **Important:** If you change the password for the Service user, you must also change this password in the Settings tab of the CIS Synchronization Adapter page. For more information, see ***Viewing and changing global synchronization connection settings*** (on page 94).In the **Password**

field, type a new password.

Note: When you create a password, you must follow the rules and requirements defined in the Configuration Settings page. For more information, see ***Viewing and changing security settings*** (on page 47).

5 In the **Confirm Password** field, retype the password.

6 Click **Save**.

Changing the activation state of a user

You can change the activation state of a user when the administrative role of the user changes.

1 Select **Settings** > **Security**.

The Security Administration page appears with the Users tab selected.

2 Click the row of the user you want to change.

The Edit User page appears with the Profile tab selected.

3 Select **State**.

The State tab appears.

4 In the **User state** field, click the appropriate user state: **Active**, **Inactive**, or **Terminated**.

Note: For a newly created user, CIS Administration sets the User state to Inactive.

5 Click **Save**.

Viewing roles and associated domains for a user

1 Select **Settings** > **Security**.

The Security Administration page appears with the Users tab selected.

2 Click the row of the user you want to view.

The Edit User page appears with the Profile tab selected.

3 Select **Roles**.

The Roles tab appears with the Modify Roles view selected.

4 Select **View Current Roles**.

The Roles tab displays the domains and roles that are currently assigned to the user.

5 If you want to change the view based on domains, select a domain from the **Filter Domains** drop-down list.

Changing roles associated with a user

You can change the roles granted to a user and the domain associated with the role. The roles are used to create an association with a user, a role, and a domain.

1 Select **Settings** > **Security**.

The Security Administration page appears with the Users tab selected.

2 Click the row of the user you want to change.

The Edit User page appears with the Profile tab selected.

3 Select **Roles**.

The Roles tab appears with the Modify Roles button selected and a list of current roles.

4 Click **Modify Roles**.

The Modify Roles view appears.

5 If you want to change the domain with which the role is associated, select a domain from the **Filter Domains** drop-down list.

6 In the **Granted** column:

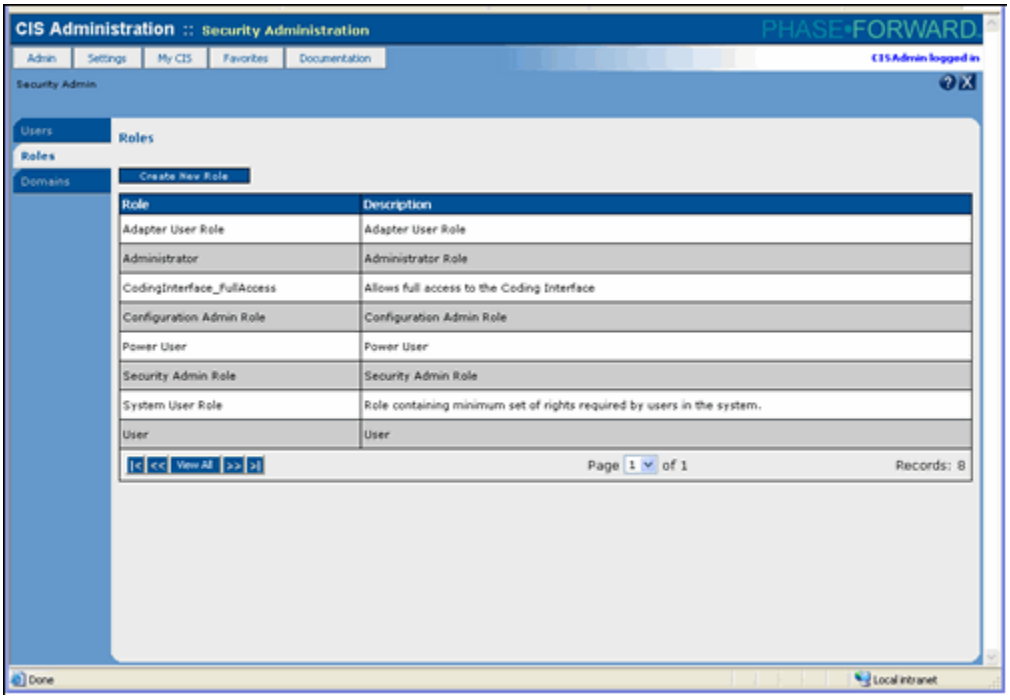
- Select the checkbox for each user you want to associate with the role.
- Deselect the checkbox for each user you want to remove from the role.

7 Click **Save**.

Managing roles

Overview of managing roles

You can view and manage information about a role from the Roles tab of the Security Administration page.



From the Roles tab on the Security Administration page, you can:

- ***View a list of security roles*** (on page 58).
- ***Create a new security role*** (on page 58).
- ***Change a security role*** (on page 59).

Viewing a list of security roles

From the Roles tab on the Security Administration page, you can view a list of security roles already defined.

1 Select **Settings** > **Security**.

The Security Administration page appears with the Users tab selected.

2 Select **Roles**.

The Roles tab appears and displays a list of currently defined roles.

3 If there are multiple pages containing information about roles, you can:

- Select the specific page you want to view from the **Page** drop-down list
- Use the navigation buttons at the bottom of the page to navigate through the pages. To view the:
  - **First page**—Click the single left-pointing arrow.
  - **Previous page**—Click the double left-pointing arrow.
  - **All rows of the table on a page that scrolls**—Click **View All**.
  - **Next page**—Click the double right-pointing arrow.
  - **Last page**—Click the single right-pointing arrow.

Creating a new security role

You can create a new security role that you can associate with users, rights, and an associated domain.

1 Select **Settings** > **Security**.

The Security Administration page appears with the Users tab selected.

2 Select **Roles**.

The Roles tab appears and displays a list of currently defined roles.

3 Click **Create New Role**.

The New Role wizard page appears.

4 In the **Role name** field, type the name of the role.

5 In the **Role description** field, type a description of the role.

6 Click **Finish**.

CIS Administration displays the New Role page with the name and description you entered and adds the role to the Roles tab of the Security Administration page. The New Role page includes the Edit Current Role and Create New Role buttons so that you can edit the role you just created

or create another role.

Changing a security role

You can add or remove rights for a role and add or remove users to the role.

1 Select **Settings** > **Security**.

The Security Administration page appears with the Users tab selected.

2 Select **Roles**.

The Roles tab appears and displays a list of currently defined roles.

3 Click the row of the role you want to change.

The Security Administration Edit Role page appears with the Profile tab selected. This tab displays the name and description for the selected role.

4 Review assignments or make any of the following changes as needed:

- To change the rights associated with the role, select **Rights**.

  The Rights tab appears and displays a tree view of rights and a list of currently defined rights for the role. From this tab, you can add or remove rights for a role.

- To view the rights available for a specific feature of the CIS environment, click a node in **Filter Rights**. For example, if you click **CISSynchronization**, the node expands, and the **Modify Current Rights** table displays the rights available for synchronizations. The **Description** column displays a description of the right.

- To add rights to a role, in the **Granted** column, select the checkbox for each right that you want to add to the role.

  Note: Be sure to review the rights on all pages of the rights list, or use the View All option in the multiple-page control to enable a scrolling display of rights.

- To view all users associated with the selected role, select **Users**.

  The Users tab appears in the Modify User view.

- To view a list of users associated with the role, select **View Current Users**. You can filter this view by selecting a domain from the **Filter Domains** drop-down list.

- To change users associated with a role, select **Users**.

  The Users tab appears in the Modify Users view and displays a list of users currently associated with the role.

- To change the domain with which the user role is associated, select a domain from the **Filter Domains** drop-down list.

5 In the **Granted** column:

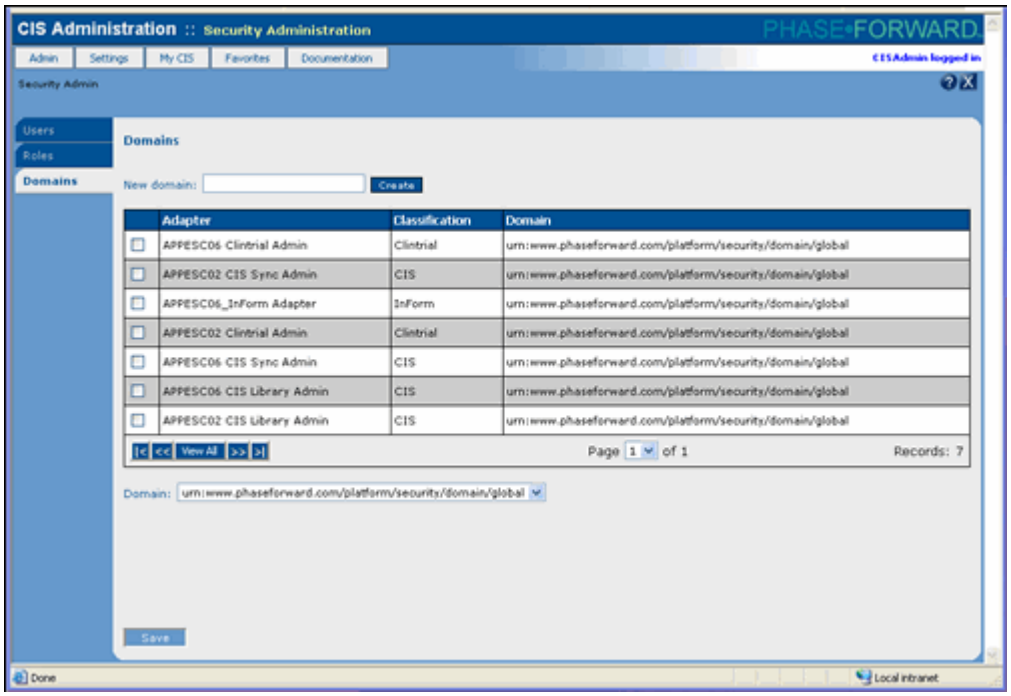
- Select the checkbox for each user you want to associate with the role.
- Deselect the checkbox for each user you want to remove from the role.

6 Click **Save**.

Managing domains

Overview of managing domains

You can view and manage information about adapter domains from the Domains tab of the Security Administration page.



Domains are used to group multiple adapters so that you can assign different roles to each adapter domain.

An adapter then uses its assigned domain when it grants a user access to the CIS administrative features for the adapter. The tasks a user can perform are determined by the roles that have been granted to a user for a specific domain.

Note: The Service user is used by CIS to contact adapters during adapter administration. Therefore, the Service user must have roles assigned to the domains for the adapters.

From the Domains tab of the Security Administration page, you can perform the following tasks:

- ***View a list of adapters and assigned domains*** (on page 60).
- ***Assign an adapter to a domain*** (on page 61).
- ***Create a new domain*** (on page 61).

Viewing a list of adapters and associated domain

1 Select **Settings** > **Security**.

The Security Administration page appears with the Users tab selected.

2 Select **Domains**.

The Domains tab appears and displays a list of adapters and domains.

From this tab, you can view a list of adapters and their assigned domains.

Assigning an adapter to a domain

1 Select **Settings** > **Security**.

The Security Administration page appears with the Users tab selected.

2 Select **Domains**.

The Domains tab appears and displays a list of adapters and domains.

3 Select the checkbox for each adapter you want to assign.

4 From the **Domain** drop-down list, select the domain to which you want to assign the selected adapters.

5 Click **Save**.

Creating a new domain

1 Select **Settings** > **Security**.

The Security Administration page appears with the Users tab selected.

2 Select **Domains**.

The Domains tab appears and displays a list of adapters and domains.

3 In the **New domain** field, enter the name of the new domain.

4 Click **Create**.

CHAPTER 3

Administering synchronization connections

In this chapter

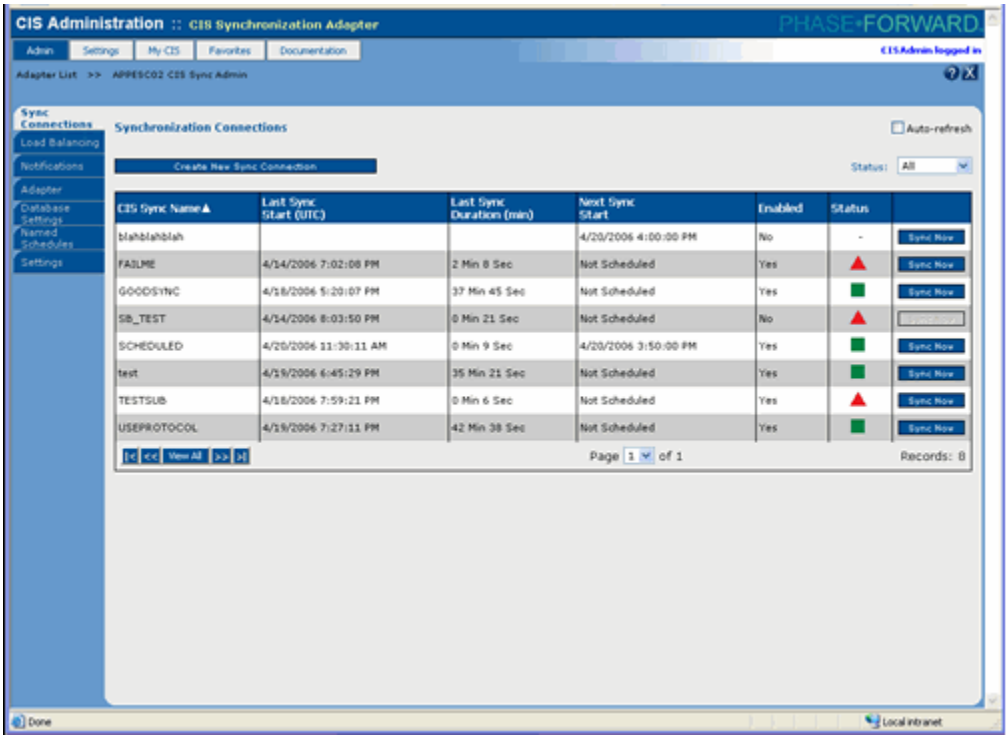
Definition of synchronization

Synchronization is the process of transferring metadata and clinical data between the InForm software and the Clintrial software. To enable synchronization, you define a *synchronization connection* from an InForm study to a study protocol within a target Clintrial database instance that is addressable by the CIS machine.

During synchronization, CIS transfers InForm transactions to the CIS Adapter. From the CIS Adapter, the Clintrial Adapter transfers transactions to the Clintrial database. Return transactions carry query data from the Clintrial software to CIS and from there to the InForm software.

Overview of synchronization connection administration tasks

To perform monitoring, maintenance, and management tasks associated with administering synchronization connections, you use the CIS Synchronization Adapter page and its tabs.



Tab name	Purpose
Sync Connections	View and manage synchronization connections. You also use this tab to create a new synchronization connection.
Load Balancing	View and manage load-balanced CIS servers.
Notifications	View and manage email notifications for synchronization connection failures.
Adapter	View and manage information about the CIS Sync adapter.
Database Settings	View and manage references to Clintrial database instances.
Named Schedules	View and manage named schedules that can be selected for a specific synchronization.
Settings	View and set global values that apply to all CIS synchronization connections.

From these pages, you can perform setup, administrative, and monitoring tasks for synchronization connections in a CIS environment. These tasks include:

- ***Viewing information about synchronization connections*** (on page 67).
- ***Creating a synchronization connection*** (on page 72).
- ***Monitoring and editing synchronization connections*** (on page 83).
- ***Viewing and changing global values for synchronization connections*** (on page 94).
- ***Removing a synchronization connection*** (on page 97).
- ***Resetting a protocol and replaying synchronization transactions*** (on page 99).
- ***Autocreating a Clintrial software study book*** (on page 73).
- ***Monitoring load balancing*** (on page 122).
- ***Managing email notifications*** (on page 102).
- ***Managing synchronization schedules*** (on page 107).
- ***Managing Clintrial database instances*** (on page 110).
- ***Starting synchronization manually*** (on page 114).
- ***Recovering data*** (on page 115).

Viewing synchronization connections

Overview of viewing synchronization connections

The Sync Connections tab on the CIS Synchronization Adapter page displays a list of current synchronization connections and provides details about each synchronization connection.

For more information, see:

- ***Sync Connections tab of the CIS Synchronization Adapter page - Fields*** (on page 69).
- ***Adapter tab of the Admin Adapter page - Fields.*** (on page 38)

You use the Sync Connections tab of the CIS Synchronization Adapter page to view and manage synchronization connections. From the Sync Connections tab, you can:

- ***View a list of synchronization connections*** (on page 67).
- ***Enable and disable auto-refresh*** (on page 67).
- ***Filter the list based on status*** (on page 68).
- ***Sort the list of synchronization connections*** (on page 68).

Viewing a list of synchronization connections

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

Enabling and disabling auto-refresh of a CIS Synchronization Adapter

You can enable or disable the auto-refresh option for adapters. If you enable the option, the page automatically refreshes based on the value entered for the auto-refresh rate.

For more information, see ***Setting a home page and auto-refresh rate*** (on page 29).

Note: Depending on the auto-refresh rate and your environment, selecting Auto-refresh might impact the performance of the application.

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 To enable or disable auto refresh, select one of the following:

- To automatically refresh the page at the configured rate, select **Auto-refresh**.
- To specify that the page refreshes manually, deselect **Auto-refresh** (the default).

4 Click **Save**.

Filtering the synchronization connection list by status

You can change which synchronization connections appear in the table by selecting a different view Status.

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 From the **Status** drop-down list box, select the status you want to view.

The table changes to display synchronization connections that match the status you selected.

Sorting the synchronization connection list

You can change how the synchronization connections appear in the table by clicking each column heading to sort the column. For example, if you click the column heading CIS Sync name, the sort order switches between ascending or descending alphabetical order.

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose

synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Click the column heading you want to use to sort the table.

The columns in the table sort based on your selection.

Sync Connections tab of the CIS Synchronization Adapter page—Fields

Field	Description
Auto-refresh	• **If selected**—The page refreshes automatically at the interval specified on the Settings tab of the My CIS page. • **If not selected**—The page does not refresh automatically.
Create New Sync Connection	Click to display the first page of the CIS Synchronization Connection Wizard and start to create a new synchronization connection.
Status (filter)	List of possible synchronization connection statuses. To display only synchronization connections in a specific status, select the status from the drop-down list. Possible status filters are: • All • Complete • Running • Fault
The columns of the synchronization connection table display information about each synchronization connection.	
CIS Sync Name	Name of the synchronization. This is the name entered when the synchronization connection was created.
Last Sync Start (UTC)	Last time the synchronization started. Synchronization schedule time is stored as Universal Coordinated Time (UTC) time.
Last Sync Duration (min)	Number of minutes and seconds it took to complete the synchronization.
Next Sync Start	Next time the synchronization is scheduled to start. Synchronization schedule time is stored as Universal Coordinated Time (UTC) time.
Enabled state	• **Yes**—The synchronization is enabled. The synchronization runs using the schedule you define. • **No**—The synchronization is disabled. **Note:** If a synchronization is disabled, you can start the synchronization manually by clicking **Sync Now**.

Field	Description
Status (synchronization connection)	Run status of the synchronization. A synchronization can have the following status: • **Green Square**—Indicates that the last synchronization was successful and all transactions for that synchronization were sent to both the InForm software and the Clintrial software. However, this column only displays the status for the last synchronization and does not indicate that all transactions have been synchronized. If additional transactions were generated by the InForm software or the Clintrial software, these transactions do not appear until the next synchronization completes. • **Orange Diamond**—Indicates the synchronization is still running. • **Red Triangle**—Indicates an error has occurred.

Adapter tab of the Admin Adapter page—Fields

Field	Description
The top section of the page displays information about the adapter.	
Auto-refresh	• **If selected**—The page refreshes automatically at the interval specified on the Settings tab of the My CIS page. • **If not selected**—The page does not refresh automatically.
Name	Name of the adapter.
Status	• **Green check mark**—Adapter status is OK. • **Red X**—Adapter status is Error.
Product Type	Product with which the adapter is associated: • **CIS**—For CIS Synchronization Adapters. • **Clintrial**—For Clintrial Adapters. • **InForm**—For InForm Adapters.
Adapter Type	Type of adapter: • **CIS Synchronization**—For CIS Synchronization Adapters. • **Clintrial Admin**—For Clintrial Adapters. • **InForm Admin**—For InForm Adapters.
URL	URL for the adapter.
Enabled	• **Yes**—Adapter is enabled. • **No**—Adapter is disabled.

Field	Description
If the adapter is an InForm Adapter, the lower section of the page displays information about the end points (trials) for the adapter.	
Name	Name of the InForm trial.
Registered Name	Registered name of the InForm trial.
Status	• **Green check mark**—End point status is OK. • **Red X**—End point status is Error.
Details	Link to additional information about an end point with an Error status.

Creating a synchronization connection

Overview of setting up a connection

The CIS software uses synchronization to update clinical data or metadata between the InForm database and the Clintrial database.

To enable synchronization, you define a synchronization connection from an InForm study to a study protocol within a target Clintrial database instance addressable by the CIS machine.

If the target protocol does not exists in the Clintrial library, the CIS software creates it. Otherwise, the CIS software updates the existing protocol with metadata or clinical data synchronized from the InForm study.

Connections and time settings

Synchronization depends on the coordination of system clocks on the machines between which the synchronization occurs. Phase Forward strongly recommends installing a time synchronization tool on each machine involved in a CIS synchronization and making sure all clocks are set accurately before setting up a synchronization connection.

Additionally, you should be aware of how times and synchronization schedules are stored in each software component.

System date times

The CIS software components store system dates and timestamps as follows:

Software component	Storage of system dates and timestamps
InForm software	Stored as Universal Time (also called Greenwich Mean Time) (UTC or GMT) and displayed according to the time zone of the user site.
CIS software	Stored as UTC/GMT.
Clintrial software	Stored as local time on the Oracle machine. In Clintrial audit tables, the ENTRY_DATETIME column reflects the time the record was updated in InForm software (in UTC/GMT), and the MERGE_DATETIME column reflects the time the value was updated in the Clintrial software (in the local time of the Clintrial machine).

Because the InForm and CIS machines store the same system dates and timestamps, there is no need for the machines to be set to the same time zone as long as their system clocks are synchronized. You should set the Clintrial machine to the time zone you want to use for analyzing data; UTC/GMT is suggested to minimize confusion.

Synchronization schedule time

Synchronization schedule time is stored in UTC, and run times shown at the locations of the source and destination computers are the same.

Dates and times in patient data

When a form calls for the entry of date and time information, the InForm software database stores it as entered. Such dates and times are synchronized, without any time zone conversion, to the columns to which they are mapped in the Clintrial software.

Clintrial study book autocreation

Overview of autocreating Clintrial study books

When the CIS software performs a synchronization for the first time, it creates, optionally:

- A Clintrial protocol, panels, and panel items if they do not already exist.
- The study books, page templates, and page sections, either during the initial synchronization or afterwards.

When study book autocreation is enabled, during synchronization, the CIS software:

- Creates new enrollment, non-patient data, and patient data study books in the target protocol if they do not already exist.
- Regenerates study books if they do exist in the target protocol, overwriting the existing study books.

> **Note:** If a non-CIS user, such as a user of the Clintrial Design module, has updated a pre-existing element, the CIS software ignores the element and does not regenerate it during regular synchronization processing. However, if you request immediate study book generation by using the Actions tab of the CIS Synchronizations page, you can specify that the CIS software regenerates elements updated by a non-CIS user and overwrites those elements.

The CIS software can detect most changes that a user makes to a protocol with the Clintrial Design module. However, some changes are not detectable by the CIS software. If a user of the Design module makes any of the following changes, the CIS software does not detect them and overwrites those changes:

- Deleting the last page template from a block.
- Deleting the last block from a study book.
- Changing the order of page sections in a page template.

You can enable study book autocreation by:

- ***Creating a synchronization connection with study book autocreation enabled*** (on page 76).
- ***Changing a synchronization connection definition to enable study book autocreation*** (on page 88).
- ***Requesting immediate study book autocreation*** (on page 74).

Timing of study book autocreation

After generating a complete set of XML definitions for the study books of a protocol, the CIS software creates the study books and their components.

Study book autocreation can occur:

- When a user requests study book autocreation by clicking the Create Study Books button on the Actions tab of the CIS Synchronizations page in the CIS Administration application.
- When the CIS software detects that autocreation is necessary. The CIS software determines that autocreation is needed if it processes any of the following types of transactions from the InForm software:
  - STUDYVERSION XML definitions.
  - Data mappings.
  - Any InForm metadata that causes an autogenerated codelist to be attached to a Clintrial item. Examples are metadata definitions for radio controls and dropdown lists.

The CIS software does *not* autocreate study books if any of the following are true:

- The protocol is closed for revision or is locked.
- The synchronization connection is not defined to autocreate study books.

Requesting immediate autocreation of a study book

If a synchronization connection exists, you can have the CIS software autocreate or update the study books for the Clintrial protocol immediately.

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Click the row of the synchronization connection that you want to update.

The CIS Synchronizations page appears.

4 Select **Actions**.

The Actions tab appears.

5 Click **Create Study Books**.

A confirmation page appears.

6 If you want the study book autocreation process to overwrite changes made by non-CIS users (for example, users of Clintrial Design), select **Overwrite non-CIS changes**.

7 Click **Create Study Books**.

Clintrial panel and item autocreation

Overview of autocreating Clintrial panels and items

By default, the CIS software creates a Clintrial protocol, panels, and panel items during synchronization if they do not already exist. If a protocol, panels, and panel items exist, and new metadata is received in mapping definitions, the CIS software updates the protocol, panels, and panel items to match the mapping definitions.

This behavior is optional. When you define or update a synchronization connection, you can specify whether you want the CIS software to create or update the protocol, panels, and panel items.

For more information, see:

- ***Creating a synchronization connection using the connection wizard (Specifying a Clintrial protocol)*** (on page 77).
- ***Viewing and changing settings for a synchronization connection*** (on page 88).

The following table summarizes the impact of choosing for the CIS software not to create or update Clintrial protocol, panels, and panel items.

Software area	Effect on synchronization if Create panels and items = No
Study book creation	None.
Codelist creation	None.

Software area	Effect on synchronization if Create panels and items = No
Mappings	The CIS software does not create the panels and items defined by mapping definitions. However, the following validation occurs to determine whether the Clintrial panels or items match the incoming mappings: • When the CONTEXTPANEL tag is received, the CIS software verifies that a CONTEXT panel exists for the protocol. If a CONTEXT panel does not exist, validation fails. • For CTITEM tags inside the CONTEXTPANEL tag, no additional validation is performed. • When a CTPANEL tag is received, the CIS software verifies that the panel exists and is installed. If the panel does not exist or is not installed, validation fails. • For a CTITEM tag inside the CTPANEL tag, the CIS software verifies that the item exists in the panel. The item type is not checked. If the item does not exist in the panel, validation fails • The CIS software ignores all other properties of the panel from the mappings, including the master-detail information. If validation fails, synchronization stops processing. To continue, make corrections in the Clintrial software or in the mapping definitions and the CIS software: • Alter the protocol in Clintrial Design so it passes the CIS validation. • Remove the synchronization connection in the CIS software, alter the mapping definitions so they will pass validation, and re-create the synchronization connection to the same protocol.
Rules	The CIS software does not create or update Clintrial rules and derivations. No validation checks are performed to verify that rules or derivations exist in the Clintrial protocol.
Protocols	The CIS software does not create a Clintrial protocol. If the protocol specified in the synchronization connection definition does not exist, synchronization fails.

Creating a synchronization connection using the connection wizard

Overview of creating a synchronization connection using the connection wizard

To help you create a synchronization connection, CIS Administration provides a synchronization connection wizard. Using the pages of the synchronization connection wizard, you:

1 Specify how the synchronization connection communicates.

2 Specify the Clintrial software database instance with which the synchronization connection communicates.

3 ***Specify the Clintrial software protocol with which the synchronization connection***

communicates (on page 77).

4 ***Select the InForm Adapter, trial, and mapping definition used by the synchronization connection*** (on page 77).

5 ***Select or define a synchronization schedule, or specify that the synchronization connection does not use a schedule*** (on page 78).

6 ***Review and save the definition of the synchronization connection*** (on page 78).

Specifying how the synchronization connection communicates

You begin creating a new synchronization connection from the main CIS Administration page. If you are not logged on to CIS Administration, see ***Logging on to the CIS Administration application*** (on page 18).

To provide general information about the synchronization connection:

1 Select **Admin > CIS Sync**.

The CIS Synchronization Adapter page appears.

2 Click **Create New Sync Connection**.

The CIS Synchronization Connection Wizard - Connection Settings page appears.

3 Complete the fields on the page, and click **Next**.

The CIS Synchronization Connection Wizard - Clintrial Instance page appears.

For more information, see ***CIS Synchronization Connection Wizard - Connection Settings page - Fields*** (on page 79).

Identifying the Clintrial database instance

1 If the **Clintrial Machine** field has a drop-down list, select the computer where the Clintrial instance for the synchronization connection is installed.

2 If the **Clintrial Machine** field has a drop-down list, in the **Clintrial Instance** group, click **Register new**.

3 Complete the fields on the page, and click **Next**.

The CIS Synchronization Connection Wizard - Clintrial Protocol page appears.

For more information, see ***CIS Synchronization Connection Wizard - Clintrial Instance page - Fields*** (on page 80).

Specifying a Clintrial protocol

- Complete the fields on the page, and click **Next**.

The CIS Synchronization Connection Wizard - InForm Trial page appears.

For more information, see ***CIS Synchronization Connection Wizard Clintrial Protocol page - Fields*** (on page 80).

Selecting an InForm trial

1 From the **InForm machine** drop-down list, select the computer where the InForm Adapter is

registered.

The CIS software populates the InForm trial drop-down list when you select a machine.

Note: If only one Adapter is registered, this drop-down list does not appear.

2 From the **InForm trial** drop-down list, select the InForm software trial for the synchronization connection.

The CIS software populates the Mapping drop-down list with the names of the mapping definitions that exist for the selected trial.

3 From the **Mapping** drop-down list, select the mapping definition to use when synchronizing data for the trial.

4 Click **Next**.

The CIS Synchronization Connection Wizard - Schedule page appears.

Specifying a schedule

For the synchronization connection, you can select an existing named schedule, create a custom schedule, or not schedule the synchronization. If you do not define a schedule for the synchronization connection, you must manually run the synchronization. For more information, see ***Starting synchronization manually*** (on page 114).

To select a schedule or define a new schedule for a synchronization connection:

1 Select the type of schedule that you want for the synchronization connection.

2 Complete the fields on the page, and click **Next**.

The CIS Synchronization Connection Wizard - Summary wizard page appears.

For more information, see ***CIS Synchronization Connection Wizard - Schedule page - Fields*** (on page 81).

Reviewing and saving a new connection

After you provide information for the synchronization connection, use the Summary page to review the information about the synchronization connection. If you want to make changes, you can navigate to previous pages to make changes, or you can save the synchronization connection.

1 If the synchronization connection is not correct, click **Previous** to return to a page to make corrections and then use **Next** to return to the summary page.

2 When the synchronization connection is correct, click **Finish** to save it.

The Synchronization connection created successfully summary page appears. From this summary page, you can:

- ***View all synchronization connections for this server*** (on page 67).
- ***View the synchronization connection you just defined*** (on page 83).
- ***Create another synchronization connection*** (on page 76).

CIS Synchronization Connection Wizard—Connection Settings page—Fields

Field	Description
Sync name	Name of the synchronization connection.
Sync description	Description of the synchronization connection.
Enabled	• **Yes**—Connection is enabled when created. When you enable a synchronization, the synchronization begins immediately when it is created. After that, the synchronization runs using the schedule you define. • **No**—Connection is not enabled when created. **Note:** If a synchronization is disabled, you can start the synchronization manually by clicking **Sync Now** on the Sync Connections tab of the CIS Synchronization Adapter page.
CIS Metadata Locale	Specifies the language to use when synchronizing the trial.
InForm Metadata only	• **Yes**—Connection transfers only metadata. • **No**—Connection transfers both metadata and patient data.
Auto-generate codelist	Indicates whether CIS automatically generates Clintrial codelists when synchronizing metadata that includes radio and pulldown controls from InForm software: • **Yes**—CIS automatically generates codelists. • **No**—CIS does not automatically generate codelists.
Number of transactions per message	Number of transactions in a message. The number of transactions per message is the number of transactions per operation, including the sending and receiving of transactions between InForm Adapters and Clintrial Adapters. In general, the more transactions per message, the faster the synchronization completes because fewer requests are made to the adapters. However, when typing a value for this option, you should consider that all transactions in each operation are in memory. Therefore, if you have a number of synchronizations running, a high number of transactions per operation could result in a greater demand on memory. Phase Forward recommends that you accept the default value of 500 for this option. A lower value might slow down a synchronization.

CIS Synchronization Connection Wizard—Clintrial Instance page—Fields

Field	Description
Instance	Name of the Clintrial database instance.
CISUSER password	Password for the CISUSER user in the database instance.
Get State Options	Click to populate the State to map queries as open list box.
State to map queries as open	Clintrial discrepancy status that corresponds to the InForm Open query status. There is no default; you must specify a value. This information is used for transfer of query (discrepancy) information from the Clintrial database back to the InForm database. If the value you specify for "State to map queries as open" matches the value in the Clintrial software for "Discrepancy initial status" for the Clintrial rule, the Clintrial discrepancy maps as an Open query in the InForm software. If the values do not match, the Clintrial discrepancy maps as a Candidate query in the InForm software. **Note:** If in the Clintrial software the value for "Discrepancy initial status" of a Clintrial rule is not specified, the CIS software assumes the default value "Ready to Send".

CIS Synchronization Connection Wizard—Clintrial Protocol page—Fields

Field	Description
Clintrial protocol	Clintrial protocol that is the target of the synchronization connection: • **Existing protocol**—Indicates that the synchronization connection connects to the Clintrial protocol selected in the drop-down list. • **New protocol**—Indicates that the synchronization creates and updates the Clintrial protocol specified in the text field. **Note:** The value specified in this field becomes the name of an Oracle user. Therefore, the new protocol name must meet Oracle requirements for user names. **Note:** The protocol name you specify must adhere to the following rules for naming Clintrial software objects: ▪ Name cannot exceed 20 characters. ▪ First character must be alphabetic. ▪ Alphabetic and numeric characters are allowed. ▪ Do not use any special characters, except the underscore (_). ▪ Do not use Clintrial software reserved words. For more information, see the Clintrial *Reference Guide*.

Field	Description
New mappings	Specifies how the synchronization connection processes new mapping definitions: • **Assume no pre-existing data**—If mapping definitions for data items for which no mappings originally existed are synchronize later, the CIS software continues to ignore the previously unmapped data. For those data items, the CIS software processes only data that arrives subsequent to the mapping definitions. • **Replay sync to gather pre-existing data**—When a new mapping definition arrives, the CIS software replays all transactions that contain the control path in the new mapping. If the CIS software finds any new mappings, it inserts the data in the appropriate Clintrial database column. • **Stop sync for intervention**—When a new mapping definition arrives, the CIS software stops the message queue and waits for a manual intervention.
Auto-create study books	• **Yes**—CIS creates study books for the Clintrial protocol, including page templates and page sections, by using the study component definitions synchronized from InForm software. • **No**—CIS does not create study books for the Clintrial protocol. For more information, see ***Autocreating Clintrial study books*** (on page 73).
Create panels and items	• **Yes (default)**—CIS creates or modifies Clintrial panels and items as defined in the mappings. • **No**—CIS does not create or modify Clintrial panels and items. For more information, see ***Autocreating Clintrial panels and items*** (on page 75).

CIS Synchronization Connection Wizard—Schedule page—Fields

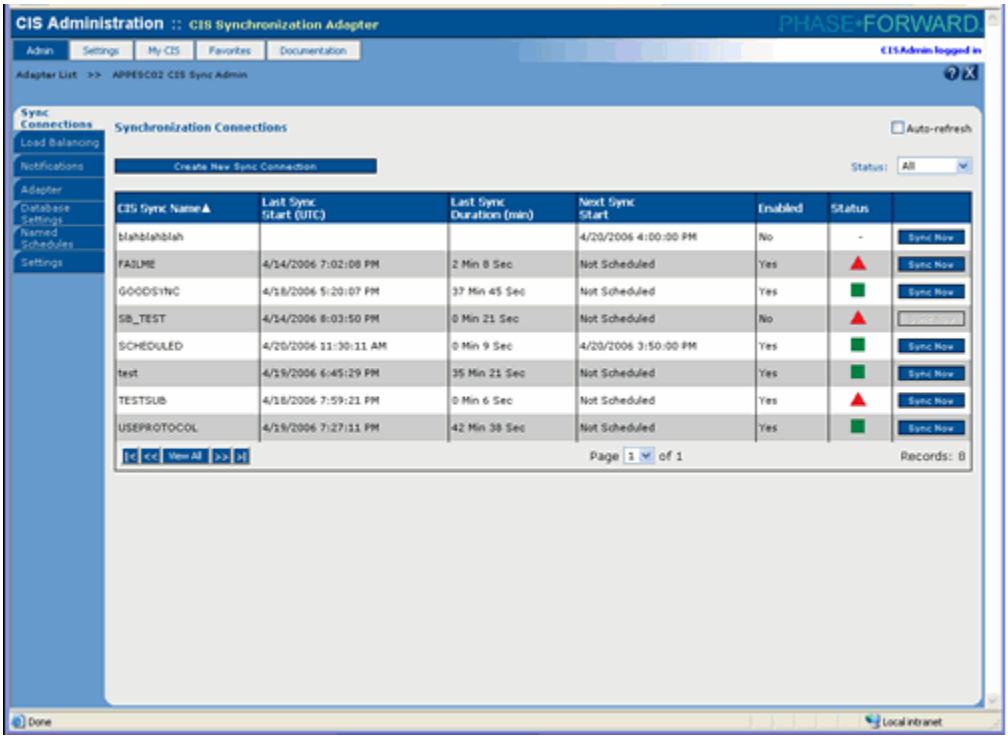
Field	Description
None	The synchronization connection does not use a schedule. **Note:** If you do not define a schedule, you must manually run synchronization on the synchronization connection. For more information, see ***Starting synchronization manually*** (on page 114).
Named	The synchronization connection uses the schedule selected from the drop-down list.
Custom	The synchronization connection uses the custom schedule defined in the Days, Start time (UTC), End Time (UTC), and Run every fields.
Days	Days of the week to which the custom schedule applies. Select each day on which to run synchronization.

Field	Description
Start time (UTC)	Time for synchronization to begin running. Specify the time in hours and minutes.
End time (UTC)	Time for synchronization to stop. Specify the time in hours and minutes.
Run every	Interval on which to start synchronization within the specified Start time (UTC) and End time (UTC). For example, if you have a Start Time of 1:00 and an interval of 5 Minutes, the scheduled synchronization begins at 1:00, 1:05, 1:10, and so on. Type a number, and select Hours or Minutes.

Monitoring and editing synchronization connections

Overview of monitoring and editing synchronization connections

CIS Administration enables you to monitor the status of synchronization connections, to view detailed information about individual synchronization jobs, and to edit the transactions that are saved to the CIS database. You monitor synchronization connections from the Sync Connections tab of the CIS Synchronization Adapter page. From this tab, you can view a list of synchronization connections defined for your environment, and you can select specific synchronization connections to monitor and manage.



From the Sync Connections tab, you can:

- ***View a summary of synchronization connection transactions and the status of synchronization connection jobs*** (on page 84).
- ***View details about transactions for a specific synchronization connection job*** (on page 84).
- ***View a history of all jobs for a specific synchronization connection*** (on page 85).
- ***View error details for the last failed synchronization job*** (on page 84).
- ***View error details for previously failed synchronization jobs*** (on page 85).
- ***View and edit transaction XML for a synchronization job.*** (on page 86)
- ***Edit New Mapping options*** (on page 87).
- ***View general information about a synchronization connection*** (on page 87).
- ***View and change settings for a synchronization connection*** (on page 88).

For additional assistance in monitoring synchronization status, CIS Administration includes a

notification feature. When you set up email notifications, you can specify the addressees who should receive email notification when a synchronization fails or a synchronization processor goes offline. For more information, see ***Managing email notifications*** (on page 102).

Viewing a summary of all CIS synchronization transactions

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Click the row of the synchronization connection you want to monitor or change.

The Status tab of the CIS Synchronization Connection page appears.

For more information, see ***Status tab of the CIS Synchronization Connection page - Fields*** (on page 88).

Viewing synchronization error details for the last job

You can view error details for the last synchronization connection job from the Status tab of the CIS Synchronizations page.

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Click the row of the synchronization connection you want to view.

The Status tab of the CIS Synchronization Connection page appears.

4 Click **View Error** next to the job in the table.

The Synchronization Connection Error Details page appears. This page provides information about when the errors occurred, the source of the error, and details about the error.

Depending on the type of error, buttons at the bottom of the page are enabled, and you can either edit transactions or specify new mapping if the synchronization connection is defined to allow intervention for stopped synchronizations. For more information, see:

- ***Viewing and editing transactions*** (on page 86)
- ***Managing new mappings*** (on page 87).

Viewing all jobs for a specific synchronization connection

The Job History tab of the CIS Synchronization Adapter page displays information about all jobs for a specific synchronization.

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Click the row of the synchronization connection that you want to view.

The Status tab of the CIS Synchronization Connection page appears.

4 Click **View Jobs History**.

The Synchronization Connection Job History view of the CIS Synchronizations Status tab appears. This page displays a list of all jobs for the synchronization connection. From this page, you can view details about transaction errors for the job or return to the Status page.

Viewing error details for a job in the job history table

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Click the row of the synchronization connection you want to view.

The Status tab of the CIS Synchronization Connection page appears.

4 Click **View Jobs History**.

The Synchronization Connection Job History view of the CIS Synchronizations Status tab appears.

5 Click **View Error** next to the job for which you want to view errors.

The Synchronization Connection Error Detail view of the CIS Synchronizations page Status tab appears. This page displays error details for the selected synchronization connection. This page provides information about when the errors occurred, the source of the error, and details about the error.

Viewing and editing transactions

You can edit the transaction that caused the last synchronization to fail from the Status tab of the CIS Synchronization page.

Caution: Phase Forward recommends that you edit transactions only when no other option is available. You should also have a well-documented process that meets good clinical practice guidelines when you edit a transaction. Editing a transaction will make the Clintrial data different from the InForm data.

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Click the row of the synchronization connection you want to view.

The Status tab of the CIS Synchronization Connection page appears.

4 Click **View Error**.

The Error Detail view appears.

5 Click **Edit Transaction**.

The Synchronization Connection Transaction Edit screen of the CIS Synchronizations Status tab appears.

6 In the text box, locate the GUID of the transaction that caused the error in the last synchronization and correct the transaction.

7 In the **Reason for edit** field, type the reason for correcting the transaction and the corrections made.

8 Click **Validate** to validate the transaction.

9 Click **Save**.

Managing new mappings

If a synchronization connection has **Stop sync for intervention** selected, the New Mapping Options button is enabled when a synchronization fails because the CIS software has encountered new mappings. Use this button to specify how the new mappings should be processed.

To manage mapping options for the synchronization job:

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Click the row of the synchronization connection you want to view.

The Status tab of the CIS Synchronization Connection page appears.

4 Click **View Error**.

The Synchronization Connection Error Detail view of the CIS Synchronizations page Status tab appears.

5 Click **New Mapping Options**.

The Synchronization Connection New Mapping Options view of the CIS Synchronizations Status tab appears.

6 Complete the fields on the page, and click **Save**.

For more information, see ***Synchronization Connection New Mapping Options, CIS Synchronizations Status tab - Fields*** (on page 90).

Viewing general information about a synchronization connection

You can view general information about the Clintrial and InForm computers for the selected synchronization. The General tab is only for viewing information. You cannot change information in this tab after the synchronization is created.

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Click the row of the synchronization connection you want to view.

The Status tab of the CIS Synchronization Connection page appears.

4 Select **General**.

The General tab of the CIS Synchronizations Connection page appears.

For more information, see ***General tab of the CIS Synchronizations Connection page - Field*** (on page 91)s.

Viewing and changing settings for a synchronization connection

You can view and change synchronization connection information for a specific synchronization connection.

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Click the row of the synchronization connection you want to view.

The Status tab of the CIS Synchronization Connection page appears.

4 Click **Settings**.

The Settings tab of the CIS Synchronization Connection page appears.

5 Complete the fields on the page, and click **Save**.

For more information, see ***Settings tab of the CIS Synchronization Connection page - Fields*** (on page 92).

Status tab of CIS Synchronization Connection page—Fields

From the Status tab of the CIS Synchronization Connection page, you can view:

- Transaction summary information.
- Summary information and error details about the last synchronization connection that ran.
- Information about the job history for the synchronization connection.

Note: In very large studies, the Status tab of the CIS Synchronization Connection page could fail to appear if a query that determines the transaction count times out. If this happens, you cannot view the Status page until the synchronization completes or fails. To prevent this situation, make sure that database statistics are kept up-to-date.

Field	Description
Sync name	Synchronization connection name entered when the synchronization connection was created.
Transaction Summary	The upper part of the page displays information about the total number of transactions in the InForm trial and the Clintrial protocol. The number of transactions displayed in this section is more current than the number displayed in the lower section due to how transactions are processed and how the information for the page is updated.
Direction	• **InForm to Clintrial**—The fields in this row provide information about transactions moving from the InForm to the Clintrial software. • **Clintrial to InForm**—The fields in this row provide information about transactions moving from the Clintrial to the InForm software.
Total Transactions	• **InForm to Clintrial**—Total number of transactions sent from the InForm database to the Clintrial database for the last synchronization job. • **Clintrial to InForm**—Displays the total number of transactions sent from the Clintrial database to the InForm database for the last synchronization job.
Total Processed	• **InForm to Clintrial**—Total number of transactions processed from the InForm software database to the Clintrial software database after the last synchronization job completes. • **Clintrial to InForm**—Total number of transactions processed from the Clintrial software database to the InForm software database after the last synchronization job completes.
Latest Job Status	The lower part of the page displays information about the status for the last synchronization. **Note**: Even though the **Job Status** displays a status of **COMPLETE**, you might notice a discrepancy in the number of transactions for the **InForm to Clintrial Progress** and the **Clintrial To InForm Progress** columns. The discrepancy occurs because although transactions sent by CIS to the InForm Adapter are processed immediately, they are not sent from the InForm Adapter immediately, but are delayed by a predefined interval. As a result, the number of transactions displayed in the **Clintrial To InForm Progress** column can be higher**.** This usually occurs the first time a synchronization runs for the synchronization connection.
Job Status	Status for the last synchronization job—Fault, Complete, or Running.
Machine	Name of the machine that performed the last synchronization job.
Start Time (UTC)	Start date and time of the job for the last synchronization job.
End Time (UTC)	End date and time of the last synchronization job.

Field	Description
Last Action	Details about the progress of the last synchronization job. Possible values are: • JOB_CREATED • MACHINE_ASSIGNED • JOB_INITIALIZED • CREATING_PROTOCOL • PROCESSING_MAPPINGS • INFORM_TO_CLINTRIAL • CLINTRIAL_TO_INFORM
InForm to Clintrial Progress	Total number of transactions sent from the InForm database to the Clintrial database for the last synchronization job.
Clintrial to InForm Progress	Total number of transactions sent from the Clintrial database to the InForm database for the last synchronization job.
View Error	Click to view errors that occurred during the last synchronization job when it has a status of Fault.
View Jobs History	Click to view the history of all jobs for the selected synchronization connection.

New Mapping Options view of CIS Synchronizations Status tab—Fields

Field	Description
Sync name	Synchronization connection name entered when the synchronization connection was created.
Choose new mapping option	• **Assume no data**—If mapping definitions for data items for which no mappings originally existed are synchronize later, the CIS software continues to ignore the previously unmapped data. For those data items, the CIS software processes only data that arrives subsequent to the mapping definitions. • **Replay transactions**—When a new mapping definition arrives, the CIS software replays all transactions that contain the control path in the new mapping. If the CIS software finds any new mappings, it inserts the data in the appropriate Clintrial database column.

Field	Description
Temporarily apply to continuous mappings?	• **Yes**—Apply the option selected in the Choose new mapping option field to all consecutive mapping transactions. • **No**—Apply the option selected in the Choose new mapping option field to a single mapping transaction. **Note:** If No is selected, the synchronization stops for every mapping transaction, and you must select a mapping option each time.
Start sync?	• **Yes**—Start the synchronization immediately. • **No**—Do not start the synchronization immediately. When this option is selected, the synchronization either runs when scheduled or if a user manually runs the synchronization.

General tab of CIS Synchronization Connection page—Fields

Field	Description
Sync name	Synchronization connection name entered when the synchronization connection was created.
CIS Metadata Locale	Specifies the language to use when synchronizing the trial.
Clintrial	Clintrial information about the synchronization connection definition.
Machine	URL of the Clintrial Adapter.
Instance	Clintrial database instance for the synchronization.
Protocol	Clintrial protocol to which the synchronization connection transfers data.
Metadata Only	• **True**—Only metadata is included in the synchronization. • **False**—Metadata and clinical data are included in the synchronization.
Auto-generate Codelist	• **True**—CIS automatically creates a Clintrial codelist for each InForm radio group or pulldown control mapped to a Clintrial item. • **False**—CIS does not create Clintrial codelists.
InForm	InForm information about the synchronization connection definition.
Machine	URL of the location of the InForm Adapter.
Trial	Name of the InForm trial.
Mapping	Name of the mapping definition used for the synchronization.

Settings tab of CIS Synchronization Connection page—Fields

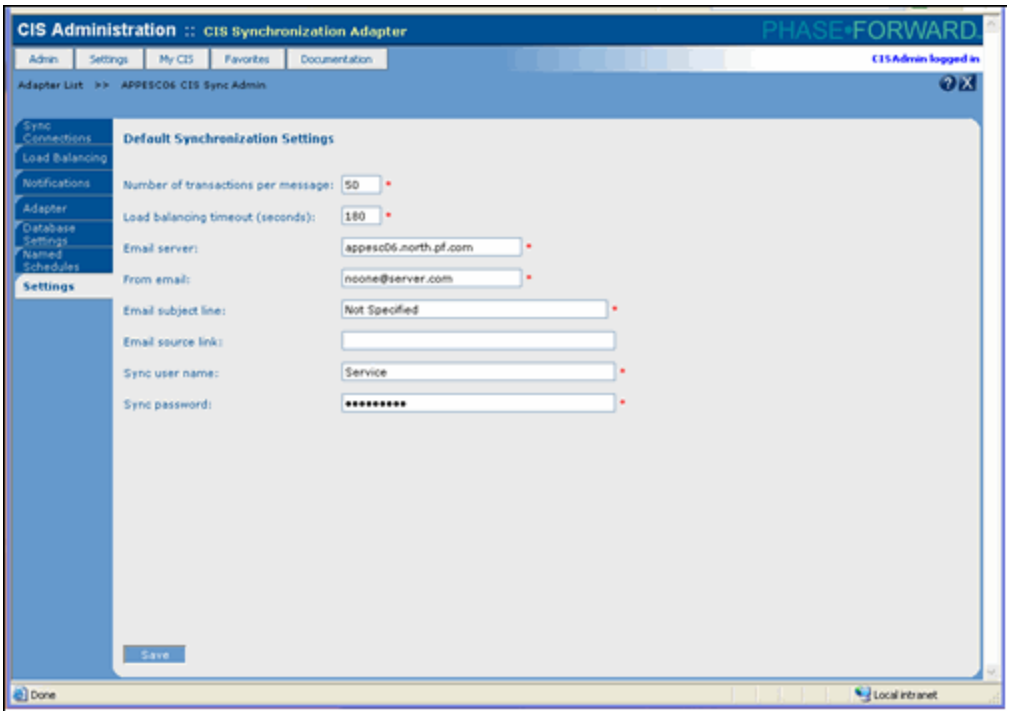
Field	Description
Sync name	Name of the synchronization connection.
Sync description	Description of the synchronization connection.
Enabled	• **Yes**—Connection is enabled when created. When you enable a synchronization, the synchronization begins immediately when it is created. After that, the synchronization runs using the schedule you define. • **No**—Connection is not enabled when created. **Note:** If a synchronization is disabled, you can start the synchronization manually by clicking **Sync Now** on the Sync Connections tab of the CIS Synchronization Adapter page.
Number of transactions per message	Number of transactions in a message. The number of transactions per message is the number of transactions per operation, including the sending and receiving of transactions between InForm Adapters and Clintrial Adapters. In general, the more transactions per message, the faster the synchronization completes because fewer requests are made to the adapters. However, when typing a value for this option, you should consider that all transactions in each operation are in memory. Therefore, if you have a number of synchronizations running, a high number of transactions per operation could result in a greater demand on memory. Phase Forward recommends that you accept the default value of 500 for this option. A lower value might slow down a synchronization.
New mappings	Specifies how the synchronization connection processes new mapping definitions: • **Assume no pre-existing data**—If mapping definitions for data items for which no mappings originally existed are synchronize later, the CIS software continues to ignore the previously unmapped data. For those data items, the CIS software processes only data that arrives subsequent to the mapping definitions. • **Replay sync to gather pre-existing data**—When a new mapping definition arrives, the CIS software replays all transactions that contain the control path in the new mapping. If the CIS software finds any new mappings, it inserts the data in the appropriate Clintrial database column. • **Stop sync for intervention**—When a new mapping definition arrives, the CIS software stops the message queue and waits for a manual intervention.

Field	Description
Auto-create study books	• **Yes**—CIS creates study books for the Clintrial protocol, including page templates and page sections, by using the study component definitions synchronized from InForm software. • **No**—CIS does not create study books for the Clintrial protocol. For more information, see ***Autocreating Clintrial study books*** (on page 73).
Create panels and items	• **Yes (default)**—CIS creates or modifies Clintrial panels and items as defined in the mappings. • **No**—CIS does not create or modify Clintrial panels and items. For more information, see ***Autocreating Clintrial panels and items*** (on page 75).
Schedule type	Type and definition of the schedule on which synchronization runs for this synchronization connection: • **None**—The synchronization connection does not use a schedule. **Note:** If you do not define a schedule, you must manually run synchronization on the synchronization connection. For more information, see ***Starting synchronization manually*** (on page 114). • **Named**—The synchronization connection uses the schedule selected from the drop-down list. • **Custom**—The synchronization connection uses the custom schedule defined in the Days, Start time (UTC), End Time (UTC), and Run every fields.
Days	Days of the week to which the custom schedule applies. Select each day on which to run synchronization.
Start time (UTC)	Time for synchronization to begin running. Specify the time in hours and minutes.
End time (UTC)	Time for synchronization to stop. Specify the time in hours and minutes.
Run every	Interval on which to start synchronization within the specified Start time (UTC) and End time (UTC). For example, if you have a Start Time of 1:00 and an interval of 5 Minutes, the scheduled synchronization begins at 1:00, 1:05, 1:10, and so on. Type a number, and select Hours or Minutes.

Viewing and changing global synchronization connection settings

Overview of changing global synchronization connection settings

You use the Settings tab of the CIS Synchronization Adapter page to ***view and change the values for all synchronization connection settings*** (on page 95).



From the Settings tab, you can set values for the following:

- Number of transactions to send per message during a synchronization. The default value comes from the installation. Changing this value applies only to new synchronizations that you create. Existing synchronizations are not affected by this change.
- The timeout period for load balancing. The default value comes from the installation.
- The email server to use to email notifications when a synchronization failure occurs. This field has no default value. You must set this value for email notifications. For more information, see ***Managing email notifications*** (on page 102).
- The email address that appears in the From field of the email notification.
- The text that appears in the Subject field of the email notification.
- The password for the Sync user.

> **Note:** Changing the password here does not actually change the password of this user. You must also make the change in the Profile tab of the CIS Administration Edit User page. For more information, see ***Editing a user profile*** (on page 55).

Viewing and changing global synchronization connection settings

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Select **Settings**.

The Settings tab of the CIS Synchronization Adapter page appears.

4 Complete the fields on the page, and click **Save**.

For more information, see ***Settings tab of the CIS Synchronization Adapter page - Fields*** (on page 95).

Settings tab of the CIS Synchronization Adapter page—Fields

Field	Description
Number of transactions per message	Number of transactions in a message. The number of transactions per message is the number of transactions per operation, including the sending and receiving of transactions between InForm Adapters and Clintrial Adapters. In general, the more transactions per message, the faster the synchronization completes because fewer requests are made to the adapters. However, when typing a value for this option, you should consider that all transactions in each operation are in memory. Therefore, if you have a number of synchronizations running, a high number of transactions per operation could result in a greater demand on memory. Phase Forward recommends that you accept the default value of 500 for this option. A lower value might slow down a synchronization.
Load balancing timeout (seconds)	Number of seconds for CIS to wait before setting a load-balancing machine on which synchronization has stopped to offline.
Email server	Fully-qualified domain name of the email server being used to send notifications, for example, smtp.company.com.

Field	Description
From email	Email address that will be used as the **From** address in email notifications. **Note:** The address you specify must be a valid email address that has been defined in your email system. The CIS Administration does not prevent you from entering and saving an email address that contains spaces and might not be treated as a single entity. To specify an email address that contains spaces, enclose the email address in double quotes.
Email source link	Web link to the CIS administration login page in the body of the email message.
Sync user name	User name for the CIS Administration user. **Note:** The Sync user name is the Service user.
Sync user password	Password for the CIS Administration user **Important:** Although you can change the Sync user password in this page, you must first change the password for the Service user in the Profile tab of the Security Administration Edit User page. For more information, see ***Editing a user profile*** (on page 55). Then you can make changes in this page.

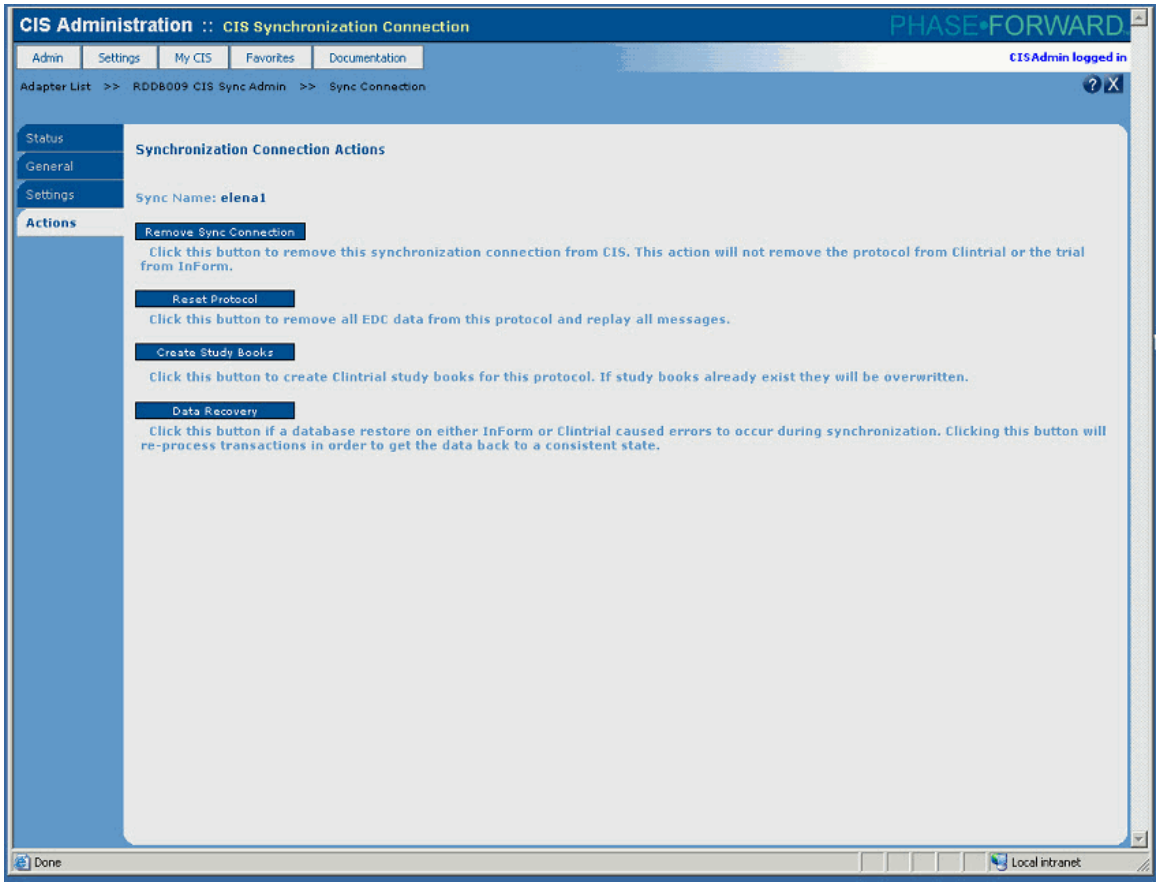
Removing a synchronization connection

Overview of removing a synchronization connection

If you make an error defining a synchronization connection, or if you no longer need a synchronization connection, you can remove the synchronization connection definition.

Note: Removing a synchronization connection does not remove the InForm trial or the Clintrial protocol.

To remove a synchronization connection, you use the Actions tab of the CIS Synchronization Adapter page.



Removing a synchronization connection

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose

synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Click the synchronization connection you want to remove.

The CIS Synchronizations page appears.

4 Select **Actions**.

5 The Actions tab appears.

6 Click **Remove Sync Connection**.

A confirmation page appears.

7 Click **Remove Sync**.

Resetting a protocol and replaying synchronization transactions

Overview of resetting a protocol

If you experience a synchronization failure and need to correct your metadata or mapping definitions by backing out previously synchronized data and metadata, use the Reset Protocol option to restart a synchronization for a specific synchronization connection after making the trial definition corrections.

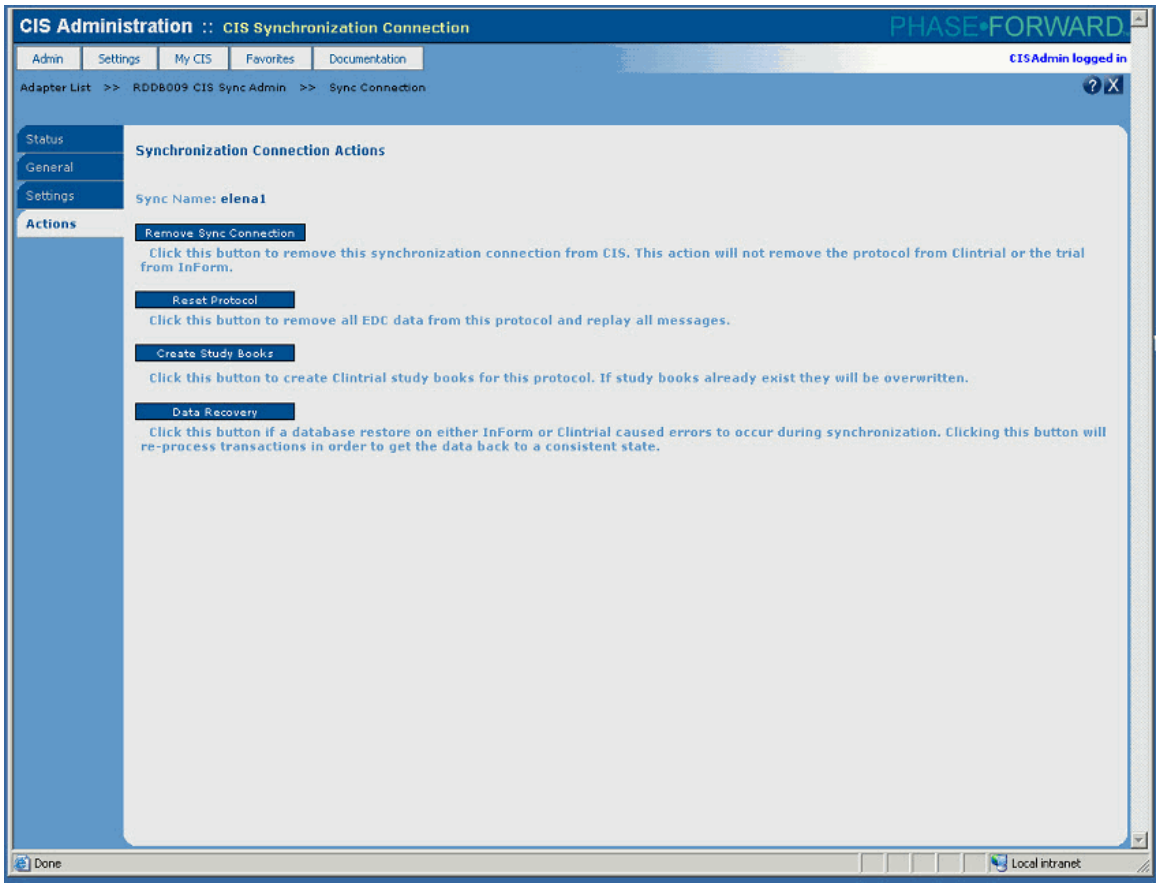
When you reset a protocol, the CIS software:

- Removes all data for EDC subjects including lab loaded data.
- Restarts the synchronization from the beginning and replays all the transactions in the database.

Because all messages are replayed, if your study uses Clintrial rules on EDC data, transactions that are replayed regenerate queries and post them to the InForm software, even if they had previously been resolved.

Caution: This option is intended as a debugging tool when you are developing an integrated trial. Reset Protocol deletes existing Clintrial protocol data before running the synchronization again. Therefore, if you do use this option in a production environment, you should only use it with assistance from Phase Forward Customer Support.

To reset a protocol, you use the Actions tab of the CIS Synchronization page.



Resetting a protocol

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Click the row of the synchronization connection.

The Status tab of the CIS Synchronization Connection page appears.

4 Select **Actions**.

The Actions tab appears.

5 Click **Reset Protocol**.

A confirmation page appears.

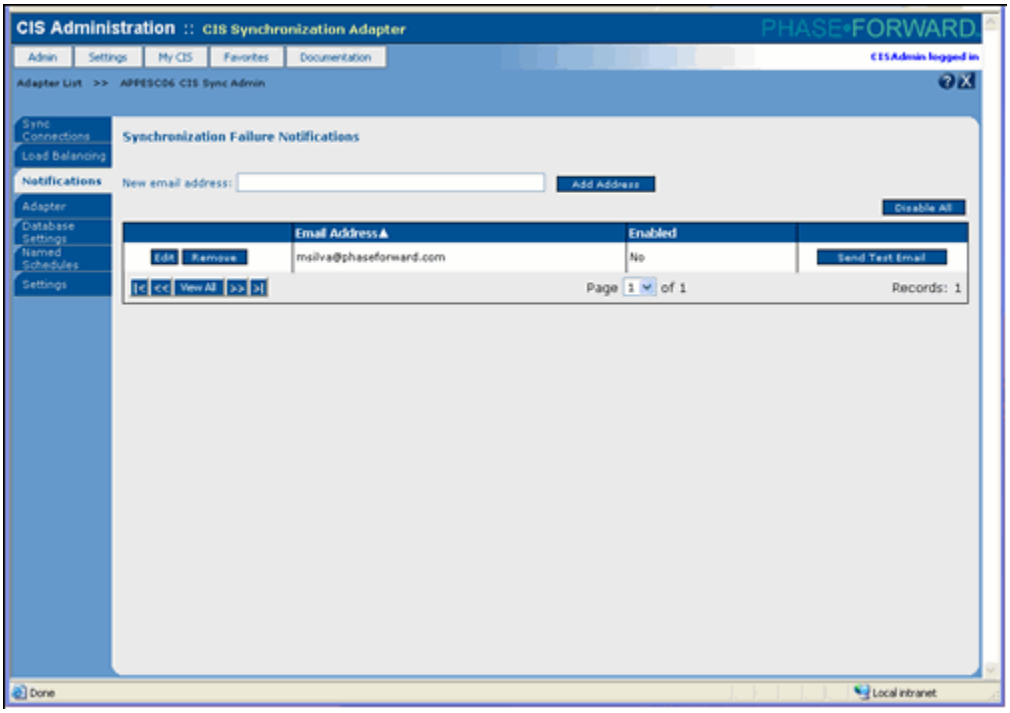
6 Click **Reset Sync**.

Managing email notifications

Overview of managing email notifications

You can configure CIS Administration to send email notifications to specific email addresses if a synchronization fails or a processor goes offline. The text of the notification is the synchronization error message.

To manage email notifications, you use the Notifications tab of the CIS Synchronization Adapter page.



From the Notification tab, you can:

- ***View a list of email addresses*** (on page 102).
- ***Add a new email address*** (on page 103).
- ***Edit an email address*** (on page 104).
- ***Disable all email notifications*** (on page 104).
- ***Remove an email address*** (on page 105).
- ***Send a test email message*** (on page 105).

You can also set global values that apply to all notifications. For more information, see ***Viewing and changing global synchronization connection settings*** (on page 94).

Viewing email notification addresses

To view a list of email addresses that could receive an email notification when a failure occurs:

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Select **Notifications**.

The Notifications tab of the CIS Synchronization Adapter page appears.

This page displays a list of email addresses.

- **Yes** displays in the **Enabled** column if that email address is enabled to receive messages.
- **No** appears in the column if the address is not enabled to receive messages.

For more information, see ***Editing an email address*** (on page 104).

Adding a new email address

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Select **Notifications**.

The Notifications tab of the CIS Synchronization Adapter page appears.

4 In the **New email address** field, type the email address.

Note: The address you specify must be a valid email address that has been defined in your email system. The CIS Administration does not prevent you from entering and saving an email address that contains spaces and might not be treated as a single entity. To specify an email address that contains spaces, enclose the email address in double quotes.

5 Click **Add Address**.

The new address appears in the list of email addresses.

Note: By default, a new email address is enabled to receive messages. To change the enabled setting, see ***Editing an email address*** (on page 104).

Editing an email address

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Select **Notifications**.

The Notifications tab of the CIS Synchronization Adapter page appears.

4 In the **Synchronization Failure Notifications** table, click **Edit** next to the email address you want to change.

The page becomes enabled.

5 In the **Email Address** field, type the new address.

Note: The address you specify must be a valid email address that has been defined in your email system. The CIS Administration does not prevent you from entering and saving an email address that contains spaces and might not be treated as a single entity. To specify an email address that contains spaces, enclose the email address in double quotes.

6 In the **Enabled** column, select Yes or No from the drop-down list to enable or disable the address.

7 Click **Update**.

Disabling all email notifications

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Select **Notifications**.

The Notifications tab of the CIS Synchronization Adapter page appears.

4 Click **Disable All**.

A confirmation page appears.

5 Click **Disable All**.

Note: When you use Disable All to disable email notifications, you must enable each email notification individually. For more information, see ***Editing an email address*** (on page 104).

Removing an email address

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Select **Notifications**.

The Notifications tab of the CIS Synchronization Adapter page appears.

4 In the **Synchronization Failure Notifications** table, click **Remove** next to the email address you want to remove.

A confirmation page appears.

5 Click **Proceed with Deletion**.

Sending a test email notification

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Select **Notifications**.

The Notifications tab of the CIS Synchronization Adapter page appears.

4 In the row for the addressee to whom you want to send a test email message, click **Send Test Email**.

CIS Administration sends a test email to the specified email address.

Note: Email notifications will not necessarily be received immediately. Your specific environment and SMTP configuration can impact how quickly a message is received.

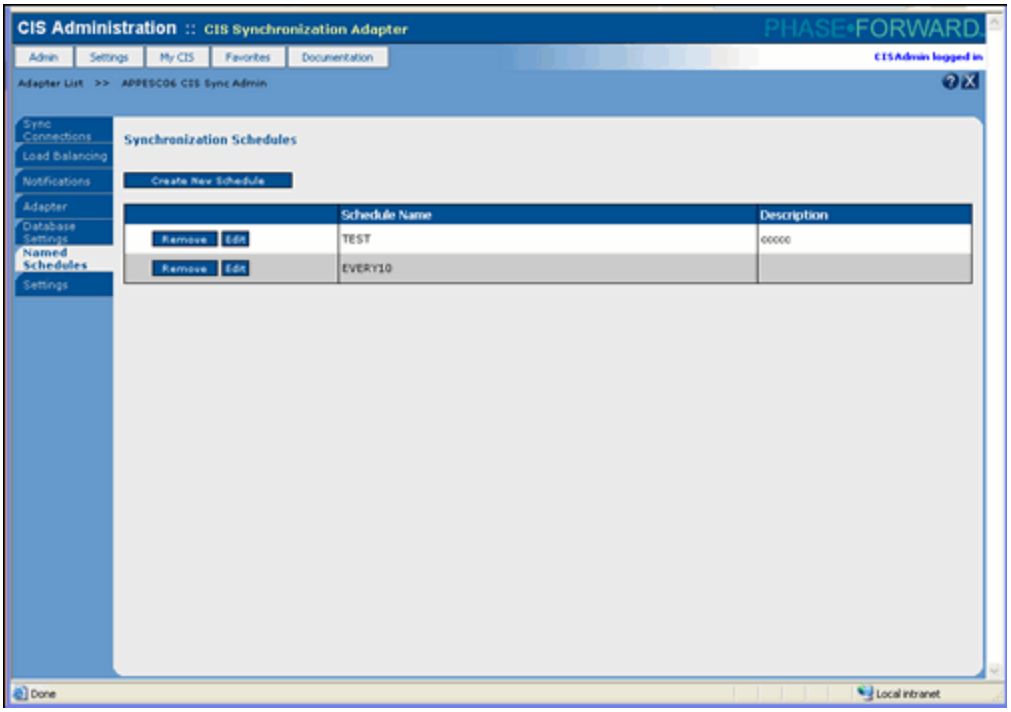
Managing named synchronization schedules

Overview of managing named synchronization schedules

CIS Administration enables you to create named synchronization schedules that one or more synchronization connections can use. When you create a synchronization connection, you can specify the specific named schedule that the synchronization connection uses.

Note: **Synchronization schedule time is stored as UTC time.**

To manage named schedules, use the Named Schedules tab of the CIS Synchronization Adapter page.



From the Named Schedules tab, you can:

- ***View a list of named schedules*** (on page 107).
- ***Add a named schedule*** (on page 108).
- ***Edit a named schedule*** (on page 108).
- ***Remove a named schedule*** (on page 109).

Viewing a list of named schedules

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page

appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Select **Named Schedules**.

The Named Schedules tab of the CIS Synchronization Adapter page appears.

Adding a named schedule

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Select **Named Schedules**.

The Named Schedules tab of the CIS Synchronization Adapter page appears.

4 Click **Create New Schedule**.

The Synchronization Schedule view appears.

5 Complete the fields on the page, and click **Save**.

For more information, see ***Synchronization Schedule view of the Named Schedules tab of the CIS Synchronization Adapter page - Fields*** (on page 109).

Editing a named schedule

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Select **Named Schedules**.

The Named Schedules tab of the CIS Synchronization Adapter page appears.

4 In the **Synchronization Schedules** table, click **Edit** next to the schedule you want to change.

5 Complete the fields on the page, and click **Save**.

For more information, see ***Synchronization Schedule view of the Named Schedules tab of the CIS Synchronization Adapter page - Fields*** (on page 109).

Removing a named schedule

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Select **Named Schedules**.

The Named Schedules tab of the CIS Synchronization Adapter page appears.

4 In the **Synchronization Schedules table**, click **Remove** next to the named schedule you want to remove.

A confirmation page appears.

5 Click **Proceed with Deletion**.

Schedule view, Named Schedules tab, CIS Synchronization Adapter page—Fields

Field	Description
Name	Name of the synchronization schedule.
Description	Description of the synchronization schedule.
Days	Days of the week to which the custom schedule applies. Select each day on which to run synchronization.
Start time (UTC)	Time for synchronization to begin running. Specify the time in hours and minutes.
End time (UTC)	Time for synchronization to stop. Specify the time in hours and minutes.
Run every	Interval on which to start synchronization within the specified Start time (UTC) and End time (UTC). For example, if you have a Start Time of 1:00 and an interval of 5 Minutes, the scheduled synchronization begins at 1:00, 1:05, 1:10, and so on. Type a number, and select Hours or Minutes.

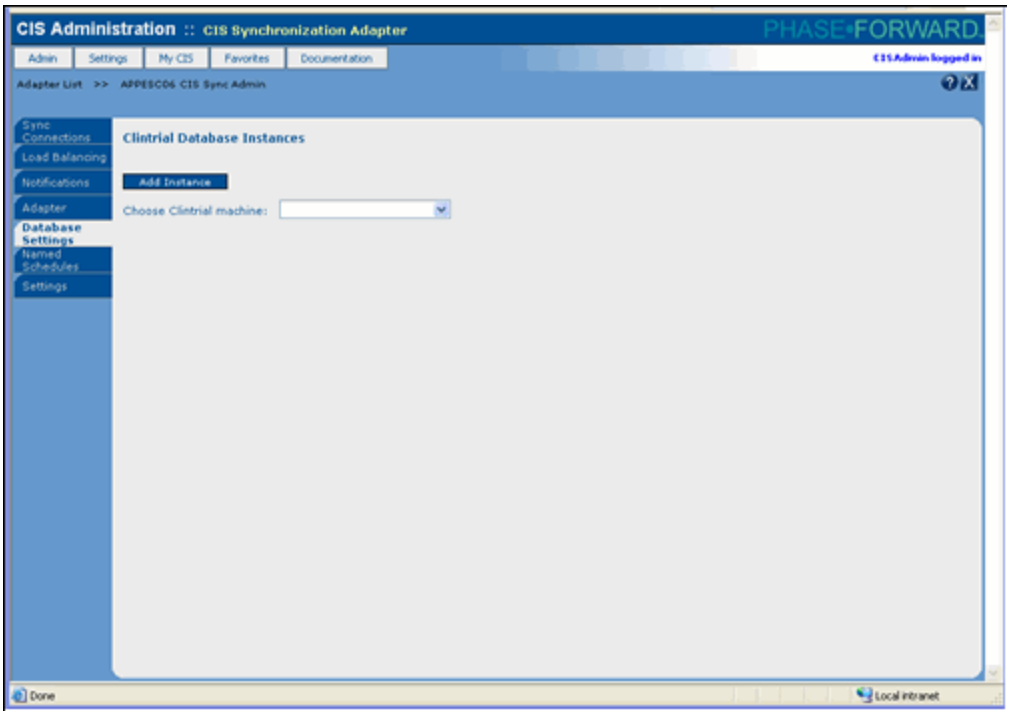
Managing Clintrial database instances for synchronizations

Overview of managing Clintrial database instances

When you install the CIS software, you specify the tnsname of the database instance and the Oracle user name and password for the CIS synchronization database.

CIS Administration enables you to review and update connection information for the Clintrial database instance.

You manage Clintrial database instances from the Database Settings tab of the CIS Synchronization Adapter page.



From the Database Settings tab, you can:

- ***View Clintrial database instances*** (on page 110).
- Add a new Clintrial database instance.
- ***Edit a Clintrial database instance*** (on page 111).
- ***Remove a Clintrial database instance*** (on page 112).

Viewing Clintrial database instances

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page

appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Select **Database Settings**.

The Database Settings tab of the CIS Synchronization Adapter page appears.

4 Select a **Clintrial machine.**

The page displays a list of Clintrial database instances.

Note: The drop-down list is populated only when there is more than one Clintrial machine. If there is only one machine, that machine name is displayed.

Adding a new Clintrial database instance

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Select **Database Settings**.

The Database Settings tab of the CIS Synchronization Adapter page appears.

4 Click **Add Instance**.

The CIS Synchronization Adapter Add Clintrial Database Instance page appears.

5 If the **Clintrial Machine** field has a drop-down list, select the computer where the Clintrial instance for the synchronization connection is installed.

6 Complete the fields on the page, and click **Save**.

For more information, see ***CIS Synchronization Adapter Add Clintrial Database Instance page - Fields*** (on page 113).

Editing a Clintrial database instance

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page

appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Select **Database Settings**.

The Database Settings tab of the CIS Synchronization Adapter page appears.

4 In the **Clintrial Database Instance** table, click **Edit** next to the database instance you want to change.

The Instance, CISUSER Password, and Open Query State fields are enabled.

5 In the **Instance** field, type a new tnsname for the instance.

6 In the **CISUSER Password** field, type a new password.

Important: If you want to change this password, you must first change the Clintrial instance password for Oracle. What you specify for the CISUSER password must be the same as the Oracle password for the Clintrial instance.

7 From the **Open Query State** drop-down list, select the Clintrial discrepancy status that corresponds to the InForm open Query status.

8 Click **Update**.

Removing a reference to a Clintrial database instance

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Select **Database Settings**.

The Database Settings tab of the CIS Synchronization Adapter page appears.

4 In the **Clintrial Database Instances** table, click **Remove** next to the instance for which you want to remove the reference.

A confirmation page appears.

5 Click **Proceed with Deletion**.

Note: This action removes the reference to the instance. It does not remove the actual instance.

CIS Synchronization Adapter Add Clintrial Database Instance page—Fields

Field	Description
Instance	Name of the Clintrial database instance.
CISUSER password	Password for the CISUSER user in the database instance.
Get State Options	Click to populate the State to map queries as open list box.
State to map queries as open	Clintrial discrepancy status that corresponds to the InForm Open query status. There is no default; you must specify a value. This information is used for transfer of query (discrepancy) information from the Clintrial database back to the InForm database. If the value you specify for "State to map queries as open" matches the value in the Clintrial software for "Discrepancy initial status" for the Clintrial rule, the Clintrial discrepancy maps as an Open query in the InForm software. If the values do not match, the Clintrial discrepancy maps as a Candidate query in the InForm software. **Note:** If in the Clintrial software the value for "Discrepancy initial status" of a Clintrial rule is not specified, the CIS software assumes the default value "Ready to Send".

Starting a synchronization manually

Overview of starting a synchronization manually

Sync Now allows you to start a synchronization manually. This option is usually used when there is no schedule defined for the synchronization connection. For more information, see:

- ***Managing named synchronization schedules*** (on page 107).
- ***Monitoring and editing synchronization connections*** (on page 83).

You start a synchronization manually from the Sync Connections tab of the CIS Synchronization Adapter page.

Starting a synchronization manually

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

Note: You cannot use Sync Now if the synchronization is already running.

3 In the row for the synchronization you want to start, click **Sync Now**.

The synchronization begins.

Data recovery

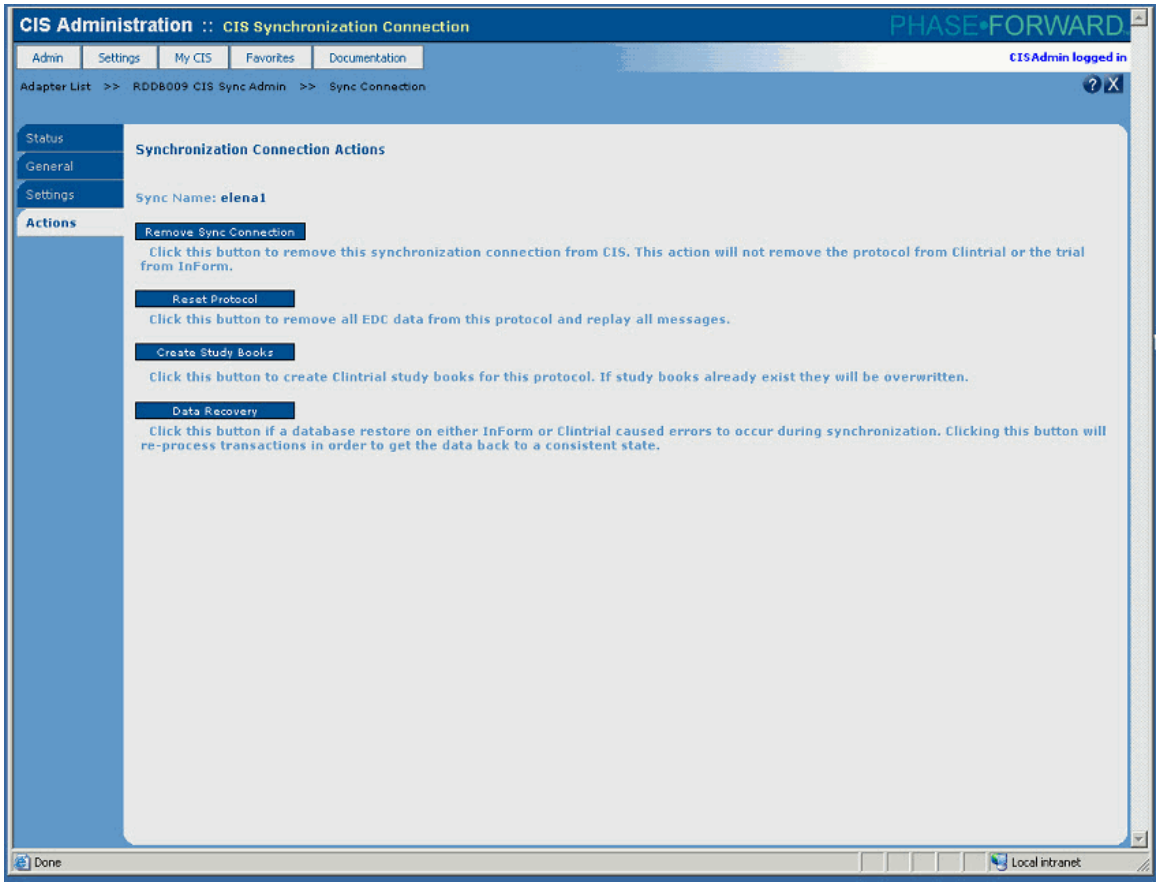
Overview of data recovery

As with all systems that process critical data, you should back up the servers in your CIS environment regularly at a frequency that meets your organization's disaster recovery requirements. Typical schemes include both frequent incremental backups and full backups at a less frequent interval.

Any time you restore from a backup, you must also recover data that was entered between the backup time and the time that the system failed. CIS Administration provides a way to recover lost transactions without re-creating synchronization connections or reentering data manually, by:

- Detecting discrepancies between transactions sent and received on each synchronization connection in the CIS system.
- Stopping the synchronization until a user intervenes. After discrepancies are detected and the user completes the necessary tasks to begin the synchronization, the CIS software then goes through all transactions until both the InForm software and the Clintrial software have all the transactions.

To recover data, you use the Actions tab of the CIS Synchronization Connection page.



Data recovery scenario

Three databases are involved in synchronizing clinical data and metadata between the InForm

software and the Clintrial software:

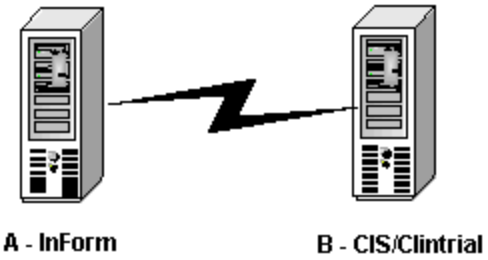
- InForm trial database
- CIS database
- Clintrial instance

These databases can be backed-up independently of one another.

Note: It would be possible for CIS Sync Adapter to automatically recover after a database is restored rather than going into a Data Recovery mode. However, database recoveries are judged to be rare enough and serious enough that user intervention will be required.

Consider the following example.

A CIS configuration consists of one server running the InForm software and one running the CIS and the Clintrial software. A trial on the InForm server A is synchronized through CIS to an InForm protocol on server B. All databases are backed up every 24 hours, and all systems synchronize automatically every 30 minutes.



Disk failure on CIS and Clintrial server B

System B is restored from a nightly backup. All data entered during the last 13 hours on server B is lost. EDC data that has been synchronized from server B exists on server A. The synchronization connection between servers A and B is in a discrepancy state.

Note: Only EDC data can be recovered; data entered directly into the Clintrial software server must be re-created manually.

The recovery process is initiated by the user from the Actions tab of the CIS Synchronizations page. During recovery, all EDC data that was synchronized from server B to server A is synchronized back. For more information, see ***Recovering data*** (on page 117).

After recovery, EDC data on Server B is restored up to the later of:

- The most recent backup.
- The last successful synchronization before failure.

Note: Non-EDC Data on Server B is restored only up to the point of the backup.

Disk failure on InForm software server A

Server A is restored from a nightly backup. All data entered during the last 13 hours on server A is lost. Data that has been synchronized from server A exists on server B. There is a discrepancy between the number of transactions sent and received on the synchronization connection between servers A and B. Therefore, the synchronization connection is in a discrepancy state.

The recovery process is initiated by the user from the Actions tab of the CIS Synchronizations page. During recovery, all data that was synchronized to server B before the failure synchronizes back from server B to server A. For more information, see ***Recovering data*** (on page 117).

After recovery, data on Server A is restored up to the later of:

- The most recent backup.
- The last successful synchronization before failure.

Unrecovered data

In each of these scenarios, the CIS Administration application can detect and restore missing transactions only if:

- The synchronization connection exists, and the messages that created the connection are part of the backup from which you restore the database.
- The transactions have been involved in a synchronization process and are stored in the transaction history of a server that has not failed.

To insure that you recapture all transactions, after recovering you must manually re-enter any data that is not captured in one of the following:

- A database backup.
- A synchronization process.

Additionally, you must manually re-enter data that was entered with the Enter module of the Clintrial software if the Clintrial server fails and is restored.

Recovering data

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Click the row of the synchronization connection for which you want to recover data.

4 Select **Actions**.

The **Actions** tab appears.

5 Click **Data Recovery**.

A confirmation page appears.

6 Click **Recover Data.**

CHAPTER 4

Monitoring and managing load balancing

In this chapter

Overview of monitoring load balancing

Load balancing is a process that:

- Distributes the processing load among multiple machines so that more data can be processed in a shorter period of time.
- Provides fail-over capability by assigning the synchronization processing to another machine when one machine fails.

As implemented in the CIS software, load balancing is a set of software components within the CIS system that distribute synchronization jobs among a pool of machines, called processors. If the CIS software is installed on a single server, it performs all of the load balancing actions described in this section but distributes data only to the single server in the pool.

Load balancing takes place in the following steps:

- A synchronization connection starts to run, either according to a schedule or when requested by a user clicking the Sync Now button in CIS Administration.
- The CIS scheduling software starts a synchronization job.

CIS Administration enables you to check the status of the load-balanced machines in your configuration and to place machines online or offline.

For additional assistance in monitoring synchronization status, CIS Administration includes a notification feature. When you set up email notifications, you can specify the addressees who should receive email notification when a synchronization fails or a synchronization processor goes offline.

How the CIS software selects a processing machine

The load balancer performs selection by:

- Selecting the machine with the highest amount of available processing power (processing threshold minus the current processing load).
- Randomly selecting a machine from all machines with the same power if more than one machine has the same power.

Note: To implement load balancing all CIS servers must use the same Oracle credentials.

Configuring CIS load balancing

When you install the CIS software in an environment where the processing load will be distributed over multiple CIS machines, verify that all CIS servers being used for load balancing use the same Oracle credentials and tnsnames for the CIS and Clintrial databases.

In addition, if you use a hardware load-balancing machine to distribute transaction processing to different InForm Adapters, you must register the load balancing machine with CIS administration. For more information, see ***Registering an InForm Adapter*** (on page 32).

If problems occur during load balancing

Load balancing problems could occur when a machine fails.

Machine failure

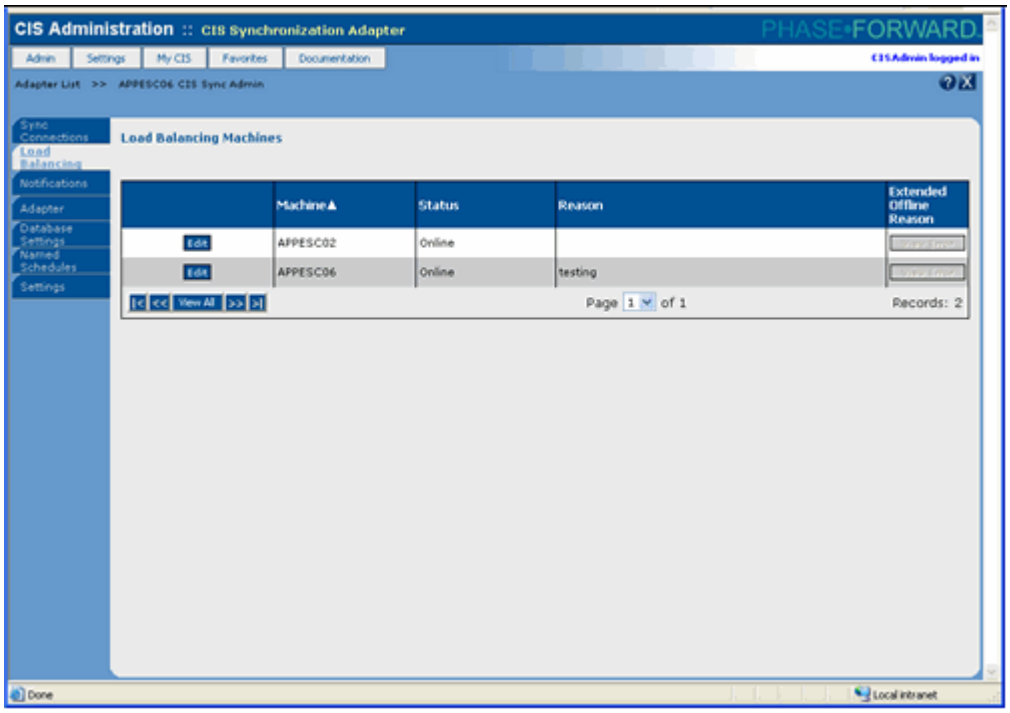
A background thread that runs in the load balancer periodically checks that each processor continues to update its status more frequently than the processing time-out. If the load balancer determines that one of the processors has not responded in time, it automatically marks that processor offline and assigns the synchronization connection to the next available machine.

Recovering from a machine failure

After the load-balancing error has been corrected, you can use the CIS Administration application to set a load-balance machine back online.

Performing load balancing activities

You view and manage the state of a load-balancing machine using the Load Balancing tab of the CIS Synchronization Adapter page.



From the Load Balancing tab, you can:

- ***View load-balancing machine status*** (on page 124).
- ***Take a load-balance machine offline*** (on page 125).
- ***Set a load-balance machine back online*** (on page 125).

Viewing load-balancing machine status

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Select **Load Balancing**.

The Load Balancing tab appears and displays status information about the machines being used for load balancing.

Taking a load-balancing machine off line

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Select **Load Balancing**.

The Load Balancing tab appears and displays status information about the machines being used for load balancing.

4 In the Load Balancing Machines table, click **Edit** next to the load-balance machine whose status you want to change.

The Status and Offline Reason fields are enabled.

5 In the **Status** column for the machine you want to change, select Offline from the drop-down list.

6 Optionally, in the **Offline Reason** column, type a reason for taking the machine off line.

7 Click **Update**.

CIS places the load-balanced machine off line. Synchronization transactions bypass the offline machine and are processed on the next available load-balanced machine.

Setting a load-balancing machine online

1 Select **Admin** > **CIS Sync**.

If only one adapter is configured and registered in the CIS environment, the CIS Synchronization Adapter page appears with the Sync Connections tab selected.

or

If multiple adapters are configured and registered in the CIS environment, the Adapter List page appears and displays a list of adapters.

2 If the **Adapter List** page appears, click the row of the CIS synchronization adapter whose synchronization connections you want to view.

The CIS Synchronization Adapter page appears with the Sync Connections tab selected.

3 Select **Load Balancing**.

The Load Balancing tab appears and displays status information about the machines being used for load balancing.

4 In the Load Balancing table, click **Edit** next to the load-balancing machine whose status you want to change.

The Status and Offline Reason fields are enabled.

5 In the **Status** column for the machine you want to change, select Online from the drop-down list.

6 Click **Update**.

CIS places the machine online.

APPENDIX A

INF_Tables

In this appendix

Overview of INF_ tables

The CIS software creates the INF_ tables in the Clintrial database by CIS when the CIS software synchronizes a study from the InForm software to the Clintrial software.

INF_CODECONTROL

The INF_CODECONTROL table stores the list of InForm PFElement study components that make up a compound control, such as a drop-down list or a radio or checkbox group. Each compound control is represented by multiple records, one for each PFElement.

Rows

One row for each PFElement in a compound control that corresponds to a Clintrial codelist.

Columns

Column name	Data type	Description
CONTROLNAME	VARCHAR2(63)	RefName of a compound InForm control that corresponds to a Clintrial codelist.
CONTROLGUID	VARCHAR2(36)	GUID of the compound control.
ELEMENTNAME	VARCHAR2(63)	RefName of a PFElement study component that is part of the compound control definition.
CODE_ORDER	NUMBER(5)	Order in which the PFElement study component occurs in the compound control.

INF_CODELIST

The INF_CODELIST table stores the mapping between an InForm compound control and its corresponding Clintrial codelist. A Clintrial codelist can consist of multiple InForm compound controls, and an InForm compound control can be included in multiple Clintrial codelists.

Rows

One row for each mapping between a Clintrial codelist and an InForm compound control.

Columns

Column name	Data type	Description
CODENAME	VARCHAR2(20)	Name of a Clintrial codelist.
CONTROLNAME	VARCHAR2(63)	RefName of a corresponding InForm compound control.

INF_ERRORITEM

The INF_ERRORITEM table stores the names and values of items associated with a discrepancy generated by a Clintrial rule or an InForm query against EDC data synchronized from the InForm software. Each record in the INF_ERRORITEM table identifies a data record (with the Clintrial panel name and the CT_RECID) and an item (by the item name).

The columns in the INF_ERRORITEM and INF_ERRORITEM_AUDIT tables are exact mirrors of the VCT_ERRORITEM and VCT_ERRORITEM_AUDIT panels installed with the Clintrial Resolve module.

Rows

One row for each item that is associated with a discrepancy stored as a INF_ERRORSTATUS record. Typically, one record from the INF_ERRORSTATUS table and one or more records from the INF_ERRORITEM table compose a discrepancy record for EDC data.

Columns

Column name	Data type	Description
CT_RECID	VARCHAR2(40)	The Clintrial database identifier of the item associated with an error.
MERGE_ DATETIME	DATE	Oracle SYSDATE when the record was created or modified.
STATUS	NUMBER	Numeric code indicating the status of the record: • **3**—Batch-loaded and not yet screened. • **2**—Entered interactively and not yet verified. • **1**—Passed verification or screening. • **0**—Passed validation. • **-1**—Failed validation or merge. • **-2**—Failed verification. • **-3**—Failed screening. EDC data has a status of 0 or -1.
ENTRY_ID	VARCHAR2(20)	Clintrial or InForm user account that entered or last modified the record.
ENTRY_ DATETIME	DATE	Date and time at which the error record was created.
DB_ID	NUMBER	Unique identifier of the Clintrial database instance. 9999 for EDC data.
SUBJECT_ID	NUMBER	Unique Clintrial identifier assigned to the subject item.
CTS$REASON	VARCHAR2(2000)	Text indicating why the record was created.

Column name	Data type	Description
CTV_ERROR_ID	NUMBER	Unique identifier of the related INF_ERRORSTATUS record. This column joins INF_ERRORITEM records to a specific INFO_ERRORSTATUS record.
CTV_PANEL	VARCHAR2(30)	Name of the panel containing data associated with this discrepancy record.
CTV_DISCR_ RECID	VARCHAR2(40)	The CT_RECID item of the specific associated data record.
CTV_ITEM_ NAME	VARCHAR2(30)	Name of the specific item that you want to associate with this discrepancy record.
CTV_DISCREP_ PAGE_ID	VARCHAR2(240)	Value of the page context item in the associated data record.
CTV_DISCREP_ BLOCK	VARCHAR2(240)	Value of the block context item in the associated data record.
CTV_ITEM_ VALUE	VARCHAR2(2000)	Value of the specific item at the time the discrepancy was detected.
CTV_NEW_ VALUE	VARCHAR2(2000)	Proposed new value for the specified item (or null).
CTV_NEW_ VALUE_GIVEN	NUMBER	Flag indicating whether or not a new value has been provided.
CTV_REPEAT_I D	VARCHAR2(240)	Optional description to provide contextual information about the item.
CTV_REASON	VARCHAR2(2000)	Descriptive text or a code from the CTS_REASON_CODES codelist to describe the change made from the existing item value to the new value.
CTV_ORDER	NUMBER	Order of error items in the table. When determining the InForm item on which to place a Clintrial discrepancy, CIS processes the error items mapped to the InForm item in CTV_ORDER sequence.

INF_ERRORITEM_AUDIT

The INF_ERRORITEM_AUDIT table stores records of changes made to data items associated with discrepancy records through query updates and resolutions performed in the InForm software and synchronized back to the Clintrial software for validation. For EDC data, validation occurs automatically, and the start point of auditing is ENTRY.

Rows

One row for each changed data item.

Columns

The columns in the INF_ERRORITEM_AUDIT table are identical to those in the INF_ERRORITEM table.

INF_ERRORLOG

The INF_ERRORLOG table stores synchronization errors.

Rows

One row for each error.

Columns

Column name	Data type	Description
ERRORID	VARCHAR2(36)	GUID for the error.
SEVERITY	NUMBER	Code indicating type of error: • **0**—Error • **1**—Warning • **3**—Information
DESCRIPTION	VARCHAR2(2000)	Error text.
ERRORDATETIME	DATE	Timestamp of the occurrence of the error.
RESOLUTION	VARCHAR2(2000)	Text documenting resolution of the error as entered from the CIS Administration.
RESOLUTIONDATETIME	DATE	Timestamp of the entry of the resolution documentation.

INF_ERRORSTATUS

The INF_ERRORSTATUS table stores information about discrepancies resulting from running Clintrial rules against EDC data synchronized from the InForm software. It also stores information about queries generated by InForm rules. The INF_ERRORSTATUS table provides information about discrepancies and queries, and the INF_ERRORITEM table provides information about the items against which the discrepancies and queries are raised.

Most of the columns in the INF_ERRORSTATUS and INF_ERRORSTATUS_AUDIT tables are mirrors of the VCT_ERRORSTATUS panels installed with the Clintrial Resolve module. The INF_ERRORSTATUS and INF_ERRORSTATUS_AUDIT tables include one additional column: QUERYGUID.

When an integrated protocol is enabled for the Resolve module, the CIS software creates additional columns in the VCT_ERRORSTATUS panels.

Rows

One row for each discrepancy that is generated by a Clintrial rule running against an EDC data item.

Columns

Column name	Data type	Description
CT_RECID	VARCHAR2(40)	The Clintrial database identifier of the item associated with a discrepancy.
MERGE_ DATETIME	DATE	Oracle SYSDATE when the record was created or modified.
STATUS	NUMBER	Numeric code indicating the status of the record: • **3**—Batch-loaded and not yet screened. • **2**—Entered interactively and not yet verified. • **1**—Passed verification or screening. • **0**—Passed validation. • **-1**—Failed validation or merge. • **-2**—Failed verification. • **-3**—Failed screening. EDC data has a status of 0 or -1.
ENTRY_ID	VARCHAR2(20)	Clintrial or InForm user account that entered or last modified the record.
ENTRY_ DATETIME	DATE	Date and time at which the error record was created.
DB_ID	NUMBER	Unique identifier of the Clintrial database instance. 9999 for EDC data.

Column name	Data type	Description
SUBJECT_ID	NUMBER	Unique identifier assigned to the subject item.
CTS$REASON	VARCHAR2(2000)	Text indicating why the record was created.
CTV_ERROR_ID	NUMBER	Identifying number for a discrepancy record. ID numbers are unique within a protocol.
CTV_SOURCE	VARCHAR2(20)	Source of a discrepancy. For queries generated by InForm rules, the value is INFORM. For discrepancies generated by Clintrial rules, the standard Clintrial sources apply: • MANUAL • RULE • FLAG • CLASSIFY
CTV_CONTEXT1	VARCHAR2(240)	Value of the first context item (subject identifier) from the data record that is the source of the discrepancy.
CTV_REMARKS	VARCHAR2(240)	Description of the data error, provided by the creator of the discrepancy record. For discrepancy records created by rules, the description provided within the rule is supplied.
CTV_REPLACE_ REMARKS	VARCHAR2(2000)	Allows a review to replace the description in the CTV_REMARKS column. When this column has a value, it displays on query forms in place of CTV_REMARKS. For discrepancy records created by rules, the description provided within the rule is supplied.
CTV_ADDTL_ REMARKS	VARCHAR2(2000)	Appended to CTV_REMARKS or to CTV_REPLACE_REMARKS on standard data discrepancy forms.
CTV_ COMMENTS_1	VARCHAR2(2000)	Internal comments from the first review (data management). Blank for queries generated by InForm software rules.
CTV_ COMMENTS_2	VARCHAR2(2000)	Additional internal comments

Column name	Data type	Description
CTV_DSTATUS	VARCHAR2(30)	Discrepancy status of the record. The following values are states of EDC discrepancies in Clintrial software: • **AC**—Auto-closed by the Clintrial software; that is, the item passes when a Clintrial rule runs against its value. • **O**—Candidate or Open in Clintrial software. The following values are states of EDC queries in InForm software: • **0 (zero)**—Candidate. • **1**—Open. For an item validated by a Clintrial rule, this state occurs only when a query is reissued. • **2**—Answered. • **3**—Closed. • **4**—Deleted. • **5**—Sponsor conflict. • **6**—Site conflict.
CTV_STATUS_ CHANGE_DT	DATE	Date and time that the CTV_DSTATUS was last modified.
CTV_PRIORITY	NUMBER	Stores a user-defined priority. For example, a three-point scale can indicate discrepancies of high, medium, or low priority. • For records created by rules, the priority can be assigned automatically. • For manually entered records, the person creating the record enters a priority.
CTV_CLOSED_ DATE	DATE	Date and time the record is placed in a terminal discrepancy status (such as Resolution Applied or Linked).
CTV_ CONFIRMATION_FL A	NUMBER	Indicates that a resolution for the discrepancy record has been entered in the database, and only confirmation form the investigator is needed.
CTV_PROPOSAL_TE XT	VARCHAR2(2000)	Description of a proposed resolution. Useful for complex resolutions or if no INF_ERRORITEM records are associated with the discrepancy record.

Column name	Data type	Description
CTV_ RESOLUTION_ CODE	VARCHAR2(20)	Stores descriptive text or a code from the CTS_REASON_CODES codelist to indicate a resolution reason (for example, original value confirmed or corrected value supplied). Supplied automatically from system parameters as follows: • From CTV_APPL_RES_CODE during applied proposed value processing. • From CTV_AUTOCLOSED_RES when validation auto-closes a discrepancy record. • From CTV_OBSOLETE_RES when a discrepancy record's status is updated to Obsolete.
CTV_ RESOLUTION_ COMME	VARCHAR2(2000)	Message explaining an unusual resolution or the reason for the change.
CTV_LINKED_ ERROR_ID	NUMBER	CTV_ERROR_ID of another discrepancy record. Used for records in Linked or Reissued discrepancy status to point to the discrepancy record that remains open.
CTV_RULE_ NAME	VARCHAR2(40)	For records created by rules, stores the name of the rule.
CTV_FORM_ BATCH_NUM	NUMBER	Identifier assigned to all records in a batch of data discrepancy forms. All records in a batch have the same batch number. This number can be used to recall the batch for reprinting, or to browse for and display records once the forms are returned.
CTV_FORM_ BATCH_DATE	DATE	Date and time the batch was printed. All records in a batch have the same Form Batch Date.
CTV_BATCH_ ORDER_NUM	NUMBER	A number that sorts discrepancy records in a batch into the order in which they appeared on printed data discrepancy forms.
CTV_PANEL	VARCHAR2(30)	Name of the panel containing the primary clinical data record associated with the discrepancy record.
CTV_DISCR_ RECID	VARCHAR2(40)	CT_RECID of the primary data record associated with the discrepancy record.
CTV_ORCTABLE	VARCHAR2(20)	Oracle table where the primary data record was at the time the discrepancy was detected (that is, update or data).
CTV_DISCREP_ PAGE_ID	VARCHAR2(240)	Value of the page context item of the primary record.
CTV_DISCREP_ BLOCK	VARCHAR2(240)	Value of the block context item of the primary record.

Column name	Data type	Description
CTV_REC_ MODDATE	DATE	Date of last modification of the primary record at the time the discrepancy was detected.
CTV_ERRDT	DATE	Date and time the record was first inserted into the INF_ERRORSTATUS table.
CTV_ERRTYPE	VARCHAR2(10)	Process that created the discrepancy record: • VALIDATE—For discrepancies generated by Clintrial rules during CIS auto-validation. • INFORM—For queries generated by InForm rules.
CTV_ERRACT	VARCHAR2(20)	For records created by rules, error action (Report or Reject) taken by the rule.
QUERYGUID	VARCHAR2(36)	Unique ID assigned to the query returned to the InForm software on synchronization.

INF_ERRORSTATUS_AUDIT

The INF_ERRORSTSATUS_AUDIT table stores records of changes made to discrepancy records through query updates and resolutions performed in the InForm software and synchronized back to the Clintrial software for validation. For EDC data, validation occurs automatically, and the start point of auditing is ENTRY.

Rows

One row for each changed discrepancy record.

Columns

The columns in the INF_ERRORSTATUS_AUDIT table are identical to those in the INF_ERRORSTATUS table.

INF_FORMSTATUS

The INF_FORMSTATUS table stores information about the status of a form within the InForm software. The data in this table is used by the functions within the ct_edc_event package, and you can reference it within Clintrial rules.

Rows

One row for each instance of an InForm form.

Columns

Column name	Data type	Description
PATIENTGUID	VARCHAR2(36)	InForm patient identifier.
VISITGUID	VARCHAR2(36)	InForm visit identifier.
VISITINDEX	FLOAT	InForm visit index, if the visit is repeating.
PAGEGUID	VARCHAR2(36)	InForm page identifier.
PAGEINDEX	FLOAT	InForm page index, if the page is repeating.
RECREVISIONNUMBER	NUMBER	Revision number (timestamp) of the status change for the form. The highest number is the current revision.
PFDATETIME	DATE	Date and time when the status of the form changed in the InForm software.
USERGUID	VARCHAR2(36)	GUID of the InForm user who caused the status change.
LOCKEDSTATE	NUMBERPS(38,0)	Flag indicating whether the form is locked: • **1**—True • **0**—False
FROZENSTATE	NUMBERPS(38,0)	Flag indicating whether the form is frozen: • **1**—True • **0**—False
SIGNEDSTATE	NUMBERPS(38,0)	Flag indicating whether the form is signed: • **1**—True • **0**—False
FORMSTATE	NUMBERPS(38,0)	Bitmask summarizing the state of the form. The value is the sum of all of the form state bit values that apply. These values are described in ***FORMSTATE values*** (on page 143).

INF_ITEMINSTANCE

The INF_ITEMINSTANCE table stores identifiers and time stamp data that ties an instance of an item in the Clintrial software to:

- Its entry time in the InForm software.
- The source machine in the InForm software from which it originated.
- The reason why the item was not entered, if any.

Rows

One row for each instance of an item.

Columns

Column name	Data type	Description
CTRECID	VARCHAR2(40)	Clintrial record identifier.
ITEMNAME	VARCHAR2(36	Clintrial item name.
RECREVISIONNUMBER	FLOAT	Revision number (timestamp) of the original InForm transaction. The highest number is the current revision.
PFDATETIME	DATE	Date and time of the original InForm transaction.
SOURCEMACHINE	VARCHAR2(40)	GUID identifying the InForm machine where the data originated.
NOTDONEREASON	VARCHAR2(2000)	Reason given in the InForm software why the data was not entered for this item.

FORMSTATE values

The following table describes the bit values that make up the summary of the state of an InForm form, as stored in the FORMSTATE column of the INF_FORMSTATUS table.

Bit value component	Description	Hex Value
PFP_STARTED	Form was started with data, comments, or queries.	1
PFP_QUERIES	Form has queries.	2
PFP_MISSINGITEMS	Form has missing data.	4
PFP_SDVREADY	Form has been marked ready for source verification.	8
PFP_FROZEN	Form is frozen.	10
PFP_LOCKED	Form is locked.	20
PFP_SIGNED	Form is signed.	40
PFP_SDVCOMPLETE	Form has been marked completely source verified.	80
PFP_SDVPARTIAL	Form has been marked partially source verified.	100
PFP_MARKEDASNOTDONE	Form has been marked not completed with a form-level comment.	200
PFP_HASCOMMENT	Form has a form-level comment.	400
PFP_FORMHASDATA	Form has data.	800
PFP_DYNADELETE	Form was generated by a dynamic form rule and was subsequently deleted.	1000
PFP_DELETEDFORM	Instance of a repeating form has been deleted.	2000

INF_ITEMSTATUS

The INF_ITEMSTATUS table stores information about the status of an item within the InForm software. The data in this table is used by the functions within the ct_edc_event package, and you can reference it within Clintrial rules.

Rows

One row for each instance of an InForm item that has been source verified.

Columns

Column name	Data type	Description
PATIENTGUID	VARCHAR2(36)	InForm patient identifier.
VISITGUID	VARCHAR2(36)	InForm visit identifier.
VISITINDEX	FLOAT	InForm visit index, if the visit is repeating.
PAGEGUID	VARCHAR2(36)	InForm page identifier.
PAGEINDEX	FLOAT	InForm page index, if the page is repeating.
SECTIONGUID	VARCHAR2(36)	InForm section identifier.
ITEMSETGUID	VARCHAR2(36)	InForm itemset identifier, if the item occurs within an itemset.
ITEMSETINDEX	FLOAT	InForm itemset index, if the instance is an itemset. The corresponding Clintrial repeat identifier is stored as a suffix to the CTRECID.
ITEMGUID	VARCHAR2(36)	InForm item identifier.
RECREVISIONNUMBER	NUMBER	Revision number (timestamp) of the status change for the item. The highest number is the current revision.
PFDATETIME	DATE	Date and time when the status of the item changed in the InForm software.
USERGUID	VARCHAR2(36)	GUID of the InForm user who caused the status change.
SDVSTATE	NUMBERPS(38,0)	Flag indicating whether the item has been source verified: • **1**—True. • **0**—False. An item has a 0 value only if it has been source verified and then marked not source verified. Items that have never been source verified do not appear in the table.

INF_MSGEDIT_HISTORY

The INF_MSGEDIT_HISTORY table stores an audit record of each synchronized transaction that was changed by using the transaction edit feature of CIS Administration.

Rows

One row for each transaction that was edited.

Columns

Column name	Data type	Description
TRANSACTIONID	VARCHAR2(36)	GUID of the transaction for the edit operation (the audit trail for the edit).
EDITEDTRANSACTIONID	VARCHAR2(255)	GUID of the transaction that was edited.
EDITORMACHINE	VARCHAR2(255)	Simple machine name of the CIS application server that processed the transaction edit.
EDITUSER	VARCHAR2(255)	User name of the user who edited the transaction.
EDITUSERHOST	VARCHAR2(255)	Simple machine name of the CIS client computer that was running the web browser where a user edited the transaction. The format consists of two values that are separated by a comma: • Host name of the client computer. • IP address of the client computer. If the Host name is not available, the EDITUSERHOST value consists of two identical IP addresses that are separated by a comma.
EDITDATETIME	DATE	UTC time at which the transaction edit occurred.
REASON	VARCHAR2(2000)	Reason for editing the message.
TRANSACTIONCONTENT	LONG VARCHAR	Before and after image of the transaction XML.

INF_OBJECTS

The INF_OBJECTS table stores information about InForm objects that have special processing requirements during synchronization.

Rows

One row for each InForm object.

Columns

Column name	Data type	Description
OBJECTGUID	VARCHAR2(36)	InForm GUID for the object.
OBJECTREFNAME	VARCHAR2(64)	InForm RefName for the object. CIS uses this to associate the object with the Clintrial PageRef or VisitRef.
OBJECTTYPE	VARCHAR2(30)	Type of object: • VISIT • PAGE • CALCULATEDITEM • SPECIALCONTROL
REPEATING	VARCHAR2(1)	Boolean indicating whether a Visit or Page object has repeats.
UUID	VARCHAR(63)	UUID for InForm enrollment records. CIS uses this value during validation of enrollment data from the InForm software, to prevent Clintrial discrepancies from being sent to screening or enrollment forms in the InForm software.

INF_OUTGOINGTRANSACTIONS

The INF_OUTGOINGTRANSACTIONS table stores data about each outgoing transaction passed from the Clintrial software to the InForm software and CIS. This table is populated by a trigger on the discrepancy table so that Clintrial discrepancies can be sent back to the InForm software as query transactions. Populating this table enables CIS to send InForm queries from in-line validation as well as from validation that has been run in batch.

Rows

One row for each transaction.

Columns

Column name	Data type	Description
CTRECID	VARCHAR2(40)	Clintrial database identifier of the object that encapsulates the transaction to send to the InForm software. This joins with the CTRECID column of the INF_ERRORSTATUS table.
TRANSACTIONSEQUENCE	NUMBER	Ordinal used to identify separate transactions for the same object.
TRANSACTIONGUID	VARCHAR2(36)	Unique identifier of the transaction (NULL until sent).
TRANSACTIONREVISION NUMBER	FLOAT	Revision number that encapsulates the timestamp of the creation of the transaction record (NULL until sent).
ENTRY_DATETIME	DATE	Timestamp of the entry of this record.
TRANSACTIONTYPE	NUMBER	Identifies the transaction type as a query transaction.

INF_PANELINSTANCE

The INF_PANELINSTANCE table stores identifiers that tie together an InForm instance of data to a Clintrial instance of data. An instance of data is one of the following:

- Data from one InForm itemset row.
- Data from a non-itemset item in a single InForm form instance.

Rows

One row for each instance of data.

Columns

Column name	Data type	Description
CTRECID	VARCHAR2(40)	CTRECID for the specific Clintrial record.
PANELNAME	VARCHAR2(36)	Name of the Clintrial panel in which the record appears.
PATIENTGUID	VARCHAR2(36)	InForm patient identifier.
VISITGUID	VARCHAR2(36)	InForm visit identifier.
PAGEGUID	VARCHAR2(36)	InForm page identifier.
VISITINDEX	FLOAT	InForm visit index, if the visit is repeating.
VISITREPEAT	NUMBER	Clintrial repeat identifier that corresponds to the visit index, if the visit is repeating.
PAGEINDEX	FLOAT	InForm page index, if the page is repeating.
PAGEREPEAT	NUMBER	Clintrial repeat identifier that corresponds to the page index, if the page is repeating.
ITEMSETINDEX	FLOAT	InForm itemset index, if the instance is an itemset. The corresponding Clintrial repeat identifier is stored as a suffix to the CTRECID.

INF_PATHMAP

The INF_PATHMAP table stores InForm GUIDs that identify a unique InForm path, along with other data that specifies a Clintrial mapping definition. CIS uses this information to identify the columns in which to store each piece of data entered or updated on an InForm form.

Rows

One row for each unique InForm path.

Columns

Column name	Data type	Description
VISITGUID	VARCHAR2(36)	GUID of an InForm visit.
PAGEGUID	VARCHAR2(36)	GUID of an InForm form.
SECTIONGUID	VARCHAR2(36)	GUID of an InForm section.
ITEMSETGUID	VARCHAR2(36)	GUID of an InForm itemset.
ITEMGUID	VARCHAR2(36)	GUID of an InForm item.
CONTROL1GUID	VARCHAR2(36)	GUID of an InForm control.
CONTROL2GUID, CONTROL3GUID, CONTROL4GUID, CONTROL5GUID	VARCHAR2(36)	GUID of an InForm control nested within another control. Each additional column denotes another level of nesting, up to the five levels supported by the InForm software.
BLOCKKEY	VARCHAR2(100)	Page key value specified for the mapping.
PAGEKEY	VARCHAR2(100)	Block key value specified for the mapping.
PANELNAME	VARCHAR2(36)	Name of the Clintrial panel targeted by the InForm path that the GUIDs define.
ITEMNAME	VARCHAR2(36)	Name of the Clintrial item targeted by the Clintrial path that the GUIDs define.
SUBSETVALUE	VARCHAR2(2000)	Subset Value to store with the InForm path that the GUIDs define.
SUBSETITEM	VARCHAR2(36)	Name of the Clintrial item in which to store the Subset Value.

Column name	Data type	Description
DATEPART	NUMBER	Date time control component to be stored in the Clintrial item, if the components are being stored separately: • **1**—Month • **2**—Day • **3**—Year • **4**—Hour • **5**—Minute • **6**—Second
INFSITEUSERMAP	NUMBER	Not used.
INFSITEUSERPROPERTY	VARCHAR2(64)	Not used.

INF_PENDINGVALIDATIONS

The INF_PENDINGVALIDATIONS table stores information about the validation status of Clintrial data records that have changed during transaction processing.

Rows

One row for each changed Clintrial record identified by a CTRECID and a panel name.

Columns

Column name	Data type	Description
VALIDATION SEQUENCE	NUMBER	Sequence in which the record is validated.
PANELNAME	VARCHAR2(36)	Name of the panel requiring validation.
CTRECID	VARCHAR2(40)	Clintrial ID of the record requiring validation.
VALIDATION EXECUTED	NUMBER	Boolean indicating whether validation has been run: • **0 (default)**—Validation has not been run. • **1**—Validation has been run.
VALIDATIONDATE	DATE	Oracle SYSDATE (localized date and time from the Oracle server) at which validation was run.
VALIDATIONERROR	NUMBER	Flag indicating the validation error status: • **0**—No error or the error was recorded in CTS.JOB_LOG. • **1**—An error occurred that was too serious to be recorded in CTS.JOB_LOG.

INF_PFELEMENT

The INF_PFELEMENT table stores information about transactions that pass PFElement data from an InForm compound control, such as a pulldown, radio, or checkbox control, to a Clintrial codelist. A PFELEMENT transaction describes a single entry in a codelist, including the code and value of the codelist entry.

Rows

One row for each InForm PFELEMENT transaction.

Columns

Column name	Data type	Description
ELEMENTNAME	VARCHAR2(63)	RefName of the PFElement study component.
LABEL	VARCHAR2(80)	Label of the PFElement study component.
VALUE	VARCHAR2(80)	Data value of the PFElement study component.
ELEMENTTYPE	VARCHAR2(10)	Data type of the PFElement study component: • TEXT (InForm String>). • FIXED (InForm Integer or Float).

INF_RULE

The INF_RULE table stores information about Clintrial rules or derivations that are synchronized to a Clintrial protocol from the InForm software.

Rows

One row for each rule or derivation.

Columns

Column name	Data type	Description
NAME	VARCHAR2(255)	InForm RefName of the rule or derivation. The name is converted to upper-case.
TYPE	NUMBER(1)	0 for a rule; 1 for a derivation.
XMLDATA	LONG	MedML RULE definition.

INF_SIMPLECONTROL

The INF_SIMPLECONTROL table stores information about transactions that pass SIMPLECONTROL data from an InForm compound control, such as a pulldown, radio, or checkbox control, to a Clintrial codelist. A simple control study component wraps a PFElement study component in a radio or checkbox group. A SIMPLECONTROL transaction maps the RefName of the simple control to the RefName of the PFElement.

Rows

One row for each InForm SIMPLECONTROL transaction.

Columns

Column name	Data type	Description
CONTROLNAME	VARCHAR2(63)	RefName of the simple control that wraps a PFElement study component in a compound control that CIS converts to a Clintrial codelist.
ELEMENTNAME	VARCHAR2(63)	RefName of the PFElement for which the simple control is a wrapper.

INF_SITE_AUDIT, INF_SITE_DATA, INF_SITE_UPDATE

The INF_SITE_AUDIT, INF_SITE_DATA, and INF_SITE_UPDATE panels store are a set of type 0 panels that hold InForm site information in a Clintrial protocol. This information is not associated with any specific subject, block, and page context.

The _AUDIT, _DATA, and _UPDATE tables associated with these panels have identical formats.

Rows

One row for each site in an InForm trial.

Columns

Column name	Data type	Description
MERGE_DATETIME	DATE	Date and time of the latest modification to the site record.
STATUS	NUMBER	Numeric code indicating the status of the record. This is set to 1 and not changed by CIS processing.
ENTRY_ID	VARCHAR2(20)	User account of the user who entered or last modified the record. For InForm SITE tables, the account is INFORM.
ENTRY_DATETIME	DATE	Date and time at which the site record was entered in the InForm software.
CT_RECID	VARCHAR2(40)	Unique record ID assigned to the record in the Clintrial software.
DB_ID	NUMBER	Unique identifier of the Clintrial database instance. The DB_ID for EDC data is 9999.
SUBJECT_ID	NUMBER	Unique identifier automatically assigned to the subject item. For SITE tables, the value is 1.
CTS$REASON	VARCHAR2(2000)	Reason that the record was modified or deleted.
SITEFAXNUMBER	VARCHAR2(255)	Fax number of the site.
SITEDAYPHONENUMBER	VARCHAR2(32)	Daytime phone number of the site.
SITECOUNTRY	VARCHAR2(127)	Country in which the site is located.
SITEPOSTALCODE	VARCHAR2(64)	Zip or postal code of the site's location.
SITECITY	VARCHAR2(127)	City in which the site is located.
DISABLED	NUMBER	Not used currently.

Column name	Data type	Description
SITESERVER	VARCHAR2(255)	Name of the server designated as the site server. In an InForm configuration where synchronization is used, the site server is dedicated for specific activities such as randomization, screening and enrollment, and generating patient numbers.
SITETIMEZONE	VARCHAR2(64)	Time zone in which the site is located, used to convert from internal universal system time to local time.
SITEALTPHONE NUMBER	VARCHAR2(32)	Alternate phone number for the site.
GROUPDESCRIPTION	VARCHAR2(255)	Not used currently.
SITESTUDYTERMINATION	DATE	Date that the site came off line; for example, date that the last patient was signed off and locked.
SITESTATEPROVINCE	VARCHAR2(64)	State or province in which the site is located.
SITEBEEPER	VARCHAR2(255)	Beeper number of the site.
SITEDATEFORMAT	VARCHAR2(32)	The format of the date as displayed for the site, if a format is not specified at the user level. • **0**—Month/Day/Year • **1**—Day/Month/Year • **2**—Year/Month/Day
SITESTUDYINITIATIOND	DATE	Date that the site came on line. Users cannot add data for a site before the specified date.
GROUPNAME	VARCHAR2(255)	Name of the site group to which the site belongs. If no site group is specified, site name is used.
GROUPCONFLICT	NUMBER	Not used currently.
SITEMNEMONIC	VARCHAR2(32)	Abbreviated name with which to refer to the site.
SITEEMAILADDRESS	VARCHAR2(255)	Email address of the site.
SITECONTACTUSER	VARCHAR2(64)	Not used currently.
SITEADDRESS1	VARCHAR2(255)	First line of the mailing address of the site.
SITEADDRESS2	VARCHAR2(255)	Second line of the mailing address of the site.

INF_SUBJECT

The INF_SUBJECT table stores the mapping between the InForm representation of a patient and the Clintrial representation of a patient.

Rows

One row for each patient.

Columns

Column name	Data type	Description
PATIENTGUID	VARCHAR2(36)	GUID that uniquely identifies a patient within the InForm software.
SITEGUID	VARCHAR2(36)	GUID of the InForm site to which the patient belongs.
SUBJECT_ID	NUMBERPS(18,0)	Unique subject identifier generated by the Clintrial software for the patient.
ENTRY_DATETIME	DATE	Date time (localized on the Oracle database server) when the row was inserted or updated in the database.

INF_STUDYVERSION

INF_STUDYVERSION table that is created for each protocol.

INF_STUDYVERSION rows

One row for each InForm STUDYVERSION transaction.

INF_STUDYVERSION columns

Column name	Data type	Description
TRANSACTIONID	Number	A value from INF_TRANSACTION.TRANSACTIONID. When a study book is to be generated, the row of INF_STUDYVERSION with the highest TRANSACTIONID is used to find the current InForm study version.

INF_SUBJECT_AUDIT

The INF_SUBJECT_AUDIT table stores a record of each changed SUBJECT_ID. The CIS software copies the INF_SUBJECT record to the INF_SUBJECT_AUDIT table before updating the SUBJECT_ID.

Rows

One row for each changed SUBJECT_ID.

Columns

The INF_SUBJECT_AUDIT table has the same columns as the INF_SUBJECT table.

Note: The ENTRY_DATETIME column, which could be NULL in the INF_SUBJECT table for records that existed in previous versions of the CIS software, cannot be NULL in the INF_SUBJECT_AUDIT table. If INF_SUBJECT.ENTRY_DATETIME is NULL, then the CIS software creates a value for the new row in INF_SUBJECT_AUDIT.ENTRY_DATETIME that is one second less than the ENTRY_DATETIME of the updated row in INF_SUBJECT.

INF_TRANSACTION

The INF_TRANSACTION table stores information identifying and specifying the status of EDC transactions passed between the InForm software and the Clintrial software through the CIS software.

Rows

One row for each transaction.

Columns

Column name	Data type	Description
TRANSACTIONGUID	VARCHAR2(64)	GUID of the transaction.
TRANSACTIONID	NUMBER	Oracle sequence number incremented automatically for each transaction added.
TRANSACTIONSTATUS	NUMBER	Boolean indicating whether the transaction has been processed. This is set to 1 when the transaction is added to the INF_TRANSACTION table.

INF_TRANSACTIONDATA

The INF_TRANSACTIONDATA table stores the XML text of EDC transactions passed between the InForm software and the Clintrial software through the CIS software.

Rows

One row for each transaction.

Columns

Column name	Data type	Description
TRANSACTIONID	NUMBER	Local ID of the transaction. This joins with the TRANSACTIONID column of the INF_TRANSACTION table.
TRANSACTIONDATA	CLOB	Full XML text of the transaction.

INF_USER_AUDIT, INF_USER_DATA, INF_USER_UPDATE

The INF_USER_AUDIT, INF_USER_DATA, and INF_USER_UPDATE panels store are a set of type 0 panels that hold InForm user information in a Clintrial protocol. This data is not associated with any specific subject, block, and page context.

The _AUDIT, _DATA, and _UPDATE tables associated with these panels have identical formats.

Rows

One row for each InForm user.

Columns

Column name	Data type	Description
MERGE_DATETIME	DATE	Date and time of the latest modification to the user record.
STATUS	NUMBER	Numeric code indicating the status of the record. This is set to 1 and is not changed by CIS processing.
ENTRY_ID	VARCHAR2(20)	User account of the user who entered or last modified the record. For InForm USER tables, the account is INFORM.
ENTRY_DATETIME	DATE	Date and time at which the user record was entered in the InForm software.
CT_RECID	VARCHAR2(40)	Unique record ID assigned to the record in the Clintrial software.
DB_ID	NUMBER	Unique identifier of the Clintrial database instance. The DB_ID for EDC data is 9999.
SUBJECT_ID	NUMBER	Unique identifier automatically assigned to the subject item. For USER tables, the value is 1.
CTS$REASON	VARCHAR2(2000)	Reason that the record was modified or deleted.
USERDISPLAYNAME	VARCHAR2(64)	User name as displayed on the navigation pane in the InForm trial.
USERDELETESTATE	NUMBER	Flag that indicates whether the user has been terminated: • **1**—True • **2**—False
USERFIRSTNAME	VARCHAR2(127)	First name of the user.
USERDAYPHONE NUMBER	VARCHAR2(255)	Daytime phone number for the user.

Column name	Data type	Description
USERAUTHTYPE	VARCHAR2(32)	Not used currently.
USEREMAILADDRESS	VARCHAR2(255)	Email address of the user.
USERSUBJECTGUID	VARCHAR2(255)	GUID of the user; not used currently.
USERNAME	VARCHAR2(255)	Name the user enters to log on to InForm software.
USERSTATEPROVINCE	VARCHAR2(64)	State or province in which the address of the user is located.
USERPOSTALCODE	VARCHAR2(64)	Zip or postal code of the address of the user.
USERIMAGEID	VARCHAR2(36)	GUID of the resource storing the image of the user; not used currently.
USERHOMESCREENURL	VARCHAR2(255)	Local or external URL identifying the initial screen that appears when a user logs in to the InForm software. The address must include the http:// prefix and identify the server on which the file is located by name or IP address.
USERADDRESS1	VARCHAR2(255)	First line of the address of the user.
USERADDRESS2	VARCHAR2(255)	Second line of the address of the user.
USERRESETPASSWORD	NUMBER	Flag indicating whether the user must reset the password when logging in to the InForm software for the first time: • **1**—False • **0**—True
USERCONFLICT	NUMBER	Not used currently.
USERFAXNUMBER	VARCHAR2(255)	Fax number of the user.
USERCITY	VARCHAR2(127)	City where the user is located.
USERTITLE	VARCHAR2(255)	Title of the user.
USERLASTNAME	VARCHAR2(127)	Last name of the user.
USERDESCRIPTION	VARCHAR2(255)	Description of the user; for example, role of the user in the trial.
USERALTPHONE NUMBER	VARCHAR2(32)	Alternate phone number for the user.
USERLANGID	VARCHAR2(64)	Preferred language of the user. English Language is the default.

Column name	Data type	Description
USERDATEFORMAT	VARCHAR2(32)	Desired date format of the user for viewable InForm pages: • **0**—Month/Day/Year • **1**—Day/Month/Year • **2**—Year/Month/Day
USERBEEPER	VARCHAR2(255)	Beeper number of the user.
USERACTIVESTATE	NUMBER	Flag indicating whether the user is active: • **1**—Active • **0**—Inactive
USERCOUNTRY	VARCHAR2(127)	Country where the user is located.
USERTYPE	NUMBER	Type of user: • **0**—System • **1**—Site • **2**—Sponsor

APPENDIX B

CIS_Tables

In this appendix

Overview of CIS_Tables

The CIS_LB_MACHINES, CIS_SYNCH_JOBS, and CIS_DEFAULT_PROPERTIES tables are used to support load balancing.

CIS_LB_MACHINES

The CIS_LB_MACHINES table stores the available (online) processors used for load balancing.

CIS_LB_MACHINES rows

Each load-balancing machine can have multiple rows. When a load-balancing machine is updated, a new row is inserted using the same MACHINEGUID but a higher MACHINEVERSION. The combined values of MACHINEGUID and MACHINEVERSION make a row unique. The row with the highest MACHINEVERSION is the current row for the load-balancing machine.

CIS_LB_MACHINES columns

Column name	Data type	Description
MACHINEGUID	VARCHAR2(50) not null	Unique identifier for a specific processor.
MACHINEVERSION	INTEGER not null	Record version for a machine of a given GUID. MACHINEVERSION is used for auditing.
MACHINENAME	VARCHAR2(75) null	User specified name of the processor.
MACHINEDESCRIPTION	VARCHAR2(250) null	User-specified description of the machine.
MACHINEURL	VARCHAR2(500) null	User-specified URL of the machine. This entry is used to construct WE Web service calls to interfaces with the processor's CIS Sync Adapter.
STATUS	VARCHAR2(50) null	String representing the current status of the machine. Possible values are: • ONLINE • OFFLINE
OFFLINEREASON	VARCHAR2(100) null	String explaining why the machine was brought offline.
OFFLINEREASONEXCEPTIONMSG	CLOB null	String containing the exception message caught when the machine is placed offline by the code instead of manually by the administrator.
MAXLOAD	INT null	User-specified parameter indicating how many synchronization jobs the processor is capable of running concurrently.

Column name	Data type	Description
DELETED	INT default 0 null	Parameter indicating that the machine has been removed from the load-balance pool. 1 = deleted 0 = not deleted

CIS_SYNCH_JOBS_QUEUE

The CIS_SYNCH_JOBS_QUEUE table stores basic information about synchronization jobs. The information in this table is used by the load-balancing process to process the jobs one at a time.

CIS_SYNCH_JOB_QUEUE rows

A new row is added every time a synchronization is executed. This row contains information for that specific synchronization (for example, the Start time and End time).

CIS_SYNCH_JOBS_QUEUE columns

Column name	Data type	Description
JOBQUEUEGUID	VARCHAR2(36) not null	Unique identifier for synchronization job.
JOBQUEUESTATUS	VARCHAR2(50)null	String representing the current status of the job. Possible values are: • PENDING • COMPLETE • RUNNING • FAULT
JOBQUEUESTARTTIME	DATE null	Start Time for synchronization job.
JOBQUEUELASTUPDATE	null	Time of last heartbeat as entered by the Synchronization Monitor (SM) thread.
JOBQUEUEENDTIME	DATE null	End time for synchronization job.
SYNCHGUID	VARCHAR2(36) null	Foreign key to synchronization connection table (CIS_SYNCHCONNECTIONS) establishing the synch connection to which a particular job is related.
SYNCHVERSION	INTEGER null	Foreign key to Synch Connection table (CIS_SYNCHCONNECTIONS) establishing the version of the synch connection to which a particular job is related.
MACHINEGUID	VARCHAR2(50) null	Foreign key to load-balance machine table (CIS_LB_MACHINES) establishing the processor handling a connection.

Column name	Data type	Description
MACHINEVERSION	INTEGER null	Foreign key to load-balance machine table (CIS_LB_MACHINES) establishing version of the processor handling a connection.
CURRENTACTION	VARCHAR2(50) null	String further describing the current activity on an active synchronization. Possible values are: • JOB_CREATED • MACHINE_ASSIGNED • JOB_INITIALIZED • CREATING_PROTOCOL • PROCESSING_MAPPINGS • INFORM_TO_CLINTRIAL • CLINTRIAL_TO_INFORM • SYNC_JOB_COMPLETE
CLINTRIALPROCESSED	INT null	Number indicating the cumulative number of transactions that have been processed by the Clintrial software for this job.
INFORMPROCESSED	INT null	Number indicating the cumulative number of transactions that have been processed by the InForm software for this job.

CIS_DEFAULT_PROPERTIES

The CIS_DEFAULT_PROPERTIES table stores information about global settings.

CIS_DEFAULT_PROPERTIES rows

Information that is specified in the Settings tab is global to the CIS software (for example, Email settings, Time out settings and so on).

CIS_DEFAULT_PROPERTIES columns

Column name	Data type	Description
CONFIGVERSION	FLOAT not null	Version of the configuration. The only active configuration is the latest one. Previous versions exist for audit purposes.
CONFIGXML CLOB	null, constraint	Property-value pairs contained in an XML format. The following shows these property-value pairs: <settings> <EmailServer></EmailServer> <FromEmail></FromEmail> <EmailSubject></EmailSubject> <NumberTransactions></NumberTransactions> <timeout></timeout> <PlatformUser></PlatformUser> <PlatformPassword></PlatformPassword> <SyncPort></SyncPort> <LBRetryWait></LBRetryWait> <HBTimePeriod></HBTimePeriod </settings>

APPENDIX C

Data transfer and storage

In this appendix

Overview of data transfer and storage

This appendix describes the data stores used in the CIS system and the mechanisms used for transporting data between the CIS software components. This section also describes how data is audited in the CIS system and how the Clintrial software and the InForm software handle data deletions.

Databases in the CIS system

The CIS environment, comprising the Clintrial software, InForm software, and CIS software, includes several Oracle databases that manage data storage for the activities performed by the three software products.

Clintrial database

The Clintrial server in a CIS environment hosts a database of clinical data. Site personnel, monitors, data managers, and project managers use the Clintrial client modules to:

- Enter, update, verify, and validate paper-based clinical data.
- Import clinical data in batch mode.
- Analyze and archive studies.

Additionally, if an integrated study is set up to use Clintrial rules and derivations to validate EDC data, those rules and derivations usually run automatically against data synchronized from an InForm study. Rules and derivations are not run automatically when:

- There are cross-panel dependencies in rules scripts. Rules in the Clintrial are attached to one panel and there is no way of determining (before a rule generates a query) that rules should run when data on a different panel changes.
- Rules are changed.

In these situations, you should run manual validation.

Queries generated in the Clintrial software by validation failure synchronize back to the InForm study for resolution.

Important data structures in the Clintrial database

The Clintrial database for a specific protocol stores data used in integrated studies in the following tables. For full descriptions of data structures in the Clintrial database, refer to the Clintrial *Reference Guide*.

Data	Tables
Clinical data	UPDATE, DATA, and AUDIT clinical data tables When a panel defining a set of clinical data items is installed, the Clintrial software creates one of each of these tables. The name of the table is in the format panelname_tabletype, for example, DMG_DATA. • **UPDATE**—When a user first enters data, it is stored in the update table. The update table stores data that has not been merged. • **DATA**—After data passes validation in the update table, you can merge, or move, the data to the data table. • **AUDIT**—The audit table stores copies of clinical data records as they existed before modification or deletion. Data in the audit table cannot be changed. Clintrial protocol data can be audited after data entry or after validation. EDC data transferred from an integrated study is audited after data entry.
Clintrial discrepancy data	VCT tables These tables, VCT_ERRORITEM_UPDATE and VCT_ERRORSTATUS_UPDATE, are copied from the CTVRESOLVEREF protocol into each protocol that you set up as a Resolve protocol. These tables track items that are associated with a discrepancy.
Error data	ERRORLOG table This table stores information about errors that occur during screening, validation, merging, and global change or deletion.
Flag and note data	TAGS tables This table stores information about flags and notes that are attached to clinical data.

Data	Tables
EDC protocol management data	INF_ tables When CIS synchronizes a protocol used for EDC data to Clintrial software, it creates a set of tables to hold information required for processing the EDC data. These tables hold: • **Query data**—These tables track items that are associated with queries generated by Clintrial rules on EDC data. The tables have the same columns as the corresponding VCT tables in the Clintrial software, except that the INF_ERRORSTATUS tables have an extra column for QUERYGUID. • **Mapping specifications**—These tables identify the correspondences between the InForm software and Clintrial software study objects. • **Non-clinical study data**—These tables store InForm site and user information. • **Status**—These tables store form and item state information. • **Other tables**—Additional EDC data tables store information about study objects that require special handling, such as calculated items; synchronization errors; the audit trail for edited transactions; and outgoing transactions sending queries back to the InForm software. The names of these tables have the prefix INF_.

Clinical data table structure

Each UPDATE, DATA, and AUDIT table has the same structure, consisting of a column for each:

- System item created by the Clintrial software. System items are:
  - **ENTRY_DATETIME and MERGE_DATETIME**—Entry and merge datetime stamps.
  - **DB_ID, CT_RECID, ENTRY_ID, and SUBJECT_ID**—Internal database, record, user, and subject IDs.
  - **STATUS**—Record status.
  - **CTS$REASON**—Reason that the record was changed or deleted.
- CONTEXT panel item identifying the study subject and the block and page with which the clinical data row is associated. The record might contain additional CONTEXT panel items defined by the study designer and used to uniquely identify the record.
- Clinical data item.

InForm databases

The InForm server in a CIS environment has the following databases by default:

- InForm study database, which contains:
  - Study definition metadata.
  - Mapping definition metadata.
  - Production clinical data entered through the InForm EDC interface at a web browser.
- INFORMADMIN database, which contains study configuration data.

Important data structures in the InForm databases

For the most part, the study database and INFORMADMIN database schemas are designed to optimize performance but do not organize information in a way that is relevant to study sponsor personnel.

CIS databases

The CIS server in a CIS environment has the CIS database that contains synchronization information. This database also stores the encrypted CISUSER password for each Clintrial database instance. The CIS server and Clintrial server must either be the same machine or must be on the same local area network.

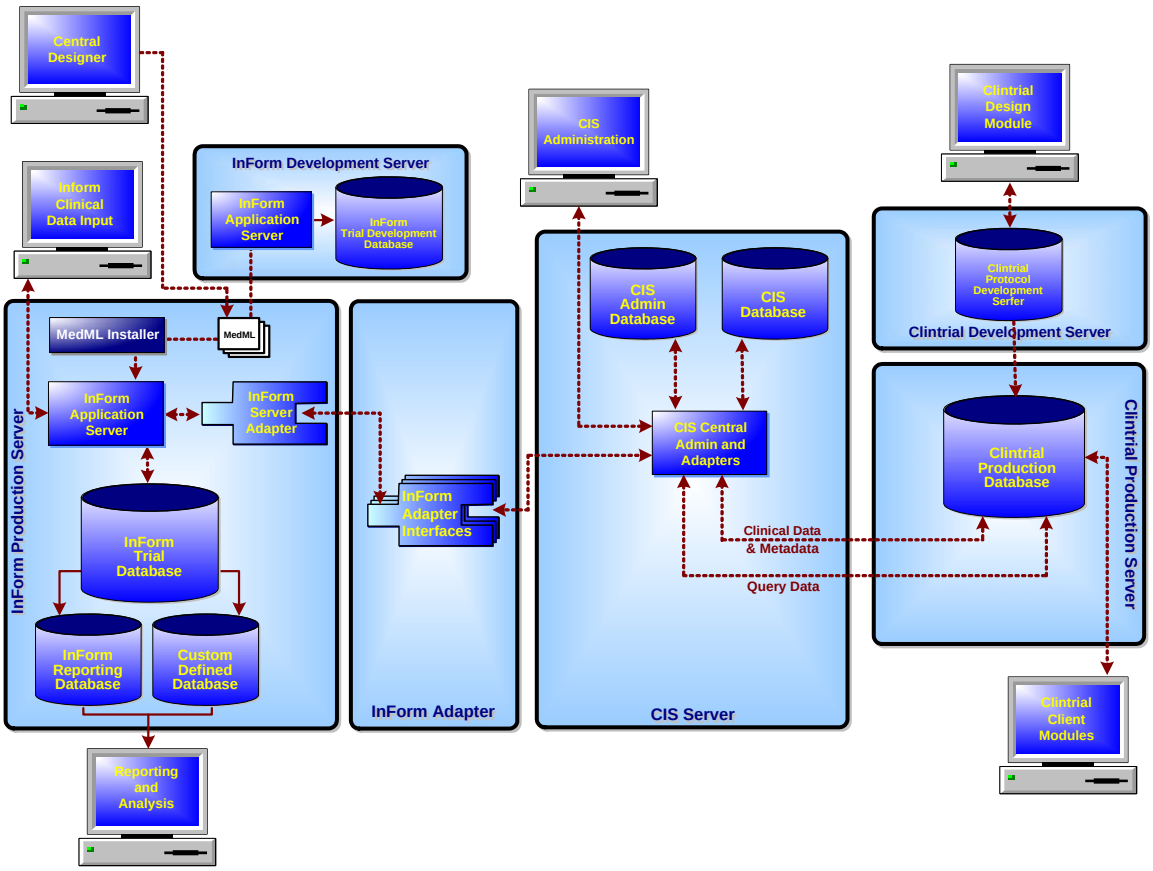
Important data structures in the CIS database

The tables in the CIS database hold:

- Version and revision information.
- User definitions.
- Reference to the Clintrial instance with which a protocol is associated.
- Data that identifies and defines:
  - Translated protocol objects.
  - Mappings between protocol data items and Clintrial data table columns.

Data transfer summary

The following diagram and table summarize the metadata and data transfers that occur during the development and production phases of an integrated study.



Data/Metadata	From	To	Process
Clintrial protocol metadata	Clintrial software	CIS Library	When you register a Clintrial protocol in a CIS library, the CIS software translates the protocol to study MedML, generates Clintrial mappings, transfers the MedML, and stores the study metadata and mappings in the library. This occurs over an OLEDB connection.

Data/Metadata	From	To	Process
Central Designer deployment package	Central Designer software	InForm software	When you deploy a study created in the Central Designer software to the InForm software, the Central Designer study components and workflow are translated to InForm study components. The conversion to InForm study components is based on both the data definition of each study component and the layout specified for each form or item in the Central Designer software. For more information, see the information about Central Designer and InForm study component correspondences in the ***Central Designer*** *User's Guide* ***Volume 3, Working with Study Objects***, in the chapter ***Validating and Deploying a Study***.
InForm study metadata and EDC clinical data	InForm software	Clintrial software via CIS software	When you synchronize a study definition or clinical data from the InForm software to a Clintrial protocol, the CIS software: 1 Initiates the synchronization. 2 Creates the protocol if it does not already exist. 3 Gets metadata and data transactions from the InForm software through the InForm Adapter. 4 Puts the metadata and data into the Clintrial database. 5 Gets transactions from the Clintrial software for queries only and sends them back to the InForm software through the InForm Adapter.
Clintrial queries	Clintrial software	InForm software	When a study is designed to validate EDC data with Clintrial rules and derivations, and the validation results in the generation of queries.

Deletion and undeletion processing

When EDC data is deleted in the InForm software and the action is synchronized to the Clintrial software, the CIS software processes deletions and other related transactions in the Clintrial tables as follows.

InForm action	Clintrial table updates
Delete a record.	• **Data**—Delete the corresponding UPDATE and DATA table row, and add a record to the AUDIT table, containing a copy of the data before deletion. • **Comments**—Delete the corresponding row from the TAGS table. • **Discrepancies**—Auto-close discrepancies on the deleted records, and rerun validation on any panels that have discrepancies with error items that refer to the deleted records.
Add a comment to a deleted record.	Add a record to the TAGS_AUDIT table.
Add a query to an empty form.	Create a record in the UPDATE table for the panel to which the InForm item is mapped, if the InForm item is mapped to the Clintrial software. If the InForm path for the query is mapped to multiple Clintrial panel items, CIS creates a query record for only one of the mappings.
Add a query to a deleted record.	Discard the query.

InForm action	Clintrial table updates
Undelete an itemset row or repeating form instance.	• **Data**—Create a row in the UPDATE table, using the CTRECID of the data from before the deletion, obtained from the AUDIT table. Populate the row with data from the AUDIT table. If a patient number changes in the InForm software, and then a deleted record associated with that patient is undeleted, the AUDIT table used to obtain the rest of the deleted data holds the old patient number. In this case, CIS obtains the new patient number from the enrollment panel. **For protocols started before CIS 4.0 SP4**—Until the 4.0 SP4 release, CIS did not delete records in the Clintrial software when processing an InForm delete transaction. Instead, CIS set items in the UPDATE table to NULL. These all-NULL records might still exist in the Clintrial database. CIS processes an undelete on these records as follows: ▪ If the UPDATE table already includes a row for the itemset or repeating form record containing all NULL values, update the row with the itemset or repeating form values, using data from the AUDIT table. ▪ If the DATA table already includes a row for the itemset or repeating form record containing all NULL values, delete the row in the DATA table and insert a row in the UPDATE table, using data from the AUDIT table. It is possible for CIS to transfer data from the InForm software to a record that contains all NULL values. If such a data transaction is then followed by an undelete, synchronization fails. In the very unlikely event that a failure occurs because of this circumstance, please contact Phase Forward support for assistance. • **Comments**—Recover any deleted comments from the TAGS_AUDIT table. • **Discrepancies**—CIS does not recover any deleted discrepancies. To recover a manual query, a user must re-enter the query. Validation must be run again to open discrepancies.

Caution: A delete or undelete action can affect multiple rows in multiple panels.

Audit processing

Transactions in an integrated study cause the creation of audit records in the Clintrial and InForm databases. This section describes general audit processing in an integrated study and discusses the following specific audit considerations:

- Auditing of manually edited transactions.
- Processing of entry and merge date times in the Clintrial software.

General audit trail information

Auditing of transactions that occur in an integrated study occurs in both the Clintrial software and the InForm software.

Auditing in the Clintrial software

In the Clintrial software, auditing tracks changes to clinical data and notes associated with clinical data:

- For data entered with the Enter module, study designers can configure the point at which auditing begins, and auditing tracks changes or deletions made to records and notes after the audit start point: Entry, Verification, Validation, Validity, or Merge.
- For EDC data, when you synchronize metadata for an integrated study designed with the Central Designer software to a Clintrial protocol, CIS creates new panels if they do not already exist in the protocol. When CIS creates Clintrial panels, it automatically sets the audit start point of each panel to Entry.

Note: If you create a panel with the Design module of the Clintrial software to be used for EDC data, you must manually define the panel with an audit start point of Entry. Similarly, do not change the audit start point for panels created by CIS. Creating or changing a panel to an audit start point other than Entry can result in the inability to reinstate data that has been deleted in the InForm software.

Audit data is stored in the AUDIT table for each clinical data panel in a protocol.

The Audit Record Report, available in the Manage module of the Clintrial software, shows changes and deletions made to a selected panel's records after the audit start point has been reached.

Auditing in the InForm software

In the InForm software, auditing tracks all additions, changes, and deletions made to clinical data from the point of original entry.

Users of the InForm software can track audit data on the Audit screen for each data item of an electronic CRF. For each addition, change, or deletion, the Audit Trail screen shows the server, date and time of change, user, change data, and change reason.

The source machine of each transaction appears in the Server column of the Audit Trail screen. For an EDC transaction, the source machine is the one on which the InForm software is installed. For a query transaction originating in the Clintrial software and synchronized to the InForm software through CIS, the audit trail shows the Oracle TNS name used by the CIS machine to connect to the

database, along with the name of the protocol, in the format *TNSName.ProtocolName*.

Transaction edits

The Transaction Edit Screen page of CIS Administration enables authorized users to edit failed transactions from the synchronization job so that synchronizations can continue.

Changes to synchronization transactions made through CIS Administration do not update the InForm audit trail or Clintrial audit tables as do data changes performed through the InForm software or the Clintrial Enter module data entry screens. Changes appear in the Clintrial Enter module but do not appear in the InForm interface. For more information, see the ***INF_MSGEDIT_HISTORY*** (on page 145) table.

Audit trail for manual transaction edits

To ensure that synchronization transaction changes are nevertheless recorded and available for audit, the following occurs when a user edits a transaction:

- An audit transaction is created and processed immediately the transaction edit. This XML contains the following information:
  - Transaction IDs.
  - User who edited the transaction.
  - CIS application server computer and client computer where the edit occurred.
  - Time and date of the change.
  - Reason for the edit as entered on the Transaction Edit Screen.
  - Body of the original transaction text.
  - Body of the updated transaction text.

A sample of audit transaction XML follows, showing old and new transaction text within the <OLDDATA> and <NEWDATA> tags:

```
<?xml version="1.0" encoding="utf-8" ?>
<TRANSACTION GUID="{1FFF25A1-3A49-4ED8-8262-965C3DCB3B12}"
REVISION="75725136419.000" USERGUIDREF="System User" TIME="5/27/2003 11:45:36
AM" SOURCEMACHINE="SRV34" INFORMVERSION="4.001" xmlns="PhaseForward-Sy_u99
?XML-Inform4">
    <MESSAGEEDIT GUID="{13333333-3A49-4ED8-8262-965C3DCB3B12}" USER="JDOE"
USERIP="MEF.NORTH.PF.COM" REASON="fix external mapset refname">
        <!-- OLDDATA_contains original transaction or message data -->
        <OLDDATA>
            _ <TRANSACTION GUID="{822C85AB-B71C-48AE-BADF-DD81BC68CC94}"
REVISION="82308121856091.000" USERGUIDREF="System User" TIME="8/11/2003
8:22:01 PM" SOURCEMACHINE="{F3DD9640-32A1-4F86-AAA2-19E3E6564473}"
INFORMVERSION="4.0024359">
            _ <EXTERNALMAPSET REFNAME="M1" xmlns="PhaseForward-MedML-TDE"
ACTIVE="true" AUTOGEN="true" TYPE="CLINFORM" GUID="{98A7BC6E-23FD-4391-B203-
5EB915C87D71}" REVISION="82308121856091.000" />
            _ </TRANSACTION>
        </OLDDATA>
        <!-- NEWDATA_contains modified transaction or message data -->
        <NEWDATA>
            _ <TRANSACTION GUID="{822C85AB-B71C-48AE-BADF-DD81BC68CC94}"
REVISION="82308121856091.000" USERGUIDREF="System User" TIME="8/11/2003
8:22:01 PM" SOURCEMACHINE="{F3DD9640-32A1-4F86-AAA2-19E3E6564473}"
INFORMVERSION="4.0024359">
            _ <EXTERNALMAPSET REFNAME="MAPPINGS2" xmlns="PhaseForward-MedML-TDE"
ACTIVE="true" AUTOGEN="true" TYPE="CLINFORM" GUID="{98A7BC6E-23FD-4391-B203-
5EB915C87D71}" REVISION="82308121856091.000" />
          … </TRANSACTION>
        </NEWDATA>
    </MESSAGEEDIT>
</TRANSACTION>
```

- If the InForm software encounters an audit transaction message, it stores audit information in the trial-specific INF_MSGEDIT_HISTORY table.
- The INF_MSGEDIT_HISTORY table has the following format:

INF_MSGEDIT_HISTORY	
TRANSACTIONID	VARCHAR2(36)
MESSAGEID	VARCHAR2(36)
EDITEDTRANSACTIONID	VARCHAR2(36)
EDITORMACHINE	VARCHAR2(255)
EDITUSER	VARCHAR2(255)
EDITUSERHOST	VARCHAR2(255)
EDITDATETIME	DATE
REASON	VARCHAR2(2000)
TRANSACTIONCONTENT	LONG VARCHAR

Suggested workflow for tracking manual transaction edits

To ensure auditability and regulatory compliance of edits to synchronization transactions in a production environment, the following workflow and guidelines are recommended:

1 Use the transaction editing feature of CIS Administration primarily as a system implementation tool. In production, use it only when no other solution to a synchronization failure is available.

2 Before changing a synchronization transaction, notify the investigator of the planned action and

obtain formal signoff indicating that the investigator agrees to the action.

3 At the site, maintain a manual log of the occasions on which you edit synchronization transactions. This log should record:

- The user who performed the edit.
- The date and time of the action.
- The trial or protocol in which synchronization transactions were edited.

4 Update the data in the InForm software if necessary to reflect the change.

5 When an audit of integrated study transactions is required, query the INF_MSGEDIT_HISTORY table for each trial in which synchronization transactions were edited to produce the audit record of those actions. At a minimum, review the INF_MSGEDIT_HISTORY table as part of the database locking process. If any records exist, verify the existence of the required paper documentation at the site.

Note: If you do not follow similar steps to make sure your audit trail is complete, you may be using the CIS software in a way that is not fully compliant with CFR 11.

APPENDIX D

Troubleshooting

In this appendix

Suggested troubleshooting procedure

To identify the source of a synchronization problem:

1 Check the status of the synchronization connection using the CIS Administration tool.

2 Examine the content of error messages. For more information, see ***CIS Error Messages*** (on page 196).

3 Examine the following log files:

- CAConfig.log.
- CISAdapterService.log.
- CISLibraryAdapterService.log.
- CTAdapterService.log.
- InFormAdapterService.log.
- InFormAdapter.AdapterAdmin.WebService.log.
- InFormAdapter.AdapterService.WebService.log.
- InFormAdapter.ServerAdapter.WebService.log.
- InFormAdapter.TransactionAdapter.WebService.log.

4 Check the Windows Event Viewer on the Clintrial, CIS, and InForm machines. A synchronization error includes the text of any CIS error messages or messages passed through from Oracle or .NET, along with the XML text of the transaction causing the error. For easier legibility, copy and paste the error and transaction text into a text editor such as Notepad.

5 Analyze the problem. For a description of error messages originating from the CIS software, see ***CIS Error Messages*** (on page 196). Several common Oracle and .NET error messages are included in the appendix.

Environment configuration

A failure to process synchronizations correctly could be caused by incorrect configuration in your CIS environment. Check the following information:

- See the *Release Notes* for your release of the CIS software for:
  - Oracle version numbers including patch sets.
  - Operating system version number and service pack.
  - Version numbers of other required software.
- See the *Phase Forward Product Compatibility Matrix* which identifies CIS compatibility with other Phase Forward products: CIS, Clintrial, InForm Adapter, and InForm version numbers, including service pack levels.

  The *Phase Forward Product Compatibility Matrix* can be downloaded from the Phase Forward Extranet. To sign in to the Extranet, go to www.phaseforward.com and click **Customer Login**. Enter your email address and password, then navigate to the **Bulletins** section.
- Make sure that you have adjusted your MS DTC log settings and MTS time-out. For more information, see Monitoring MS DTC logs.

Synchronization connection definition

Review your synchronization connection definitions to ensure that your environment will support synchronization correctly. For more information, see ***Administering synchronization connections*** (on page 63).

Database statistics

In very large studies, the Status tab of the CIS Synchronization Connection page could fail to appear if a query that determines the transaction count times out. If this happens, you cannot view the Status page until the synchronization completes or fails. To prevent this situation, make sure that database statistics are kept up-to-date.

InForm and Clintrial data incompatibility

CIS generates mapping definitions for study components. if you generate mappings in the Central Designer software and synchronize the metadata definitions to the Clintrial software, the CIS software optionally creates Clintrial panels, if they do not already exist, and the metadata definitions match between the InForm study and the Clintrial protocol.

However, if you later add to or change the study component or protocol item definitions, you can create data incompatibilities if you do not ensure that the additions or changes are correctly reflected in both systems. This section describes common data incompatibility problems.

Column size

The following error messages indicate an incompatibility between an InForm form item and a Clintrial panel item:

```
ORA-01401: inserted value too large for column.
```

This Oracle error indicates that an InForm data item is too large for the Clintrial panel item to which it is mapped.

```
Value was either too large or too small for an Int64.
```

This .NET error can happen if the InForm item is a long string of digits too large for numeric storage in a 64-bit integer.

These errors can occur if you increase the size of an InForm form control with the Central Designer software without changing the corresponding Clintrial panel item with the Design module. To recover, do one of the following:

- Change the data in the InForm software if appropriate; then, change the size of the control on the InForm form so that it matches the size of the Clintrial panel item. Use the Central Designer software to make the necessary changes in the study, create a deployment package, and deploy it to the InForm server. For more information, see the Central Designer documentation.
- Change the size of the Clintrial panel item. In the Design module of the Clintrial software, change the DB Format of the panel item to a length that is compatible with the length of the InForm item. Save the change and implement the revision. For more information, see the Clintrial *Admin and Design* manual.

Caution: In the Clintrial software, you cannot change the design of a panel in an EDC protocol if data has already been entered in the panel. If the panel contains EDC data, you can override this restriction by selecting the Enable Modifications to EDC Panels option at the protocol level. For details, see the *CIS Designer's Guide*. Additionally, you can only change the DB Format of a panel item to a length that is larger.

Data type

If the mappings between the InForm software and the Clintrial software result in an attempt by the CIS software to insert EDC data into a Clintrial item with an incompatible data type, the synchronization fails if the CIS software cannot successfully convert the data to a compatible data type (for a list of the types of data conversions the CIS software performs during synchronization, see the *CIS Designer Guide*. In this case you might receive the following message:

```
Input string not in a correct format
```

To recover, do one of the following:

- Change the data type of the control in the InForm software so that it is compatible with the data type of the Clintrial panel. Use the Central Designer software modify the study, create a deployment package and deploy it to the InForm server.
- Change the data type of the Clintrial panel item. Deinstall the panel with the Design module of the Clintrial software. Change the data type so that it is compatible with the data type of the InForm form control, and reinstall the panel.

Caution: Deinstalling a panel removes its data. Do not perform this operation on a panel containing patient data without assistance from Phase Forward Customer Support.

If the panel contains no patient data, run the synchronization again, either when it is normally scheduled to run or by using the Sync Now option to clear the data. For more information, see ***Administering synchronization connections*** (on page 63).

If the panel contains only EDC patient data, use the Reset button of the Action tab for the specific synchronization connection. For more information, see ***Resetting a protocol and replaying synchronization transactions*** (on page 99).

APPENDIX E

CIS error messages

In this appendix

CIS Error messages

In a CIS environment, you might encounter errors from the following sources:

- Oracle errors at the database level, including:
  - Database calls from within the CIS software.
  - Pass-through of errors that occur within Clintrial packages.
- CIS errors, which can indicate a problem within the CIS code.
- .NET errors, which are generated by the Windows .NET Framework and then handled in the CIS processing code.

This appendix lists the error messages initiated by CIS processing. For more information, see ***Suggested troubleshooting procedure*** (on page 188).

Error	Description
Cannot receive comment on non-existent Patient Data.	No record exists with which to associate the given comment.
Visit or Page Information not found.	Visit or page properties not found in the INF_OBJECTS table.
Invalid parameters passed to the Data Deletion GetAllItems method.	Low level code problem. The method requires either FORM or DATA to be passed. Anything else results in this error.
Invalid parameters passed to the Data Deletion GetCTrecids method.	Similar to above.
Subject not enrolled.	Subject was not found in the INF_SUBJECT table.
No Updates allowed to the Patient Enrollment Data.	Once a patient is enrolled, changes to enrollment data cannot be made (feature of the Clintrial software).
Patient screening data has not been loaded.	No screening data has been found.
Clintrial Core module not registered.	No Clintrial installation at target instance.
Protocol not in correct state to load data.	Clintrial protocol must be in "NORMAL" state.
InForm User information not found.	InForm user is not found in the INF_USER_UPDATE table.
Cannot insert item SDV status - protocol is not in correct state to load data.	An incorrect SDV record has been received.
Query Information not found in Clintrial ErrorStatus Table.	Outgoing transaction record has CT_RECID for a query that was not found in the INF_ERRORSTATUS table.
Inform Patient Guid not found for CT Subject Id.	Clintrial SUBJECT_ID given did not have matching record in INF_SUBJECT table.

Error	Description
Source Record not found for Query in outgoing transactions.	Outgoing transaction record has CT_RECID for a query that was not found in the INF_ERRORSTATUS table.
Invalid Query-State transition.	The conflict resolver found an inconsistent query state transition.
Database Execute Exception.	General exception (not database exception) occurred during execution of a database command.
Database GetValue Exception Table: {0}, Column: {1}, RowNum: {2} - There are {3} rows in the DataSet.\n\n{4}.	General exception (not database exception) occurred during retrieval of a database value ({} values indicate where extra information is given).
Unsupported conversion to string from type {0}.	Could not convert from the given type to a string.
Unsupported conversion to BOOL from type {0}.	Could not convert from the given type to a Boolean value.
Database SetValue Exception Table: {0}, Column: {1}, RowNum: {2} - There are {3} rows in the DataSet.\n\n{4}.	General exception (not database exception) occurred during the setting of a database value.
Database Delete Row Exception Table: {0}, Column: {1}, RowNum: {2} - There are {3} rows in the DataSet.\n\n{4}.	General exception (not database exception) occurred during deletion of a database row.
Database Add Row Exception AddRow Exception - Table: {0}.	General exception (not database exception) occurred during creation of a database row.
Cannot process System Message of unknown type.	Create CIS Trial processor has been passed XML that is not a CREATECISTRIAL element.
CISMapsetProcessor can process XML tag EXTERNALMAPSET; was passed wrong tag.	Mappings processor has been passed XML that is not a EXTERNALMAPSET element.
NULL Transaction Parameter.	Transaction re-player (for new mappings feature) was passed a null transaction.
ProcessMessages() err: Access denied or SendNewData() err: Access denied.	Method was called by a user not assigned the CISManager role within the CISManager COM+ package.
startProcessMessageThread() err: concurrent processing.	Another thread (possibly on another machine) is already processing the messages. This might occur when you try to start the processing manually when directly invoking the web service.
Cannot process message. No mapping information provided.	The first message does not contain the definition of the MAPSET (or the MAPSET name has been removed from the CIS database).

Error	Description
No Vector node message found - messages available {0}.	There was no synchronization connection information in the message that was requested to be processed.
Error finding Bookmark Bookmark {0} - only {1} nodes in message.	Requested bookmark is out of bounds of the number of transactions in message.
Stopped processing due to New Mapping Exception.	Occurs if one has chosen to stop processing upon encountering a new mapping. This is the correct behavior of this new mapping option.
Invalid OnNewMapping Selection.	Incorrect new mapping selection given.
GC.Collect() has failed:	Call to Garbage Collector failed.
Cannot connect to database User: [{0}] Password: [{1}] Connection: [{2}].	Unable to connect to database.
Unsupported Clintrial Context Type	Clintrial Context items must have type between 0 and 4.
Unsupported Clintrial Item Type.	Clintrial item types must be FIXED, FLOAT, TEXT, DATE, or DATETIME.
Not a valid DB format specifier.	Oracle database format is not recognized.
The value is not a valid dimension for this DB format.	Oracle database format is recognized but appears to have invalid dimensions.
The database format dimension of an installed item cannot be made smaller.	Column already exists in database with larger dimension (width) than new specification.
The value is not a valid number of decimal places.	Invalid number of decimal places for database column.
The number of decimal places cannot exceed the database format width.	Exceeded number of decimal places for the specified column width.
Number is too large for column Number {0} is too large for column of width {1} and precision {2}.	The given number (data) is too big to fit into the column. This occurs when a numeric data point is too large for the target Clintrial item.
Floating-Point Rounding - Panel {0}, Item {1} Floating point numbers submitted to this column have exceeded the number of places specified. For example, the value {1} was rounded to the correct number of decimal places as {2} This message will not appear again for this Item.	The number has been truncated to fit into the target column. This occurs when a floating point number needs to be truncated to fit into the target Clintrial item. The CIS software issues this error as a warning. It is commonly seen with values that have been normalized in the InForm software.
Unsupported Clintrial Panel Type.	Clintrial panels must have type between 0 and 5.

Error	Description
Error_Clintrial_Tablespaces_Nearly_Full At least one of the Clintrial tablespaces (CT_META_D, CT_META_I, CT_DATA_D, or CT_DATA_I) is running low on space. CIS will not create protocols or process transactions until more space is added. The minimum required free bytes per tablespace is {0}. These tablespaces have fewer free bytes: {1}.	The value for {0} indicates the number of free bytes required for each Clintrial tablespace, and the value for {1} identifies each tablespace that has fewer bytes than the number of required bytes and the amount of free space for that table. For the CIS software to continue processing transactions, you must increase the number of bytes for a table to meet the required number of free bytes.
Unsupported Clintrial Lock Status.	Clintrial panel Lock Status must be between 0 and 2.

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