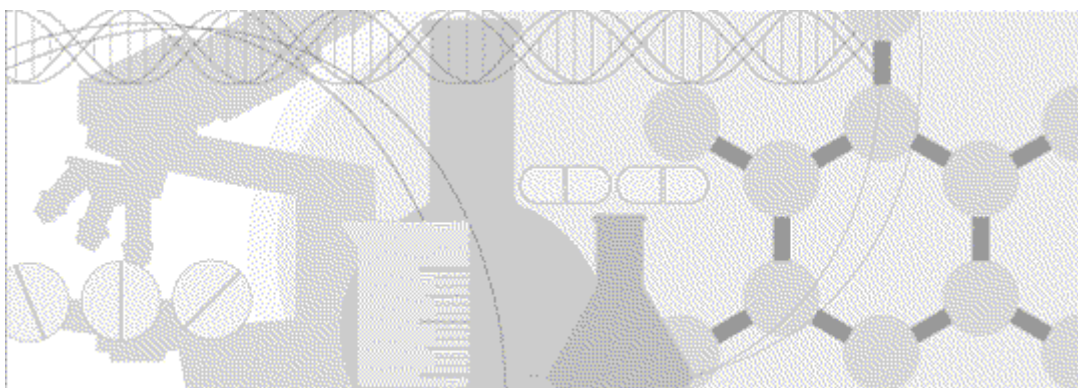


Study and Reporting Setup Guide

Oracle[®] Health Sciences InForm 6.0.1



ORACLE[®]

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Overview of this guide

The *Study and Reporting Setup Guide* describes how to perform the tasks that are required to set up an InForm study and configure the Reporting and Analysis module for the study.

Before setting up a study and configuring the Reporting and Analysis module, use the *Installation Guide* for information about how to install the software and configure the environment for the InForm application and the Reporting and Analysis module.

Audience

This guide is for system administrators who are responsible for setting up InForm studies, and for setting up the Reporting and Analysis module for each study.

Documentation

The product documentation is available from the following locations:

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

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

Document	Description
<i>Release Notes</i>	The <i>Release Notes</i> document describes enhancements introduced and problems fixed in the current release, upgrade considerations, release history, and other late-breaking information.
<i>Known Issues</i>	The <i>Known Issues</i> document provides detailed information about the known issues in this release, along with workarounds, if available.
<i>Upgrade and Migration Guide</i>	The <i>Upgrade and Migration Guide</i> provides instructions for upgrading and migrating the InForm software and InForm Portal software to the current InForm release, and for upgrading the Cognos software for use with the Reporting and Analysis module.
<i>Secure Configuration Guide</i>	The <i>Secure Configuration Guide</i> provides an overview of the security features provided with the Oracle® Health Sciences InForm application, including details about the general principles of application security, and how to install, configure, and use the InForm application securely.
<i>Installation Guide</i>	The <i>Installation Guide</i> describes how to install the software and configure the environment for the InForm application and Cognos software.
<i>Study and Reporting Setup Guide</i>	The <i>Study and Reporting Setup Guide</i> describes how to perform the tasks that are required to set up an InForm study and configure the Reporting and Analysis module for the study.
<i>User Guide</i>	The <i>User Guide</i> provides an overview of the InForm application including details on multilingual studies, how to navigate through the user interface, and how to use the application to accomplish typical tasks you perform while running a clinical study.
<i>Reporting and Analysis Guide</i>	The <i>Reporting and Analysis Guide</i> provides an overview of the Reporting and Analysis module. It includes a brief overview of the Reporting and Analysis interface, illustrates how to access the Ad Hoc Reporting feature, and describes the study management and clinical data packages available for Reporting and Analysis. It also provides detailed descriptions of each standard report that is included with your installation.

Document	Description
<i>Reporting Database Schema Guide</i>	The <i>Reporting Database Schema Guide</i> describes the Reporting and Analysis database schema, and provides information on creating Reporting Database Extracts (RDEs).
<i>Portal Administration Guide</i>	The <i>Portal Administration Guide</i> provides step-by-step instructions for setting up the InForm Portal software, and configuring and managing the InForm Portal application.
<i>Utilities Guide</i>	<p>The <i>Utilities Guide</i> provides information about and step-by-step instructions for using the following utilities:</p> <ul style="list-style-type: none"> • PFConsole utility • MedML Installer utility • InForm Data Import utility • InForm Data Export utility • InForm Performance Monitor utility • InForm Report Folder Maintenance utility <p>This guide also provides reference information for the MedML elements and scripting objects that are used to import and export data to and from the InForm application, as well as sample data import XML.</p>
MedML Installer utility online Help	<p>The MedML Installer utility online Help provides information about, and step-by-step instructions for using, the MedML Installer utility, which is used to load XML that defines study components into the InForm database.</p> <p>This guide also provides reference information for the MedML elements and scripting objects that are used to import and export data to and from the InForm application, as well as sample data import XML.</p> <p>This document is also available from the user interface.</p>
InForm Data Export utility online Help	<p>The InForm Data Export utility online Help provides information about and step-by-step instructions for using the InForm Data Export utility, which is used to export data from the InForm application to the following output formats:</p> <ul style="list-style-type: none"> • Customer-defined database (CDD) • Name value pairs <p>This document is also available from the user interface.</p>
InForm Data Import utility online Help	<p>The InForm Data Import utility online Help provides information about and step-by-step instructions for using the InForm Data Import utility, which is used to import data into the InForm application.</p> <p>This document is also available from the user interface.</p>
<i>Clinical Data API Guide</i>	The <i>Clinical Data API Guide</i> provides information about submitting data to the InForm application in InForm ODM format.

Document	Description
<i>Third Party Licenses and Notices</i>	The <i>Third Party Licenses and Notices</i> document includes third party technology that may be included in or distributed with this product.

Documentation accessibility

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

If you need assistance

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

Finding InForm information and patches on My Oracle Support

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

Creating a My Oracle Support account

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

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

Finding information and articles

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

Finding patches

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

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

The system displays details about the patch. You can view the Read Me file before downloading the patch.

- 5 Click **Download**, and then follow the instructions on the screen to download, save, and install the patch files.

Finding Oracle documentation

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

Finding Oracle Health Sciences documentation

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

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

Finding other Oracle documentation

- 1 Do one of the following:
 - Go to <http://www.oracle.com/technology/documentation/index.html>.
 - Go to <http://www.oracle.com>, point to the **Support** tab, and then click **Product Documentation**.
- 2 Scroll to the product you need, and click the link.

Finding prerequisite software for Oracle Health Sciences applications

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

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

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

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

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

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

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

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

CHAPTER 1

Setting up an InForm study

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Overview of setting up a study

To set up an InForm study, you must:

- 1 Execute a Central Designer deployment package.
- 2 Create administrative study components such as sites, users, and groups. For example:
 - Sites.
 - Users.
 - Rights and rights groups.
 - Query and item groups.
 - Reporting groups, if the installation includes the Reporting and Analysis module.
 - Display overrides.

For more information, see the *User Guide* and *Utilities Guide*.

- 3 Configure the system configuration settings.

For more information, see *Configuring the system configuration settings* (on page 8).

- 4 Additionally, depending on the requirements of your study, you might need to set up the following optional features.

For more information, see *Additional study configuration steps—Optional* (on page 9).

- A customer-defined database (CDD).
- Electronic signatures.
- Electronic study documentation.
- Email notification and customizations
- Custom Home pages.
- Itemset source verification option
- Login page customizations
- Numbering format for application-generated numbers.
- Custom text in lists on certain system forms.
- Randomization.
- Reports
- Secure Sockets Layer (SSL).
- Sponsor definitions.
- Text of a subject record transfer affidavit.

Note: Before installing your own study, you might want to install the sample study provided with the InForm software. The sample study contains examples of the types of study components you can use when you design your own study. For more information, see *Installing a study* (on page 4) and *Installing the sample study* (on page 6) .

About the InForm Service

The InForm Service must be started to create the application servers and load studies. To start or stop the InForm Service, you must be a local administrator for the machine on which you are installing the study.

About InForm servers

Every InForm study must be associated with an InForm server. Each server may house one or more studies. For production servers, it is recommended that you associate each study with its own server in a one-to-one relationship.

About Central Designer deployment packages

A deployment package for a study is an executable file that is created in the Central Designer application. A deployment package contains metadata that describes the study, along with mapping definitions for CDD or CIS mappings. When you execute a deployment package, you specify the InForm server on which to install the study, and the deployment process creates the server if it does not already exist.

Installing a study or the sample study

Before installing a study

- 1 Verify that the required services are running.
For more information, see *Verifying that required services are running* (on page 4).
- 2 Copy the Central Designer deployment package to the server that hosts the InForm study database instance.

Verifying that required services are running

Click **Administrative Tools > Services**, and check to see if the following services are started. If they are not, start the services in the following order:

- 1 MSDTC.
- 2 Oracle Service.
- 3 OracleOraHome102TNSListener.
- 4 IIS Admin service.
- 5 InForm Service.
- 6 World Wide Web Publishing service.

Note: The InForm Service must be started to create the application servers and load studies. To start or stop the InForm Service, you must be a local administrator for the machine on which you are installing the study.

Installing a study

- 1 Log in to the computer where the InForm server software is installed.
- 2 Open the Microsoft Windows Explorer application, and find the deployment package EXE file.
- 3 Double-click the deployment package file.
- 4 A Command Prompt window opens and displays messages about unpacking the executable file, updating application configuration information, and starting the installer.
- 5 Then, the welcome page of the Deployment Wizard appears.
- 6 Complete the pages of the Deployment Wizard. Click **Next** after you finish filling out each page.
- 7 On the last page of the Deployment Wizard, click **Finish** when the deployment process completes.

For more information, see *Deployment Wizard for InForm deployment—Option descriptions* (on page 5).

Note: During the installation of a study, the InForm software creates a virtual Web directory with the same name as the study name. When choosing a study name, make sure that you do not already have a virtual Web directory with the same name.

8 When the deployment process is complete, stop and restart the study.

The deployment process:

- Creates the InForm application server, if it does not already exist.
- Creates the InForm study database, if it does not already exist.
- Installs the MedML metadata definitions for the base study components. The base study components include system resources, settings, and form definitions common to all InForm studies.
- Installs the rule engine assembly.
- Installs the study-specific MedML definitions generated from the deployment package.
- Installs CDD or CIS mapping definitions.
- Creates review schema.
- Creates reporting views.
- Creates RD views.

Deployment Wizard for InForm deployment—Option descriptions

Page	Option	Description
Welcome		Introduction page.
Connecting to InForm	Connect to the InForm application and requests server and study information.	
	Message section	Informational and error messages.
	Reconnect	Reconnect to the InForm application after correcting any error conditions.
InForm Trial Parameters		Specify information about the InForm application server and study to which to deploy the package. If either the server or the study does not already exist, subsequent pages collect additional information needed to create them.
	Server Name	Name of the InForm application server.
	Trial Name	Name of the InForm study.
	Strict Mode	If selected (default)—Only complete MedML definitions of study components can be loaded into the study; an incomplete definition causes the installation to fail. If not selected —Incomplete study component definitions are permitted.
Create a New InForm Server		Specify whether the InForm server should start automatically when the InForm Service starts. This page appears if the specified InForm server does not yet exist.

Page	Option	Description
	Startup Server Automatically on InForm Startup	<p>If selected—The InForm server starts automatically when the InForm Service starts.</p> <p>If not selected—The InForm server must be started manually.</p>
Create a New InForm Trial		Specify information needed to create the study. This page appears if the specified InForm study does not yet exist.
	User Name	Oracle user name for the study database.
	User Password	Oracle password for the study database.
	Please specify a database for creating a new InForm study	<p>One of the following:</p> <ul style="list-style-type: none"> • Connect String—Connection string for the Oracle instance. • TriDSN—ODBC System DSN for the InForm study.
	Startup Trial Automatically on InForm Startup	<p>If selected—The InForm study starts automatically when the InForm Service starts.</p> <p>If not selected—The InForm study must be started manually.</p>
Ready for Deployment		View a summary of the parameters that will be used for deployment.
Deployment Results		View messages generated during deployment processing, along with the elapsed time. These messages are also collected in the StudyInstaller.log file in the directory where you execute the deployment package.

Installing the sample study

The InForm software includes the components of a sample study (PFST60) that you can install to familiarize yourself with the software. The study is available as a Central Designer deployment package.

The deployment package for the sample study is available on the InForm installation media. After installing the InForm software, you can install the sample study through the Start menu.

To install the PFST60 study:

- On the server where the InForm application is installed, click **Start > All Programs > Oracle® Health Sciences > InForm 6.0 Install Sample Study**.

The deployment package for the sample study runs and installs the study and sample administrative data, including users, sites, rights, and groups.

Managing studies in an InForm installation

After a study is installed, you might need to perform study management tasks such as stopping and starting a study or InForm application server, creating a new InForm application server, or removing a study or InForm application server. The `pfadmin` command utility is available for these tasks.

The following table lists the most commonly used `pfadmin` command options. For a complete description of all `pfadmin` command options, see *pfadmin* (on page 116).

Action	Command, issued from a Command Prompt window
View the status of InForm application servers and studies running under the InForm Service.	<code>pfadmin view service</code>
Start an InForm application server.	<code>pfadmin start server <servername></code>
Start a study.	<code>pfadmin start trial <trialname></code>
Stop a study.	<code>pfadmin stop trial <trialname></code>
Stop an InForm application server.	<code>pfadmin stop server <servername></code>

Restricting access to a study

- 1 Select **Start > All Programs > Administrative Tools > Internet Services Manager**.
The Internet Information Services window appears.
- 2 Under the machine name listed, select the **Default Website** folder.
- 3 In that folder, right-click the name of the InForm study.
- 4 Select **Properties**.
The Properties dialog box appears.
- 5 Select the **Directory Security** tab.
- 6 Change the settings for IP addresses and Domain name restrictions to suit your needs.

Configuring the system configuration settings

System configuration options are global settings that govern certain aspects of how the InForm application handles a study. The settings of configuration parameters specify customizable, system-wide InForm behaviors.

You can update system configuration settings through the InForm Admin user interface or by creating XML definitions of system configuration parameters and installing them in a study with the MedML Installer utility. When using XML definitions, you set each parameter definition with the SYSCONFIG MedML element.

```
<SYSCONFIG
  CONFIGNAME="name"
  TYPE="0"
  VALUE="text" />
```

For example, to specify that InForm user passwords must contain one numerical character and one uppercase character, use the following SYSCONFIG definitions:

```
<SYSCONFIG CONFIGNAME="OneNumericCharacter" TYPE="0" VALUE="1"/>
<SYSCONFIG CONFIGNAME="OneUppercaseCharacter" TYPE="0" VALUE="1"/>
```

The sample study PFST60 includes an XML file of system configuration parameter settings. This file is located in the \InForm \Sample_PFST60\Admin folder in the InForm installation directory.

For a complete list of SYSCONFIG parameters, see the *Utilities Guide*.

Additional study configuration steps—Optional

After a study is installed, depending on the features that you want to enable, you may need to perform additional configuration steps, using MedML, the MedML Installer utility, and other software that is external to the InForm application, such as a database for randomization.

You can perform the optional steps in any order, as needed.

Customer-Defined Database (CDD)

A CDD is an extract of clinical data from a study database. You can use a CDD to pass data into customer statistical analysis tools or other external programs. You can use either the Reporting and Analysis module or a CDD, or both, to extract data from a study.

Comparison of CDD and Reporting and Analysis module	
CDD	Reporting and Analysis module
Clinical data only	Clinical and operational data
Database structure defined by customer	Database structure based on study design
Mappings defined in Central Designer application	Mappings defined in Reporting and Analysis user interface
Requires external analysis tools	Includes report generation tools

Creating and installing CDD mappings

CDD mappings specify the source of data in a study and the target tables and columns in a CDD. You create CDD mappings by setting up a logical schema in the Central Designer application.

For more information, see the Central Designer *InForm Design Guide*.

CDD mappings are installed in a study when you run a Central Designer deployment package.

For more information, see ***Installing a study*** (on page 4).

Configuring a CDD

Note: It is recommended that the default tablespace for the CDD user should not be the InForm tablespace.

- Using the following command, make sure that the study is running.

```
pfadmin view service
```

- Create a CDD schema with the DSN name, DSN user, and DSN password:

```
pfadmin setup cdd <CDDRefName> <TrialName> /DB <oracle_connection_string>
<DSN>
```

When prompted, enter:

- The name of the study schema owner.
- The password of the study schema owner.

Note: The schema owner UID and PID must begin with a letter and contain alphabetic or alphanumeric characters. Do not use all numeric characters.

For example:

```
pfadmin setup cdd PFSTCDD pfst60 /DB testmachine_dev1 pfstcdd
```

- Make the online CDD functionality transactional:

```
pfadmin config cdd <TrialName> <CDD_DSN> [Active | Inactive]
```

For example:

```
pfadmin config cdd pfst60 pfstcdd active
```

- Enable online CDD functionality for the study:

```
pfadmin config cdd TrialName [Enable | Disable]
```

For example:

```
pfadmin config cdd pfst60 enable
```

- In a multilingual study, specify the study locale to use for the unit symbol translation that is stored in the CDD column for the unit symbol:

```
pfadmin config cdd <TrialName> <CDD_DSN> <StudyLocale>
```

For example:

```
pfadmin config cdd pfst60 pfstcdd es-ES
```

For more information, see *pfadmin* (on page 116).

Electronic signatures

To comply with regulations set forth in 21 CFR 11, CRFs and case report books must be signed by users specifically authorized to handle these functions. The InForm application supports electronic signature by using signature groups and the SIGNCRF MedML element.

When you create a study from a Central Designer deployment package, signatures are not included. You must decide which forms require signatures and which users will be authorized to sign. Then, perform these steps only if you want to include the ability to sign forms electronically.

- 1 Create the text of a signature affidavit.

For more information, see *Creating the text of a signature affidavit* (on page 12).

- 2 Create one or more signature groups and assign users.

Each signature group must have a CRF affidavit, a case report book affidavit, or both.

For more information, see *Creating a signature group* (on page 13).

- 3 Associate each form that requires signature with the appropriate signature group.

For more information, see *Associating a form with a signature group* (on page 16).

- 4 Install the XML definitions for the signature groups in the InForm database using the MedML Installer utility.

You must install MedML files in the study to indicate:

- On which forms signature information should appear.
- Which groups are required to sign.
- Whether the signature is a CRF signature or a case report book signature.

For more information, see the *Utilities Guide*.

- 5 Optionally, configure the study to disable viewing the required signature list.

For more information, see *Configuring the study to hide the required signature list* (on page 19).

- 6 Optionally, configure the signature print preview to display queries.

For more information, see *Configuring the signature print preview* (on page 20).

Creating the text of a signature affidavit

A signature affidavit is the text that specifies the meaning of the signature. This text appears when the user is signing a CRF or case report book. You define the signature affidavit text in:

- The MedML used to create or modify the signature group.
or

- A text file which is referred to by the signature group MedML file.

A separate text file must be provided for each different signature. You can associate only one CRF and one CRB signature affidavit with each signature group.

- **CRF signature**—Indicates that the signature refers only to the information on that form.
- **CRB signature**—Indicates that the signature refers to the entire case report book. This signature appears on a single form, usually at the end of a study.

To complete the compliance, make sure that:

- The First Name and Last Name of each person who will be signing CRFs are that person's full name. This ensures that the signature history bears the signer's full name.
- The text of the signing affidavit includes the signer's full name. To do this, include two %s variables in the text, one for the first name of the user and the other for the last name.
- The text of the signing affidavit includes the meaning of the signature.

Creating a signature group

A signature group identifies users with permission to sign CRFs or case report books. To be fully signed, a CRF must be signed by a representative of each signature group with which it is associated.

You can create one or more signature groups with signing affidavits by using the SIGNATUREGROUP element.

Each signature group must have a CRF affidavit, a case report book affidavit, or both.

Note: You associate CRFs and case report books with a signature group by using the SIGNCRF MedML element.

SIGNATUREGROUP element

A signature group identifies users with permission to sign CRFs or case report books. To be fully signed, a CRF must be signed by a representative of each signature group with which it is associated.

To create a signature group, use the SIGNATUREGROUP element.

```
<SIGNATUREGROUP
  GROUPNAME="name"
  [GROUPDESCRIPTION="text"]
  [UUID="id"]
  [LANGUAGE="name"]
  [CRFTEXT="text"]
  [CRFFILE="file"]
  [CRFMEANING="text"]
  [CRBTEXT="text"]
  [CRBFILE="file"]
  [CRBMEANING="text"]>
  <USERREF* attributes/>
  <TRANSLATIONS/>
</SIGNATUREGROUP>
```

Using one or more USERREF child elements, add each user that you want in the group to the SIGNATUREGROUP definition. These users must have the right to sign a CRF or case report book, as appropriate. The USERREF element has a single USERNAME attribute, which specifies the user name of the user that you are assigning to the group.

In the following SignatureGroup, users dobrien and lhill can sign.

```
<SIGNATUREGROUP GROUPNAME="CRA Signature">
  <USERREF USERNAME="dobrien"/>
  <USERREF USERNAME="lhill"/>
</SIGNATUREGROUP>
```

SIGNATUREGROUP attributes

Attribute	Description
GROUPNAME	Name of the signature group. REQUIRED.
GROUPDESCRIPTION	Text describing the signature group. OPTIONAL.
UUID	Universally Unique Identifier, a string that identifies the component uniquely across all studies, study databases, and machines. OPTIONAL.
CRFTEXT	Text of the Electronic Signature Affidavit displayed to members of the signature group when signing a CRF associated with the signature group. OPTIONAL; if used, specify either the CRFTEXT or CRFFILE attribute. If you do not specify either attribute, the MedML Installer utility uses the text provided in a default CRF signing text resource. This resource has the UUID PF_DEFAULT_CRFAFFADAVIT. The text must include the stated intention of the signer for the electronic signature to be the legal equivalent of a handwritten signature. The text should include two %s characters to represent the user's first and last names.
CRFFILE	Path name of an HTML or text file containing the text of the Electronic Signature Affidavit displayed to members of the signature group when signing a CRF associated with the signature group. The path name must be relative to the directory from which you run the MedML Installer utility. OPTIONAL; if used, specify either the CRFTEXT or CRFFILE attribute. If you do not specify either attribute, the MedML Installer utility uses the text provided in a default CRF signing text resource. This resource has the UUID PF_DEFAULT_CRFAFFADAVIT.
CRFMEANING	Text that summarizes the meaning of the signature on the CRF. This text is displayed on the Signature Details screen and in the list of completed and required signatures on the CRF. OPTIONAL. Required if either the CRFTEXT or CRFFILE attribute is specified. At least one combination of CRFTEXT or CRFFILE and CRFMEANING should be specified.

Attribute	Description
CRBTEXT	<p>Text of the Electronic Signature Affidavit displayed to members of the signature group when signing a case report book associated with the signature group.</p> <p>OPTIONAL; if used, specify either the CRBTEXT or CRBFILE attribute. If you do not specify either attribute, the MedML Installer utility uses the text provided in a default case report book signing text resource.</p> <p>This resource has the UUID PF_DEFAULT_CRBAFFADAVIT.</p> <p>The text must include the stated intention of the signer for the electronic signature to be the legal equivalent of a handwritten signature.</p> <p>The text should include two %s characters to represent the user's first and last names.</p>
CRBFILE	<p>Path name of an HTML or text file containing the text of the Electronic Signature Affidavit displayed to members of the signature group when signing a Case Book associated with the signature group. The path name must be relative to the directory from which you run the MedML Installer utility.</p> <p>OPTIONAL; if used, specify either the CRBTEXT or CRBFILE attribute. If you do not specify either attribute, the MedML Installer utility uses the text provided in a default case report book signing text resource.</p> <p>This resource has the UUID PF_DEFAULT_CRBAFFADAVIT.</p>
CRBMEANING	<p>Text that summarizes the meaning of the signature on the case report book. This text is displayed on the Signature Details screen and in the list of completed and required signatures on the CRF used for signing a case report book.</p> <p>OPTIONAL. Required if either the CRBTEXT or CRBFILE attribute is specified. At least one combination of CRBTEXT or CRBFILE and CRFMEANING should be specified.</p>

Associating a form with a signature group

You can associate CRFs and case report books with signature groups. To associate a CRF or case report book with a signature group, create XML for each form that requires an authorized signature, using the SIGNCRF MedML element.

One form represents the case report book for signature purposes. To designate a CRF as the case report book signing form, specify its RefName as the value of the FORMREFNAME attribute in the SIGNCRF element, and specify **True** as the value of the FINALCRF attribute.

SIGNCRF element

Use the SIGNCRF element to associate each form that requires signature with the appropriate signature group.

The SIGNCRF element has the following syntax:

```
<SIGNCRF
  SIGNATUREGROUPNAME="name"
  FORMREFNAME="name"
  [RESETFORMSTATE="TRUE | FALSE" ]
  [INVALIDATIONLEVEL="USER | GROUP" ]
  [FINALCRF="TRUE | FALSE" ]/>
```

Note: For more information about the RESETFORMSTATE and INVALIDATION LEVEL attributes, see the *Utilities Guide*.

For example, to ensure that a form is signed by both a sponsor and a site representative, create a signature group for the sponsor and a signature group for the site, and associate the form with both signature groups. Assign sponsor users who have signature rights to the sponsor signature group, and assign site users who have signature rights to the site signature group.

The following example illustrates the use of the SignCRF element to designate the DEM, VS, and SC forms as requiring signature by a member of the CRA Signature group. The FINALCRF attribute indicates that signing the SC form signs the case report book.

```
<SIGNCRF SIGNATUREGROUPNAME="CRA Signature" FORMREFNAME="DEM"/>
<SIGNCRF SIGNATUREGROUPNAME="CRA Signature" FORMREFNAME="VS"
  INVALIDATIONLEVEL="USER"/>
<SIGNCRF SIGNATUREGROUPNAME="CRA Signature" FORMREFNAME="SC"
  FINALCRF="true"/>
```

SIGNCRF attributes

Attribute	Description
SIGNATUREGROUPNAME	<p>Identifies the authorized signature group. The signature group must have already been defined by a SIGNATUREGROUP element.</p> <p>REQUIRED.</p>
FORMREFNAME	<p>Specifies the RefName of the CRF. The form must have already been defined in the system. Note that screening and enrollment forms cannot be signed.</p> <p>REQUIRED.</p>
RESETFORMSTATE	<p>Specifies the policy for handling already-signed forms when a new signature group is added. Values are:</p> <ul style="list-style-type: none"> • TRUE—Indicates that the form must be approved by a member of the current signature group. This resets the state of fully-signed forms specified in the FORMREFNAME attribute to not fully signed. When a form is reset, the original signatures remain valid. However, the form must now be signed by a member of the newly-associated signature group as well. • FALSE—Default. Indicates that the form need not be re-signed when a new signature group is added. <p>OPTIONAL.</p>
INVALIDATIONLEVEL	<p>Specifies whether a signature should be invalidated when a data item is imported after the form has been signed. Values are:</p> <ul style="list-style-type: none"> • USER—The form or case report book signature is invalidated if the user who signed can view the item being imported. • GROUP—The form or case report book signature is invalidated if at least one user in the signature group can view the item being imported. <p>OPTIONAL.</p> <p>If you do not specify the INVALIDATIONLEVEL attribute, the InForm application invalidates the signature whenever the form is edited, either directly or by import. For more information, see <i>Signature invalidation</i> (on page 19).</p>

Attribute	Description
FINALCRF	<p>Indicates whether the form specified in the FORMREFNAME attribute represents the entire case report book for signing purposes. Note the following restrictions on the CRF designated as the case report book signing form:</p> <ul style="list-style-type: none"> • Only one form can be marked as FINALCRF • The final CRF cannot belong to more than one regular visit or to a repeating visit • The final CRF cannot be a repeating form <p>Values are:</p> <ul style="list-style-type: none"> • TRUE—The form is the case report book signature form. • FALSE—Default. The form is not the case report book signature form. <p>OPTIONAL.</p>

Associating an affidavit with a signature group

The following SignatureGroup definition illustrates the inclusion of the signing text for a CRF. The two %s characters specify that the displayed Electronic Signature Affidavit should include the user's first and last names. Note that the tag attributes must be in single quotes because they appear within the double quotes of the CRFTEXT attribute. Additionally, the SignatureGroup definition includes the definition of a translation string for the CRFTEXT attribute.

```
<SIGNATUREGROUP GROUPNAME="PI Signature" LANGUAGE="en-US"
  CRFTEXT="&lt;font name='Arial' size='2'&gt;By my dated signature below,
  I, %s %s, verify that this case report form accurately displays
  the results of the examinations, tests, evaluations and
  treatments noted within.&lt;br&gt;&lt;br&gt;
  Pursuant to Section 11.100 of Title 21 of the Code of Federal
  Regulations, this is to certify that I intend that this
  electronic signature is to be the legally binding equivalent
  of my handwritten signature.&lt;br&gt;&lt;br&gt;
  To this I do attest by supplying my user name and password and clicking
  the button marked &t b &gt;Submit&lt;/b&gt; below.&lt;/font&gt;"
  CRFMEANING="Approval">
  <USERREF USERNAME="dobrien"/>
  <USERREF USERNAME="lhill"/>
  <TRANSLATIONS>
    <TRANSLATION NAME="CRFTEXT" LOCALE="fr-FR"
      DISPLAYTEXT="&lt;font name='Arial' size='2'&gt;Par ma signature datée
      ci-dessous,
      Moi, %s %s, je confirme que ce cas formulaire de rapport affiche avec
      précision
      les résultats des examens, des tests, des évaluations et des
      constatées dans les traitements. &lt;br&gt; &lt;br&gt;
      Conformément à la Section de 11,100 Titre 21 du Code of Federal
      Règlement, il s'agit de certifier que j'ai l'intention que ce
      signature électronique doit être juridiquement contraignant équivalent
      de ma signature manuscrite. &lt;br&gt; &lt;br&gt;
      Pour cela, je ne témoigne par la fourniture de mon nom d'utilisateur
      et mot de passe et cliquez sur
      le bouton &lt; b &gt;Submit&lt;/b&gt; ci-dessous.&lt;/font&gt;"
      <TRANSLATION NAME="CRFMEANING" LOCALE="fr-FR"
        DISPLAYTEXT="Approbation"/>
    </TRANSLATIONS>
  </SIGNATUREGROUP>
```


Signature invalidation

If a user updates a signed form, the InForm application invalidates the previous signature or signatures and updates the signature listings and each form to indicate that the form or case report book must be signed again.

Data that has been coded and imported to the InForm application has special invalidation considerations. Coded data is often designed to be hidden on a form. If the import of coded data invalidates a signature, it might not be possible to see which item caused the invalidation. Therefore, study designers can specify whether imported data invalidates a signature.

When coded data is imported to a signed CRF or case report book, invalidation of the CRF or case report book is determined by the following:

- Visibility of the imported data.
- Setting of the INVALIDATIONLEVEL attribute of the SIGNCRF MedML component that associates a form or a case report book with a signature group.

If the signing user can view the imported item, or if the INVALIDATIONLEVEL attribute is not specified, the signature is always invalidated.

If the study is designed to base invalidation on the value of the INVALIDATIONLEVEL attribute, the invalidation decision for a CRF or a case report book is based on the following rules:

- If the INVALIDATIONLEVEL value is **USER**, the signature is invalidated only if the signing user can view the imported item.
- If the INVALIDATIONLEVEL value is **GROUP**, the signature is invalidated only if at least one user in the signature group can view the imported item.

Note: Invalidation processing for case report book signatures is invoked if coded data is imported to any CRF in the case report book, whether or not the CRF requires a signature.

Configuring the study to hide the required signature list

By default, the InForm application displays a list of required signatories on each CRF that requires signatures. This feature is an option that you set with a system configuration variable. To specify whether to display a required signature list:

- 1 Create an XML file containing the following element:

```
<SYSCONFIG
  CONFIGNAME="ViewCRFSignList"
  TYPE="0"
  VALUE="n"/>
```

where *n* is a code:

- **0**—Do not display required signature list on a CRF.
 - **1**—Default. Display required signature list on a CRF.
- 2 Install the setting in the study database using the MedML Installer utility. Note that you must stop and start the study for a change in setting to take effect.

The current value of the system configuration variable is visible on the System Configuration page in the Admin user interface.

Configuring the signature print preview

The InForm Signatures page includes an option to print a preview of a form that requires a signature or a preview of the case report book. By default, if any items have open or answered queries, the queries are not included in the print preview.

To include queries in the print preview:

- 1 Create a key called PFQuery in the following registry folder:
 HKEY\SOFTWARE\ORACLEHS\InForm
- 2 Create a DWORD Value called SignaturePrintPreviewQueries.
- 3 Change the value of the SignaturePrintPreviewQueries entry to a value other than 0.

If the SignaturePrintPreviewQueries entry has a value other than 0, the signature print preview shows open and answered queries under the items to which they are attached.

Note: The registry change takes effect immediately. You do not need to stop and restart the study.

Electronic study documentation

You can create study-specific documents that users can display in the Document window during an InForm session.

Perform these steps only if you want to enable the electronic study documentation features of the InForm application.

Note: In addition to these electronic study documentation features, you can set up online Help for CRFs and CRF items through the Central Designer application. For more information, see the Central Designer *InForm Design Guide*.

- 1 Create a study protocol.
 For more information, see *Creating a study protocol* (on page 21) and *Modifying the study protocol HTML file* (on page 22).

Note: As an alternative to this method, you can enable access to the study protocol using the InForm Portal application. For more information, see the *Portal Administration Guide*.

- 2 Create a documentation definition XML file.
 For more information, see *Creating a documentation definition XML file* (on page 23).
- 3 Create links between document files.
 For more information, see *Linking between document files* (on page 23).
- 4 Enable the display of the Visit Calculator and sample case report book.
 For more information, see *Enabling the display of the Visit Calculator and sample case report book in the Document window* (on page 25).
- 5 Associate the documentation with a study version.
 For more information, see *Associating documentation with a study version* (on page 25).

Creating a study protocol

Note: As an alternative to this method, you can enable access to the study protocol using the InForm Portal application. For more information, see the *Portal Administration Guide*.

- 1 Create one or more HTML files containing the text of the study protocol.
One file per protocol section is suggested. Within each file, make the code additions and changes as described in *Modifying the study protocol HTML file* (on page 22).
- 2 Create a Table of Contents file that includes each heading or subsection to which you want users to be able to link.
- 3 Create an XML file that defines the study protocol in a Documentation tag and as many DocBody tags as there are study protocol HTML files.
Use the BOOKMARKDOC value of the DOCTYPE attribute. For information on creating this documentation definition file, see *Creating a documentation definition XML file* (on page 23).
- 4 Link each item in the Table of Contents file to the appropriate study protocol HTML file.
For more information, see *Linking between document files* (on page 23).
- 5 Include the Documentation RefName in a StudyVersionDoc definition.
For more information, see *Associating documentation with a study version* (on page 25).
- 6 Process the study documentation in the MedML Installer utility to load the files into the InForm software database.

Modifying the study protocol HTML file

- 1 Replace the `</head>` and `< body>` tags at the beginning of each file with the following JavaScript function definition and call:

```
< script language="JavaScript">
function OnLoad()
{
%s
}
</script>
</head>

< body ONLOAD="OnLoad()">
```

Note: Do not include this JavaScript function and call in the Table of Contents file.

- 2 Search each file for percent signs (%), for example in table width specifications. Except for the %s string substitution command that appears in the OnLoad function definition at the beginning of each file, precede each percent sign with another percent sign as an escape character (%%). For example:

```
< table border="0" width="80%%">
< tr>
< td width="50%%"></td>
< td width="50%%"></td>
</tr>
</table>
```

- 3 Search each file for exclamation points (!). To include an exclamation point in the text of the study protocol, insert an additional explanation point as an escape character. For example:

```
< p>< b>Warning!!</b></p>
```
- 4 Use HTML formatting tags as necessary to create a document whose structure is clear and easy to understand. The following formatting conventions are suggested:
 - Code the protocol title as an `<h1>` tag. For example:

```
< h1>PFST60 Clinical Drug Study</h1>
```
 - Code the name of each protocol section as an `<h2>` tag. For example:

```
< h2>Objectives of Study</h2>
```

Creating a documentation definition XML file

You can create a documentation definition file to load study documents into the database.

The documentation definition XML file specifies the RefNames of the HTML files used in creating study documentation and specifies the locations of those files for the MedML Installer utility. Additionally, this file characterizes the study documentation files by type and provides a count of links so that the MedML Installer utility can reserve processing space.

Note that the first and last elements in the file must be `<MEDMLDATA>` and `</MEDMLDATA>`. To create a documentation definition file, use the following elements for each study document:

- 1 Use the `DOCUMENTATION` element to define a complete study protocol.
- 2 Assign a RefName to the document using the `REFNAME` attribute.

Linking between document files

You can set up links between document files so users can navigate between them by clicking highlighted link text.

To create a link between normal HTML files, you use an `<A>` tag with an `HREF` attribute in the file that contains the link. The `HREF` attribute is set to the name of the file to which you want to link (the target file). For example, to create a link on the text “road map” to a file called `roadmap.htm`, you would enter the following HTML text in the file where the link appears:

```
<a href="roadmap.htm">road map</a>
```

If the link is to an HTML bookmark within the file, you add the bookmark name to the `HREF` attribute:

```
<a href="roadmap.htm#appwindows">application windows</a>
```

To link between HTML files defined by `DOCBODY` elements, you still use an `<A>` tag with an `HREF`, but you replace the name of the target file with the following string:

```
" javascript:top.location.href='./PFTS.dll?pfSessionCode=!s!&pfCommand=Trialmgr_Help&pfSiteID=!i!&pfDocDisp=!d!&pfDocName=DOCUMENTATION_REFNAME&pfDocBodyName=DOCBODY_REFNAME&pfDocLink=FILE_BOOKMARKNAME&pfTimeout=1' "
```

In the string, replace the italicized variables with the following information:

- **DOCUMENTATION_REFNAME** — RefName of the document in which the file appears, as defined in a `DOCUMENTATION` element; for example:

```
&pfDocName>AboutInform
```
- **DOCBODY_REFNAME** — RefName of the target file to which you want to link, as defined in a `DOCBODY` element; for example:

```
&pfDocBodyName=ROADMAP
```
- **FILE_BOOKMARKNAME** — Name of the HTML bookmark within the file. Use this part of the string only when you are linking to a location within the target file. To link to the top of the target file, leave this part of the string out. An example of the `&pfDocLink` part of the string follows:

```
&pfDocLink=appwindows
```

Example of a complete link

The following text defines a link to a subtopic describing application windows. Online, the link appears as follows:

application windows

```
<a href="javascript:top.location.href='./PFTS.dll
?pfSessionCode=!s!&pfCommand=TrialMgr_Help&pfSiteID=!i!
&pfDocDisp=!d!&pfDocName=AboutInform&pfDocBodyName=ROADMAP
&pfDocLink=appwindows&pfTimeout=1'">application windows</a>
```

Note: The names of HTML files and of bookmarks within those files must not contain spaces or special characters. Only links between files defined with DOCTYPE elements require the special string. To create a link within a single file, use a simple HTML <A HREF> tag to a bookmark.

Enabling the display of the Visit Calculator and sample case report book in the Document window

Using XML definitions and the MedML Installer utility, you can configure an InForm study to include access to the Visit Calculator (Subject schedule) and a sample case report book with blank CRF pages.

- 1 Create DOCUMENTATION definitions for the Visit Calculator and sample case report book.

For more information, see the *Utilities Guide*.

- 2 Associate the new definitions with a study version.

For more information, see *Associating documentation with a study version* (on page 25).

Example of DOCUMENTATION definitions for the Visit Calculator and sample case report book:

```
<DOCUMENTATION REFNAME="Visit"
  DOCNAME="Visit Calculator"
  DOCTYPE="VISITDOC"
  LANGUAGE="en-US"
  HELPTEXT="Click here to view Subject schedule"
</DOCUMENTATION>

<DOCUMENTATION REFNAME="CRB"
  DOCNAME="Sample Book"
  DOCTYPE="CRBDOC"
  LANGUAGE="en-US"
  HELPTEXT="Click here to view Sample Case Book forms"
</DOCUMENTATION>
```

Associating documentation with a study version

You may need to revise the documents associated with a study, including Help documents and sponsor-provided documents.

To implement a new document version:

- 1 Update the files that make up the document.
- 2 If any link counts change, or if you add or remove a file from the document, update the XML file in which you specify the document definition.
- 3 Load the new or updated document files into the database using the MedML Installer utility to process the document definition XML file.
- 4 If you have made any changes to CRF Help, use the MedML Installer utility to reload into the database the definition of each Form to which the changed help text applies.
- 5 Create a new study version to include the updated document by changing the VERSIONDESCRIPTION attribute of the STUDYVERSION definition.
- 6 Associate the new study version with each site at which it will be applied by changing the VERSIONDESCRIPTION attribute of the STUDYVERSIONSITE element to match the STUDYVERSION definition.
- 7 Associate the updated document definition with the new STUDYVERSION definition by changing the VERSIONDESCRIPTION attribute of the STUDYVERSIONDOC element to match the STUDYVERSION definition.
- 8 Use the MedML Installer utility to load the updated definitions into the database in the following order: STUDYVERSION, STUDYVERSIONDOC, STUDYVERSIONSITE.

Email

In the Central Designer application, study designers can configure rules to trigger email notification when they fire in the InForm application. For more information, see *Enabling email notification* (on page 26).

In the InForm application, after a user successfully changes their password, an email message with a temporary password and instructions on how to access their account is sent to them. A study administrator can customize the email text that is sent by the InForm application. For more information, see *Customizing email text* (on page 27).

Enabling email notification

In the Central Designer application, study designers can configure rules to trigger email notification when they fire.

To enable email notification in an InForm study:

- 1 Make sure that Microsoft SMTP is installed.
Because this is a pre-installation requirement for the InForm software, SMTP should already be available.
- 2 Set the routing option for mail delivery.
- 3 Set the smart host or remote domain of the SMTP site to point to the email gateway for message transmissions.
- 4 Register the cdonts.dll on the server hosting the InForm study.

For more information, see *Registering the cdonts.dll file* (on page 26).

Note: Although the InForm application can be configured to send emails from the trial server, the emails are not able to be encrypted. Customers must consider this fact when designing email notifications, and should not include any data in an email that is required to be encrypted.

Registering the cdonts.dll file

The execution plan for email in the sample study calls the **cdonts.dll** file to send email. cdonts.dll is no longer supported by Microsoft, and calls that use cdonts.dll do not send mail unless you install the cdonts.dll file. Therefore, if you use the sample study as a model for setting up email notification, must register the cdonts.dll file.

- 1 Install Microsoft SMTP server, and make sure it is running.
- 2 Download and unzip cdonts.dll to the C:\Windows\System32 folder. cdonts.dll is available at many Internet download sites.
- 3 Register the cdonts.dll component on the InForm study server.
 - a Click **Start > Run**.
 - b Type:

```
regsvr32 c:\Windows\system32\cdonts.dll
```
 - c Click **Enter**.

Customizing email text

The information in the email sent by the InForm application after a successful password change includes:

- The email addresses of the sender and receiver appears in the body of the email with a temporary password.
- The maximum email address length is 255 characters.

A study administrator can customize the email text that is sent by the InForm application after a user successfully resets their password.

To customize the email text:

- 1 Edit the **resetpwdnotification.txt** file, located in <installation_folder>\InForm\resources.
- 2 Use the MedML Installer utility to install the **resources.xml** file to install the updated resetpwdnotification.txt file.

Note: When you update the resetpwdnotification.txt file, do not add, move, or delete the percent (%) character. Doing so can cause an error to occur.

Customized files are overridden when you upgrade a study. If you upgrade your study, you must reinstall the email information.

Home page

A Home page is the web page that appears when a user initially logs in to an InForm study. You can set the Home page at the study, site, or user level.

Setting up an InForm Home page

You can set up Home pages in two ways:

- Create an HTML or ASP page for the study.
For more information, see *Setting up a custom Home page* (on page 28).
- Designate the InForm Portal application as a user's Home page.
For more information, see the *Portal Administration Guide*.

A forms designer is usually responsible for creating the Home page and placing it in the study hierarchy directory. The release engineer is usually responsible for adding the Home page to the study.

Setting up a custom Home page

You can create a custom Home page and set it up to appear when a user logs in to a study.

The Home page can be either an HTML or ASP file. Use ASP if you want dynamic information from the InForm database to display on the Home page.

Note: If you are using ASP, set the study web server to have Read/Write and execution permissions through the MMC (Microsoft Management Console). Then, select the ASP directory (located in the Custom folder) to use those permissions.

Each user can have a unique Home page. Home pages must be accessible to the web server. A custom directory is automatically created whenever you set up a study in the Central Designer application, or with the pfadmin utility.

The virtual directory for each study is located in the PFInForm \Trials directory. You can copy these pages into the custom folder for the study, then to the virtual custom directory using Windows Explorer or the following **xcopy** command:

```
xcopy <drive:\path to study custom pages\*.* ><drive:\path to study custom folder\ >/e
```

- **xcopy** is the Windows command.
- <drive:\path to study custom pages*.*> is the drive and path to the custom Home pages created by the clinical study developer.
- <drive:\path to study custom folder\> is the drive and path to the \Custom folder for the InForm study.
- /e is an option that indicates to copy directories and subdirectories, including empty ones.

Itemset source verification option

The default behavior for source verification (SV) of itemset items is that when a user adds data to or edits an itemset item, and the itemset was previously marked source verified, the SV status of the itemset changes to not source verified. This is true whether or not the updated item is defined to require SV.

By creating and setting an entry for a registry key, you can configure a single study or all studies on a server so that the SV status of an itemset is not unset when a user adds data to or edits an itemset item that does not require SV.

- 1 Create a key called PFMngrTrial in the following registry folder:

HKEY_LOCAL_MACHINE\SOFTWARE\ORACLEHS\InForm

- 2 Create a DWORD Value with one of the following names:

- *<studyname>*_ItemSetUNSVRequiredOnly—Sets the itemset SV behavior for the specified study.
- ItemSetUNSVRequiredOnly—Sets the itemset SV behavior for all studies that are running on the machine.

- 3 Change the value of the entry to a value other than 0.

If the *<studyname>*_ItemSetUNSVRequiredOnly or ItemSetUNSVRequiredOnly entry has a value other than 0, adding data to or editing an item in an itemset that was previously marked source verified does not unset the SV status if the updated item does not require SV.

Login page customizations

A study administrator can add support and contact information to the InForm Login page and the External Reporting Login page. By default, support and contact information does not appear on the login pages.

Customizing support contact information for the InForm Login page

By default, contact information does not appear on the InForm Login page.

To add contact information to the Login page:

- 1 Edit the **LoginScreen_SupportInfo** resource string in the **resources_auth.xml** file, located in `<installation_folder>\InForm\resources`.

You must use XML character entities instead of HTML tags for special characters in the data you enter in the resource string.

For example:

Incorrect: `Tech Support information`

Correct: `Tech Support information`

- 2 Install the updated file with the MedML Installer utility.
- 3 Navigate to the InForm Login page to verify that the contact information that appears on the page matches what you entered in the **resources_auth.xml** file.

The contact information appears at the bottom of the InForm Login page.

Note: Customized files are overridden when you upgrade a study. If you upgrade your study, you must reinstall the support contact information.

Customizing support contact information for the External Reporting Login page

By default, contact information does not appear on the External Reporting Login page.

To add contact information to the External Reporting Login page:

- 1 Edit the **portalRL_en.xml** and **portalRL_ja.xml** files, located in the `<Cognos_Installation_Directory>\templates\ps\messages` folder on the Cognos Report server and Content Manager.
- 2 Edit **string id= "IDS_TRADEMARK"** element, and save the file.
- 3 Restart the Cognos service on the Report server and Content Manager.

The next time you access External Reporting Login page, the contact information appears at the bottom of the page.

Note: Customized files are overridden when you upgrade Reporting. If you upgrade Reporting, you must update the **portalRL_en.xml** and **portalRL_ja.xml** files again.

Numbering

The InForm application automatically generates screening and enrollment numbers. Additionally, the InForm application can generate drug kit numbers when subjects are randomized. Each of these numbering types is configurable.

To set up numbering in the InForm application, the following elements are required:

- **SEQUENCETYPE**—Defines types of sequence numbers. The default sequence types are part of the base installation of the InForm application.
- **SEQUENCE**—Defines specific sequences within sequence type. The default sequences are also part of the base installation.
- **SYSCONFIG**—Defines a system configuration variable that specifies the scheme for formatting a sequence number.

Default sequence types and sequences

The base study definition that is installed when you execute a deployment package includes default sequence type and sequence definitions.

Default SEQUENCETYPE definitions:

```
<SEQUENCETYPE SEQUENCETYPENAME="Screening" />
<SEQUENCETYPE SEQUENCETYPENAME="Enrollment" />
<SEQUENCETYPE SEQUENCETYPENAME="Randomization" />
```

Default SEQUENCE definitions for screening, enrollment, and a Simple Central randomization scheme:

```
<SEQUENCE SEQUENCENAME="Screening Number Sequence"
  SEQUENCETYPENAME="Screening"
  UUID="F7F1B3B8-0B5C-11D2-A418-00A0C963E0AC" />
<SEQUENCE SEQUENCENAME="Enrollment Number Sequence"
  SEQUENCETYPENAME="Enrollment"
  UUID="EB75B898-078B-11D2-A417-00A0C963E0AC" />
<SEQUENCE SEQUENCENAME="Simple SimpleCentral"
  SEQUENCETYPENAME="Randomization"
  UUID="4F4A0246-5009-11D2-931C-00A0C9769A13" />
```

Creating sequences

If you configure your study to support a different randomization scheme, you must create a sequence definition for that scheme using the following MedML syntax:

```
<SEQUENCE
  UUID="id"
  SEQUENCENAME="name"
  SEQUENCETYPENAME="name" />
```

Specifying sequence number format

The format of screening numbers, subject enrollment numbers, and randomization numbers is specified with a formatting string.

- Specification of numbering formats for screening and enrollment numbers is optional.
- If you configure the InForm application to generate randomization drug kit numbers, specification of a randomization numbering format is required.

Note: Subject numbers can be automatically generated by the InForm application, using the format that you specify as described in this section, or you can configure the InForm application to enable site personnel to assign subject numbers manually.

The format of each type of sequence number can contain fixed text, site name, stratification code, and a sequential number that can also include a text string. These formatting specifications are in the following order:

[SPR]:[string][%][flag][width][type][string]

- *SPR*—Code that indicates the type of screening, subject enrollment, or randomization number. Codes are not case-sensitive. For more information, see **Sequence number codes** (on page 33).
- *string*—Text string that appears at the beginning of each generated number.
- *%*—Required character preceding each flag/width/type specification.
- *flag/width/type*—A series of specifications that indicates how the InForm application substitutes values in each generated number. You can include multiple flag/width/type specifications, where each specification includes the following values:
 - *flag*—Character that specifies a prefix used to fill in the numerical portion of the sequence number to maintain the number of characters specified in the width variable. For more information, see **Flag characters** (on page 33).
 - *width*—Minimum number of characters in the numerical portion of the sequence number, to be left-filled by the character specified in the flag variable. This specification is optional.
 - *type*—Code that indicates the inclusion of the site name, stratification code, and sequential number in the sequence number. Codes are not case-sensitive. For more information, see **Type codes** (on page 34).
- *string*—Text string added to the end of each generated number.

Sequence number codes

Code	Type of sequence number
SC	Simple Central randomization —The study uses one list of drug kits. Each new subject is assigned the next sequential drug kit number on the list.
CS	Central Stratified randomization —The study has multiple lists of drug kits. Each new subject is assigned to a drug kit list based on entered subject data. Then, the subject is assigned the next sequential drug kit number on that list.
SS	Simple Site randomization —Each site has a different drug kit list. Each new subject is assigned the next sequential drug kit number on the list for the subject's site.
SR	Stratified by Site randomization —Each site has multiple lists of drug kits. Each new subject is first assigned to the set of lists for the subject's site. Then, the subject is assigned to one of the site's drug kit lists based on entered subject data. Finally, the subject is assigned the next sequential drug kit number on that list.
S1	Cross-site screening number —Screening numbers are assigned sequentially across the study without regard to which site screens the candidate.
SN	Site-based screening number —Each site has a separate sequence of screening numbers.
P1	Cross-site subject number —Enrollment numbers are assigned sequentially across the study without regard to which site enrolls the subject.
PN	Site-based subject number —Each site has a separate sequence of enrollment numbers.

Flag characters

Character	Description
0	The InForm application adds zeroes to the left of the numerical sequence until the specified width is reached.
#	The InForm application adds pound signs to the left of the numerical sequence until the specified width is reached.
-	The InForm application adds hyphens to the left of the numerical sequence until the specified width is reached.

Type codes

Code	Description
S	Includes the site mnemonic. This type is optional and can be used in screening, subject, and randomization sequence numbers.
T	Includes the stratification code. This type applies to randomization sequence numbers and is required if the randomization type is Central Stratified or Stratified by Site.
Q	Includes a numeric value assigned sequentially to each new subject who is screened, enrolled, or randomized. This type is required for all sequence number format definitions.

Examples

- SC:RND-%q

Randomization sequence number for a Simple Central randomization scheme. Each number consists of the string RND and a sequential number, for example: RND-12.

- CS:RND-%t-%q-PF105

Randomization sequence number for a Central Stratified randomization scheme. Each number consists of the string RND, the stratification code, a sequential number, and the study name, PFST, for example: RND-CS_WT150-12-PFST

SN:SCR-%s-%05q—Screening sequence number. Each number consists of the string SCR, the site mnemonic, and a five-digit sequential number that is left-filled with zeroes, for example: SCR-PF-00012.

Note: Randomization number configuration is required, if you are configuring your study to support generating drug kit numbers. If you do not configure subject and screening number formats, the InForm application uses the following default formats:

Screening number—SN:SCR-%s-%q (the string SCR, followed by site mnemonic, followed by generated number)

Subject enrollment number—PN:ENR-%s-%q (the string ENR, followed by site mnemonic, followed by generated number)

Installing sequence number formats

To install the sequence number format in the database, include a SYSCONFIG element for the sequence number format in the XML file used to set configuration variable values. The following shows the default format for drug kit numbers under Simple Central randomization that appears in the core_SystemConfig.xml file in the XMLBase directory of the InForm installation.

```
<SYSCONFIG CONFIGNAME="RandSimpleCentral"
  TYPE="0"
  VALUE="SC:RND-%q" />
```


Predefined lists in system forms

The InForm application provides several predefined lists that specify default text for such things as rights, comments, and query responses. You define the entries in the change reason list of the Data Values page for changes to items and for entries in the query text list on the Queries page.

Although you should not manipulate most of these lists directly, you can modify the default text that displays in the drop-down lists for:

- Reasons for change.
- Reasons for clearing a CRF.
- Reasons for editing an item.
- Query responses (not query states).

Note: These defaults are base components and are part of the study. If you modify the settings in these files, you must reinstall the XML into the study in order for the changes to take effect.

The following table lists the text that you can change and the files in which you can make the changes.

Text to customize	File to edit
Reasons for change	XMLBase\sysform_EditItem.xml
Reasons for clearing a CRF	XMLBase\sysform_ClearCRF.xml
Reasons for editing an item	XMLBase\sysform_ItemEditReasons.xml
Query responses	<ul style="list-style-type: none"> • Resources\Enu\pfscript.js • Resources\Enu\Templates\PDFPage.xml • Resources\Enu\resources.xml • Resources\Jpn\pfscript.js • Resources\Jpn\Templates\PDFPage.xml • Resources\Jpn\resources.xml

Allowable changes include:

- Adding new label text values.
- Removing an existing option (ELEMENTREF).
- Replacing an existing text value with a new text value.

Caution: Do not delete an existing PFELEMENT definition for a predefined list, even if you remove the corresponding ELEMENTREF tag.

Changing reason text for clearing a CRF or editing an item

You can add new text values to predefined lists, and you can remove existing values or replace them with new values by changing the definitions that the InForm software references. You cannot physically delete an existing text definition in a predefined list (in other words, *do not* delete the PFELEMENT definitions of the existing values).

Note: If you change the system forms in the XML_Base folder of the InForm installation, as described in this procedure, *all* studies that you install subsequently reflect the customized reason text. To customize the reason text for only one study, save the customized system form XML files in a different location from the XML_Base folder, and install them from the saved location with the MedML Installer utility.

To change a reason text value:

- 1 Make a backup copy of the file for the list to edit.
 - **sysform_ClearCRF.xml**—Contains the list of reasons for clearing a CRF.
 - **sysform_EditItem.xml**—Contains the list of reasons for editing a CRF item.
- 2 Open the file.
- 3 Create a new PFELEMENT definition for the new text you want to add. For example,

```
<PFELEMENT REFNAME="CLEARCRF_WRONGSUBJECT"
  LABEL="Wrong Subject"
  TYPE="STRING"
  VALUE="Wrong Subject" />
  <TRANSLATIONS>
    <TRANSLATION NAME="LABEL" DISPLAYTEXT="<Japanese_text>"
      LOCALE="ja-JP" />
  </TRANSLATIONS>
```

- 4 Edit the list of ELEMENTREF definitions in the appropriate drop-down list definition:

- To add a new text value, add a new ELEMENTREF definition that uses the REFNAME value you defined in step 3. Be sure to specify the order in which you want the new text to appear in the drop-down list. For example, add a new selection for a Severe Transcription Error in the second position in the drop-down list:

```
<PULLDOWNCONTROL REFNAME="CLEARCRF_CHANGEREASONPULLDOWN"
  UUID="730C92AD-33AE-11D3-8D93-00902757C687"
  NAME="CLEARCRF_CHANGEREASONPULLDOWN">
  <ELEMENTREF REFNAME="CLEARCRF_TRANSCRERROR" ORDER="1" />
  <ELEMENTREF REFNAME="CLEARCRF_WRONGSUBJECT"
    ORDER="2" />
  <ELEMENTREF REFNAME="CLEARCRF_NEWINFO" ORDER="3" />
  <ELEMENTREF REFNAME="CLEARCRF_CHANGEDINFO" ORDER="4" />
</PULLDOWNCONTROL>
```

- To replace an existing text value with a new one, edit the ELEMENTREF definition that refers to the old value by changing the REFNAME attribute to refer to the new value you defined in step 3. For example, to substitute the new text for a Severe Transcription Error in place of the original “Transcription Error,” you would change the XML to look like this:

```
<PULLDOWNCONTROL REFNAME="CLEARCRF_CHANGEREASONPULLDOWN"
  UUID="730C92AD-33AE-11D3-8D93-00902757C687"
  NAME="CLEARCRF_CHANGEREASONPULLDOWN">
  <ELEMENTREF REFNAME="CLEARCRF_WRONGSUBJECT"
    ORDER="1" />
  <ELEMENTREF REFNAME="CLEARCRF_NEWINFO" ORDER="2" />
  <ELEMENTREF REFNAME="CLEARCRF_CHANGEDINFO" ORDER="3" />
</PULLDOWNCONTROL>
```

- To remove an existing text value, delete the ELEMENTREF definition that refers to it. Update the ORDER attributes of the remaining ELEMENTREF definitions to reflect the change. For example, to cause the InForm application to ignore both transcription error messages, change the XML to look like this:

```
<PULLDOWNCONTROL REFNAME="CLEARCRF_CHANGEREASONPULLDOWN"
  UUID="730C92AD-33AE-11D3-8D93-00902757C687"
  NAME="CLEARCRF_CHANGEREASONPULLDOWN">
  <ELEMENTREF REFNAME="CLEARCRF_NEWINFO" ORDER="1" />
  <ELEMENTREF REFNAME="CLEARCRF_CHANGEDINFO" ORDER="2" />
</PULLDOWNCONTROL>
```

Note: Take care not to remove or replace any ELEMENTREF definitions for query states.

- Save your changes.
- Install the updated system forms by using the MedML Installer utility.

Changing query text

You can change the text of standard query reasons and responses by editing the following files in the InForm installation tree:

- \Resources\Enu\pfscript.js
- \Resources\Enu\Templates\PDFPage.xsl
- \Resources\Jpn\pfscript.js
- \Resources\Jpn\Templates\PDFPage.xsl

Note: Standard query reasons and responses appear in the user's product locale in the Reporting and Analysis module. If you customize query reasons and responses, the custom text does not appear in the user's product locale in the Reporting and Analysis module.

Each set of strings, prefixed by a number in brackets, appears under different conditions in an InForm study. For more information, see *Types of query text strings in the pfscript.js and PDFPage.xsl files* (on page 38).

- Make a backup copy of each **pfscript.js** and **PDFPage.xsl** file.
- In the QO section of each **pfscript.js** and **PDFPage.xsl** file, add, edit, or remove query text strings as desired.

Separate response strings with a comma and surround each string with double quotation marks. The QO section of the **pfscript.js** and **PDFPage.xsl** files follows:

```
QO=[[ [1,2],["Item incomplete","Data does not match source","Missing
units","Make text more specific"]],
  [[7],["Original value is correct","Changed data per query","Query is
ambiguous","Data is not in patient record","Measurement skipped on this
visit"]],
  [[3],["Response from site required"]],
  [[4],["Query is invalid or does not apply","Query can be addressed
internally"]],
  [[5,6],["Response does not satisfy query"]],
  [[8],["Response satisfies query"]],
  [[9],["State chosen is acceptable"]]]
```

- 3 Use the following XML to install the updated pfscrip.js files with the MedML Installer utility:

```
<RESOURCEDATA xmlns="PhaseForward-MedML-Inform4">
<RESOURCE
  FILENAME="pfscrip.js"
  UUID="PF_RESOURCE_GENERIC_SCRIPT_MAIN"
  DESCRIPTION="Main Script"
  DATATYPE="SCRIPT"
  LANGUAGE="English" />
<HTMLTEMPLATE
  TEMPLATENAME="PF_SCRIPT_MAIN"
  BROWSERNAME="GENERIC"
  RESOURCEUUID="PF_RESOURCE_GENERIC_SCRIPT_MAIN" />
</RESOURCEDATA>

<RESOURCE
  FILENAME="pfscrip.js"
  UUID="PF_RESOURCE_GENERIC_SCRIPT_MAIN"
  DESCRIPTION="Main Script"
  DATATYPE="SCRIPT"
  LANGUAGE="Japanese" />
  <HTMLTEMPLATE
  TEMPLATENAME="PF_SCRIPT_MAIN"
  BROWSERNAME="GENERIC"
  RESOURCEUUID="PF_RESOURCE_GENERIC_SCRIPT_MAIN"
  />
```

Types of query text strings in the pfscrip.js and PDFPage.xsl file

Identifier	Default strings	When used
[1,2]	["Item incomplete","Data does not match source","Missing units","Make text more specific"]	Creating a query.
[3]	["Response from site required"]	Placing a candidate query in open state.
[4]	["Query is invalid or does not apply","Query can be addressed internally"]	Deleting a query.
[5,6]	["Response does not satisfy query"]	Reissuing a query.
[7]	["Original value is correct","Changed data per query","Query is ambiguous","Data is not patient record","Measurement skipped on this visit"]	Responding to a query.
[8]	["Response satisfies query"]	Closing a query.
[9]	["State chosen is acceptable"]	Resolving a conflict.

Randomization

The randomization feature of the InForm application enables users to assign a drug kit to a subject based on a randomization scheme that has been chosen for the study. When randomization configuration is complete, one of the study's forms contains a Drug Kit section. When a user clicks the Randomize button, the InForm application returns a drug kit number, along with associated information about the drug kit, in the Drug Kit section of the form.

Before a user can use the randomization feature, you must perform the following configuration activities:

- 1 In the Central Designer application, include an item with the Special Fields custom property value of **Randomization field (Randomization)** on the form from which users will randomize subjects.

For more information, see the Central Designer *InForm Design Guide*.

- 2 In the Central Designer application, create a randomization rule to generate the sequence and drug kit number. The Randomize function is available to help you create the rule.

For more information, see the Central Designer *Rules Reference Guide*.

- 3 Create a randomization sequence for each different list of drug kits used in the study, and install it in the study database using the MedML Installer utility.

The number of drug kit lists depends on the randomization method chosen:

- **Simple Central (Type 1)**—The study uses one list of drug kits. Each new subject is assigned the next sequential drug kit number on the list.
- **Central Stratified (Type 2)**—The study has multiple lists of drug kits. Each new subject is assigned to a drug kit list based on entered subject data. Then, the subject is assigned the next sequential drug kit number on that list.
- **Simple Site (Type 3)**—Each site has a different drug kit list. Each new subject is assigned the next sequential drug kit number on the list for the subject's site.
- **Stratified by Site (Type 4)**—Each site has multiple lists of drug kits. Each new subject is first assigned to the set of lists for the subject's site. Then, the subject is assigned to one of the site's drug kit lists based on entered subject data. Finally, the subject is assigned the next sequential drug kit number on that list.

For more information, see *Randomization sequences* (on page 40).

- 4 Configure the randomization data source manager (COM object) to be used.

For more information, see *Randomization source manager configuration* (on page 41).

- 5 Configure the format of each randomization sequence to be used.

For more information, see *Randomization sequence format configuration* (on page 42).

- 6 Configure the study to use the randomization data source.

For more information, see *Randomization source database setup* (on page 43).

- 7 Create an ODBC connection for each randomization source database.

You can do this manually or by using the pfadmin utility.

For more information, see *ODBC connection for the randomization database* (on page 48).

- 8 Configure the study to use the randomization data source defined for it.

This step is necessary only if you create the ODBC connection manually. If you perform that step by using the pfadmin utility, the utility performs both the DSN creation and configuration automatically.

For more information, see *Configuring the study to use the randomization DSN* (on page 49).

Randomization sequences

A study that uses randomization requires the following sequence definitions:

- One SequenceType definition for the Randomization sequence. This definition is included in the base study and is in the following format:

```
<SEQUENCETYPE SEQUENCETYPENAME="Randomization" />
```

- A Sequence definition for each randomization sequence needed for the study. You need to define one randomization Sequence element for each randomization source. For example:
 - If your study uses the Simple Central randomization method, you need one Sequence definition for the single list of randomization kits.
 - If your study has ten sites and it randomizes by using the Simple Site randomization method, you need ten Sequence definitions, one for each site.
 - If your ten-site study uses the Stratified by Site randomization method, and you categorize subjects into one of three stratifications, you need 30 Sequence definitions.

Each Sequence definition requires the following attributes:

- **SEQUENCENAME**—Name used when referring to the Sequence in the randomization rule and in the randomization source database.
- **SEQUENCETYPENAME**—Randomization, indicating that the sequence is of the Randomization SequenceType.
- **UUID**—Universally Unique Identifier: a string that identifies the element uniquely across all studies, study databases, and machines.

Note: The format of the UUID must follow the format used in the sample UUIDs provided in the Base study. A suggested method for generating UUIDs for Sequence definitions is to copy the UUID of the randomization Sequence definition provided in the core_DefinitionSequences.xml file and change one character for each Sequence definition you create. This ensures that the format is correct and each string is unique. Alphabetic characters in UUIDs should be uppercase.

Example of a randomization sequence

The following sample .xml file illustrates the definition of the Randomization SequenceType and several randomization sequences. The first is for a Simple Central randomization scheme, and the other two define sequences for sample randomization sources used in a Central Stratified randomization scheme.

```
<?xml version="1.0"?>

<MEDMLDATA xmlns="PhaseForward-MedML-Inform4"><!--SequenceType definition -->
<SEQUENCETYPE SEQUENCETYPENAME="Randomization"/>

<!-- Sample Randomization Sequences -->

<!-- Type 1 randomization sequence -->
<SEQUENCE SEQUENCENAME="SimpleCentral"
SEQUENCETYPENAME="Randomization"
UUID="6DFF68EE-759C-11D2-938C-00A0C9769A13" />

<!-- Type 2 randomization sequences -->

<!-- Sequence _WT150 for Weight 90 up to 150 -->
<SEQUENCE SEQUENCENAME="CS_WT150"
SEQUENCETYPENAME="Randomization"
UUID="C31355CE-7598-11D2-938C-00A0C9769A13" />

<!-- Sequence _WT275 for Weight above 150 up to 275 -->
<SEQUENCE SEQUENCENAME="CS_WT275"
SEQUENCETYPENAME="Randomization"
UUID="D5270A30-7598-11D2-938C-00A0C9769A13" />

</MEDMLDATA>
```

Randomization source manager configuration

The randomization data source is a customer-defined database that contains the drug kit information for each list of drug kits in use in the study. The randomization source manager is implemented as a COM object that accesses the randomization data source database. The randomization source manager provided with the InForm application accesses the database through ODBC.

The randomization source manager for the InForm application supports all four randomization methods and Microsoft Access or Oracle randomization source databases. To use the randomization source manager, add the configuration name and COM ProgID of the randomization source manager to the system configuration table by using the following statement in the .xml file used to set values in the system configuration table:

```
<SYSCONFIG CONFIGNAME="RandomizationSrc"
TYPE="0" VALUE="InForm.PFRandomization.1" />
```

This statement appears in the core_SystemConfig.xml file in the base study.

Randomization sequence format configuration

In the InForm application, you can configure the format of screening numbers, subject numbers, and randomization numbers. To specify the randomization sequence number format, include a SYSCONFIG component for the sequence number format in the .xml file used to set configuration variable values. The following default format appears in the core_SystemConfig.xml file in the base study:

```
<SYSCONFIG CONFIGNAME="RandSimpleCentral"  
  TYPE="0"  
  VALUE="SC:RND-%q" />
```

Randomization number configuration is required. For more information, see *Numbering* (on page 31).

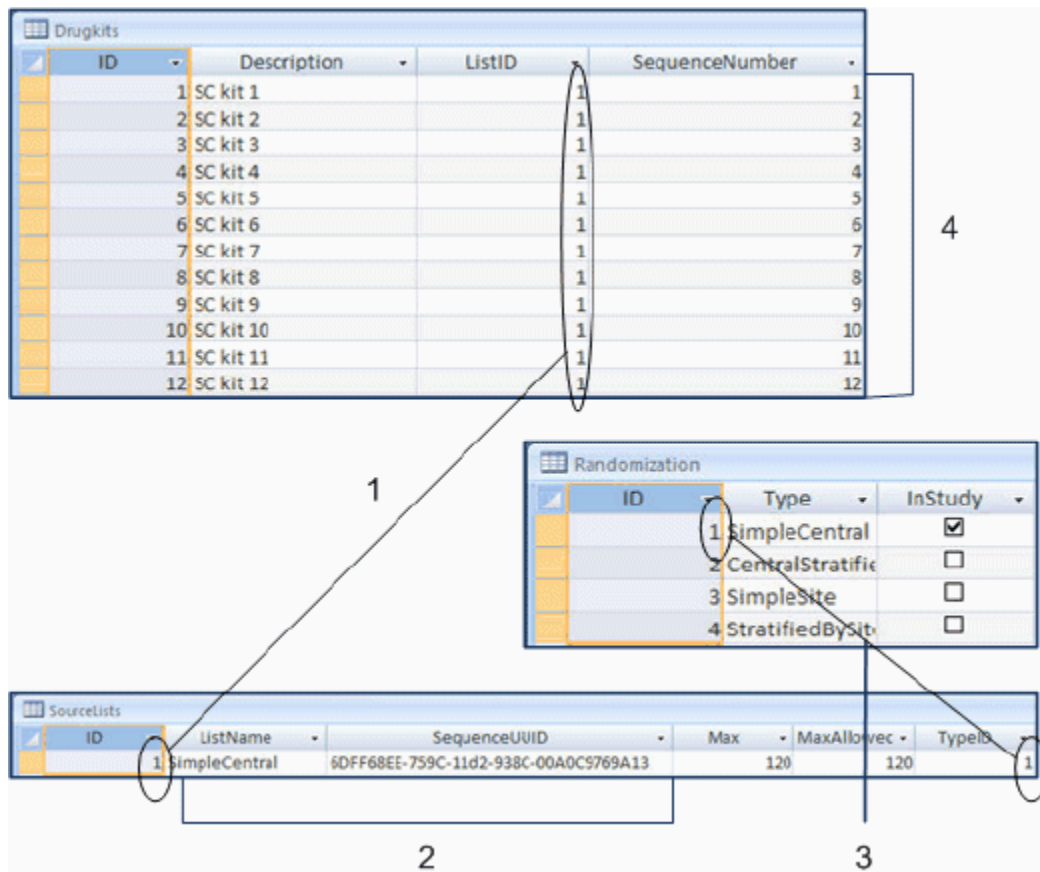
Randomization source database setup

The randomization data source is a custom database that contains the drug kit information for each list of drug kits in use in the study. The InForm application supports randomization source databases implemented with Microsoft Access or Oracle.

Note: A sample Microsoft Access database is included in the files for the PFST60 sample study. To use an Oracle randomization database, create an Oracle schema with a table structure that is identical to the sample Microsoft Access database.

The database has the following tables:

- Randomization
- Sourcelists
- Drugkits



1—Drugkits.ListID maps to Sourcelists.ID.

2—ListName and SequenceUUID are from the SEQUENCENAME and UUID attributes of the SEQUENCE XML definition.

3—Randomization.ID maps to Sourcelists.TypeID.

4—Each SEQUENCE definition has one set of sequence numbers. In this example, all drug kits are for the SimpleCentral SEQUENCE definition and randomization type.

Randomization table

The Randomization table indicates the randomization types that are in use in the study. This table has the following columns:

Column name	Data type	Description
ID	Number, primary key	Number that corresponds to the randomization TypeID in the SOUCELISTS table: <ul style="list-style-type: none"> • 1—Simple Central • 2—Central Stratified • 3—Simple Site • 4—Stratified by Site
Type	Text	Name of the randomization type; one of the following: <ul style="list-style-type: none"> • SimpleCentral • CentralStratified • SimpleSite • StratifiedBySite
InStudy	Boolean	If true, indicates that the corresponding randomization type is being used in the current study.

Sourcelists table

The **Sourcelists** table corresponds to the randomization SequenceTypes entered into the InForm database with XML and the MedML Installer utility. This table has one row for each randomization list used in the study. The table has the following columns:

Column name	Data type	Description
ID	Autonumber, primary key	Sequential list identification number that maps to the ListID in the DrugKits table.
ListName	Text	Name of the drug kit list. The randomization rule must populate the Randomization.Source property with this name.
SequenceUID	Text	UUID of the SequenceType to which the drug kit list corresponds in the InForm software database. Note: The InForm application and the MedML Installer utility convert alphabetic characters in UUIDs to uppercase.
Max	Number	Maximum number of drug kits.
MaxAllowed	Number	Maximum number of drug kits that can be used during the study.
TypeID	Number	Identification code of the randomization type. This value maps to the ID column in the Randomization table: <ul style="list-style-type: none"> • 1—Simple Central • 2—Central Stratified • 3—Simple Site • 4—Stratified by Site

Drugkits table

The Drugkits table holds drug kit information for each randomization source list. This table has the following columns.

Note: Special configuration may be required if you are using the Central Stratified randomization type. For more information, see *Setting up Central Stratified randomization* (on page 47).

Column name	Data type	Description
ID	Autonumber	Sequential drug kit identification number.
Description	Text	Drug kit information. If the randomization rule so specifies, this information is appended to the randomization number that the InForm application generates.
ListID	Number	Number that maps to the ID in the SourceLists table and enables the randomization source data manager to get the correct drug kit string.
SequenceNumber	Number	Randomization sequence number in the list identified by the ListID number.

Populating randomization source database tables

For each study, populate the tables of the randomization source database with the information about each drug kit that will be available for use in the study:

- In the **Randomization table**, specify the type of randomization to be used in the study.
- In the **Sourcelists table**, enter the source name and sequence UUID, copied from the XML file used to enter SequenceTypes into the InForm database, for each drug kit list.
- In the **Drugkits table**, enter information about each drug kit to be used.

Note: As a suggested convention, include the name of the study in the name of the randomization source database, and store the database in the study folder in the InForm installation tree.

A sample Microsoft Access database is distributed with the PFST60 sample study and provides a template for the randomization source database. The MDB file for the sample database is located in the \InForm\Sample_PFST60\Rand folder of the InForm installation.

Note: The randomization source database must physically reside on the same machine as the InForm server; you cannot map it to the InForm server machine by using a network drive.

Setting up Central Stratified randomization

For the Central Stratified type of randomization, special configuration is necessary if you want the sequence numbers in each drug kit list to start with a number other than 1. In the Central Stratified type of randomization, the study has multiple lists of drug kits. Each new subject is assigned to a drug kit list based on entered subject data. Then, the subject is assigned the next sequential drug kit number on that list.

Under Central Stratified randomization, unless each set of sequence numbers in the Drugkits table in the randomization database starts at 1, randomization fails when you try to randomize a study subject.

If you want your sequence numbers to start with a number other than 1:

- 1 Set up the Drugkits table so that:
 - Each set of sequence numbers in the SEQUENCENUMBER column starts with 1.
 - The sequence numbers you want to use are in the DESCRIPTION column.
- 2 In the rule that assigns the sequence number when a subject is randomized, use the GetNextKit method so that the values in the DESCRIPTION column are included in return value provided by the KitInfo variable.

ODBC connection for the randomization database

To configure an ODBC connection for a Microsoft Access or Oracle randomization data source, do either of the following:

- Create a randomization DSN manually, by using the ODBC manager of Microsoft Windows.
For more information, see *Creating an ODBC connection using the Windows ODBC Manager* (on page 48)
- Let the pfadmin utility create the randomization DSN automatically.
For more information, see *Creating an ODBC connection with the pfadmin utility* (on page 48).

You must create a separate DSN for each study's randomization database.

Creating an ODBC connection using the Windows ODBC Manager

- 1 Click **Start > Programs > Administrative Tools > Data Sources (ODBC)**.
- 2 Select the **System DSN** tab.
- 3 Click **Add**.
- 4 In the Create New Data Source window, select **Microsoft Access Driver**.
- 5 Click **Finish**.
- 6 Configure the data source.

For more information, see *Configuring a randomization data source* (on page 49).

Creating an ODBC connection with the pfadmin utility

The pfadmin utility is a command-line utility included in the InForm software. To use pfadmin to create a DSN for the randomization database:

- 1 Open a Command Prompt window.
- 2 If you have a Microsoft Access randomization source database, enter the following command:

```
pfadmin CONFIG Trial <StudyName> /Rnd [<MDBFilePath>]
```

- *StudyName* is the name of the study.
- *MDBFilePath* is the full pathname of the Microsoft Access or Oracle randomization source database.

or

If you have an Oracle randomization source database, enter the following command:

```
pfadmin CONFIG Trial <StudyName> /Rnd [<MDBFilePath>]
```

- *StudyName* is the name of the study.
- *MDBFilePath* is the full pathname of the Microsoft Access or Oracle randomization source database.

When prompted, enter:

- The name of the study schema owner.
- The password of the study schema owner.

For example:

```
PFAdmin config trial PFST60 /Rnd
E:PF\InForm\Sample_PFST60\Rand\RndPFST60.mdb
```

Configuring a randomization data source

- 1 In the ODBC Text Setup dialog box, enter the DSN of the randomization database as the **Data Source Name**.

As a suggested convention, include the name of the study in the name of the randomization source database; for example, if the study name is PF304, you can name the randomization DSN PF304RND.

- 2 In the **Database** section of the dialog box, click **Select Directory**, and select the randomization source database from the directory where it is stored.
- 3 Click **OK** in each dialog box.

Configuring the study to use the randomization DSN

After manually creating a randomization source DSN for a study, you must configure the study to use the DSN.

Note: This step is necessary only if you use the Control Panel ODBC manager to create the randomization DSN. If you use the pfadmin utility, it configures the study to use the randomization DSN.

Configure each study separately. Use pfadmin to do this:

- 1 Open a Command Prompt window.
- 2 Change to the \bin directory in the InForm software installation.
- 3 If you have a Microsoft Access randomization source database, enter the following command:

```
pfadmin CONFIG Trial <StudyName> /RndDSN DSN
```

- *StudyName* is the name of the study.
- *DSN* is the name of the randomization source DSN. For more information, see **ODBC connection for the randomization database** (on page 48).

or

If you have an Oracle randomization source database, enter the following command:

```
pfadmin CONFIG Trial <StudyName> /RndDSN DSN
```

- *StudyName* is the name of the study.
- *DSN* is the name of the randomization source DSN. For more information, see **ODBC connection for the randomization database** (on page 48).

When prompted, enter:

- The name of the study schema owner.

- The password of the study schema owner.

Note: The schema owner UID and PID must begin with a letter and contain alphabetic or alphanumeric characters. Do not use all numeric characters.

Examples:

- Microsoft Access randomization source database:

```
PFAdmin config trial pfst60 /RndDSN pfst60RND
```

- Oracle randomization source database:

```
PFAdmin config trial pfst60 /RndDSN pfst60RND
```


Reports

To ensure that data is reported appropriately in standard and ad hoc InForm reports, observe the study design considerations described in this section.

Study version acceptance dates

Report designers can report on the following site dates:

- **Site Activation Date**—The projected date for the activation of the site. This date is specified in the definition of the site and reflects an estimate of when the activation might occur, not the actual activation date.

You can specify site activation date by using the STARTDATE attribute of the <SITE> element in the study metadata.

- **Current Site Acceptance Date**—The date and time that a site accepts the current study version. This date is one of the following:
 - The specified value of the ACCEPTDATE attribute of the <STUDYVERSIONSITE> element defined in the study metadata. The <STUDYVERSIONSITE> element associates a site with a particular study version.
 - The system date and time when a user selects the current study version on the Site details page of the InForm application Admin user interface.
- **Sponsor Date**—The date that appears in the annotated view of the study. In the Central Designer application, you can specify this date and time (in GMT) by using the Sponsor Date property of the study definition. The default is the date and time when you generate the study XML by generating a Central Designer deployment package. In the MedML definition of the study version, this date is specified in the SPONSORDATE attribute of the <STUDYVERSION> element.

Secure Sockets Layer (SSL)

Before SSL can be active in a study, the environment must be set up to support SSL.

For more information, see the *Installation Guide*.

To enable SSL in a study, enable the InForm SSL system configuration option through the InForm user interface or the MedML Installer utility.

Enabling SSL through the InForm Admin user interface

- 1 Log in to the InForm application as a user with system administration rights.
- 2 Click **Admin > Configuration**.
- 3 Set the **Enable SSL** option to **on**.
- 4 If you are setting up the Reporting and Analysis module, change the **Reporting service full url** option to start with **https://** and to include a port number.
- 5 Click **Update**.
- 6 Stop and restart the study with the following commands

```
pfadmin stop trial <studyname>
pfadmin start trial <studyname>
```

Enabling SSL with the MedML Installer utility

- 1 Create an XML file with the following entry:

```
<MEDMLDATA>
<SYSCONFIG CONFIGNAME="SSLFLAG" TYPE="0" VALUE="1" />
</MEDMLDATA/>
```
- 2 If you are setting up the Reporting and Analysis module, include the following definition in the XML file, and change the value of URL for the reporting server to start with https://.

```
<SYSCONFIG CONFIGNAME="REPORTINGSERVER" TYPE="0" VALUE="https://<url>" />
```
- 3 Stop the study with the following command:

```
pfadmin stop trial <studyname>
```

- 4 Install the configuration options with the MedML Installer utility.
- 5 Restart the study with the following command:

```
pfadmin start trial <studyname>
```

Sponsors

Sponsor definitions specify address and contact information about a sponsor. Sponsor information is for documentation and reporting purposes only and does not appear in the InForm user interface.

Defining sponsors

To create a sponsor definition:

- 1 Create an XML file that includes the appropriate SPONSOR MedML elements.
- 2 Install the sponsor definition in the InForm study database by processing it with the MedML Installer utility.

Sponsor definition syntax

The syntax of the SPONSOR element is shown below.

```
<SPONSOR
NAME="name"
[PROGRAM="program-name of study"]
[THERAPEUTICAREA="therapeutic area of study"]
[NOTE="notes"]
[ADDRESS="addr1"]
[ADDRESS2="addr2"]
[CITY="name"]
[STATE="name"]
[PROVINCE="name"]
[ZIPCODE="code"]
[POSTCODE="code"]
[COUNTRY="name"]
[PHONE="num"]
[ALTPHONE="num"]
[FAX="num"]
[EMAIL="addr"]
[LANGUAGE="name"]
[LOGOFILE="file"]
[LOGOTYPE="GIF|JPEG|TEXT"]>
```

Subject record transfer affidavit

The subject record transfer feature of the InForm application enables users to transfer a subject's clinical record to a new site. This feature is useful in situations where:

- A subject moves to a different location.
- A subject moves seasonally to another address.
- An investigator leaves a study and closes down a site.

When a user transfers a subject to another site, the InForm application displays an affidavit that provides guidance on the responsibility of the administrative user regarding moving a subject from one site to another. The Subject Record Transfer page in the base study provides default affidavit text.

Customizing the subject record transfer affidavit

- 1 Copy the `sysform_PatientSiteChange.xml` file in the `\InForm\XMLBase` folder of the InForm software installation to the `\Custom` folder for your study.

Do not make changes directly in the `sysform_PatientSiteChange.xml` file.

- 2 Edit the affidavit portion of the `<FORM>` definition in the copy of the `sysform_PatientSiteChange.xml` file.

Within the affidavit text, you can use HTML characters for formatting and highlighting.

- 3 Add the edited copy of the file to the RSP file you use to load your study metadata into the study database.

Subject transfer affidavit XML

The `<FORM>` tag for the Subject Record Transfer page follows with the default affidavit text highlighted.

Caution: Do not change anything in the form definition other than the highlighted text.

```
<FORM REFNAME="PSC_FORM" UUID="3389a7c6-cba5-46f2-b48f8e034a28a349"
NOTE="<TABLE BORDER="0"CELLPADDING="4" CELLSPACING="0" WIDTH="100%"
ID="Table1"> <TR> <TD CLASS="ttl"><B>Patient Record Transfer Affidavit.</B></TD>
</TR> <TR> <TD><TABLE CLASS="tbl" BORDER="1" CELLPADDING="4"
CELLSPACING="0" WIDTH="100%" BORDERCOLOR="#003366" ID="Table2"> <TR>
<TD><TABLE BORDER="0" CELLPADDING="4" CELLSPACING="0" WIDTH="100%"
ID="Table3"> <TR> <TD><P><del>The sponsor takes responsibility for and has clear
processes/procedures in place around the handling of patient transfers and coordinating across
sites to ensure that.</del><P><P>1. The originating site produces or receives a certified copy of the
current CRF data created for all transferred patients prior to the transfer.</del><P><P>2. The target site
accepts responsibility for the management of any outstanding queries and data cleaning following
the patient record transfer, since the originating site will no longer have modification access.</del>
<del><P>3. Trial version differences due to protocol amendments or country specific data requirements are
acknowledged and the sponsor has appropriate regulatory approvals in place to support patient
record transfer.</del><del><P>4. The patient(s) being transferred are fully enrolled and a Case Book has
been created for each patient.</del></TD> </TR> </TABLE> </TABLE> </TABLE>
TITLE="Patient Record Transfer Form" MNEMONIC="PSC_FORM" QUESTIONWIDTH="30"
CONTROLWIDTH="70" TYPE="CUSTOMTRIAL">

<SECTIONREF REFNAME="PSC_SECT2" />

<SECTIONREF REFNAME="PSC_SECT" />

</FORM>
```

Managing study versions

Managing study versions with the Central Designer application requires little intervention in the study. You can control the behavior of new study versions using full and incremental deployment packages. You can revise the study version without updating, but this requires manual intervention after the Central Designer deployment package is installed.

Creating a new deployment package

For studies created in the Central Designer application, you manage the study versions and revisions in the Central Designer user interface. When you deploy the study to the InForm application the study version is the revision of the study design object in your study and includes:

- Title of the study design object.
- Revision number.
- Locale.

When you create a new version of a form, you must consider whether multiple versions of the form will be needed under the same STUDYVERSION.

Updates for new subjects only:

- If a form change does not require sites to collect data from subjects for whom the form has already been started, make the modifications to the form and then create a **full** deployment package which results in a new study version.

Updates for new and existing subjects:

- If a form change does require sites to collect data from subjects for whom the form has already been started, there are two options:
 - To update the study version, make the modifications to the form and create an **incremental** deployment package, which results in a new study version with alternate forms.
 - To revise without updating the study version, make the modifications to the form and create a **full** deployment package, which results in a new study version that should not be used.

Note: For more information, see the Central Designer *InForm Design Guide*.

Updating the STUDYVERSIONSITE element

When you update a study version by installing a new deployment package, you must update the STUDYVERSIONSITE element using the following syntax:

```
<STUDYVERSIONSITE
  VERSIONDESCRIPTION="text"
  [SITENAME="name" ]
  [ITEMNEMONIC="name" ]
  [ACCEPTDATE="date" ]/>
```

Revising without updating the study version

For most study definition changes, creating a new study version is strongly advised. However, from time to time you may find that you need to make minor cosmetic changes to a form and would prefer not to create an entirely new version of the study. For example, you may want to correct a typographical error on a form, change the position of a caption, or mark an item as SV required.

To make a revision without updating the study version:

- 1 Make the modifications to the form and create a **full** deployment package, which results in a new study version. Install the deployment package in the study, but do not update the site associations to the new study version (using `STUDYVERSIONSITE` definitions).
- 2 Create definitions of the `UPDATE_FORM_SECTION` or `UPDATE_SECTION_ITEM` MedML elements based on the new or changed study objects defined in the new study version. Install the `UPDATE_FORM_SECTION` or `UPDATE_SECTION_ITEM` definitions in the study using the MedML Installer utility. Associate them with the current study version. For more information, see the *Utilities Guide*.

Caution: Making study definition changes without creating a new study version violates Good Clinical Practice (GCP), and can cause problems with study data. Be sure you understand the consequences of making changes this way before you implement those changes.

Test the change in a test environment by entering data in the revised item, and verifying that the data in the Reporting and Analysis module is as expected. Also if there is any data already entered that pertains to the revised item ensure that data can be seen in the Reporting and Analysis module as expected.

When to use revising without versioning

You can make the following types of changes without creating a new study version:

- Corrections of spelling errors in question text.
- Changes to the labels of controls.
- Additions of options in radio controls and check box lists.
- Expansion of date ranges in a date time control.
- Changes to item properties, such as Required, SDV.
- Expansion of the length of a text field.
- Addition of items in a section.

Note: Such changes could have regulatory impact if the meaning of the question is changed.

When not to use revising without versioning

The following types of changes could have regulatory impact or result in data loss if made without updating the study version. For these changes you should *not* use revising without reversioning.

Type of change	Impact
Updates to question text that change the meaning of data collected. For example, changing the text from "Age >=18?" to "Age>18?"	Regulatory impact—Changes the meaning of data that has already been collected.
RefName.	Loss of previously collected data. Without the original RefName, the data cannot be accessed.
Removing an item.	Loss of previously collected data, unless no data has been collected for the item in any subject case report book.
Changing the structure of controls in an item.	Loss of previously collected data. Changing the structure of controls changes the RefName path of the controls.
Removing the SDV Required property.	Loss of SDV status in previously collected items.

Updating a section without revising the study version

To update a section in a form without revising the study version, use the UPDATE_FORM_SECTION MedML element. This element is used to modify an existing section on a form. It cannot be used to add a new section. If subject data already exists for this section, it is linked to the old version of the section. Data entered after the update is linked to the newer version of the section.

Note: To determine the RefNames for the CRF and section to update, it is recommended that you run the InForm RefName Report in the Central Designer application. For more information, see the Central Designer *InForm Design Guide*.

When deleting items with this element, keep in mind that the data will still exist in the database, but will not show up on the form. Instead of removing form items through this method, it is preferable to remove them by updating the study version for the study.

UPDATE_FORM_SECTION syntax

```
<UPDATE_FORM_SECTION
  FORM_REFNAME="name"
  FORM_REVISION="number"
  SECTION_REFNAME="name"
  SECTION_REVISION="number"/>
```

Attribute	Description
FORM_REFNAME	The RefName of the form to modify. Required.
FORM_REVISION	The revision number of the form to modify. Required.
SECTION_REFNAME	The RefName of the section to modify. Required.
SECTION_REVISION	The revision number of the section to modify. Required.

Using the UPDATE_FORM_SECTION element to update a section definition

- 1 Stop the study and make sure that no one can access the study or modify the study data.
- 2 Make the necessary changes to the XML for the section you want to modify.
- 3 Install the new version of the section using the MedML Installer utility.
- 4 Generate the XML for the "UPDATE_FORM_SECTION." You can use SQL to retrieve the new and old section revision numbers or you can look in the database directly.
- 5 For FORM_REVISION number, open the PF_PAGE table and look up the latest (highest number) PAGEREVISIONNUMBER for the corresponding PAGEREFNAME. For SECTION_REVISION number, open the PF_SECTION table and look up the most recent (highest number) SECTIONREVISIONNUMBER for the corresponding SECTIONREFNAME.
- 6 Run the MedML Installer utility and apply the "UPDATE_FORM_SECTION" XML. The MedML Installer utility validates that the form RefName and revision are correct, and that the form contains the section you updated.
- 7 Restart the study.
- 8 Test the updated form version after applying this change. The MedML Installer utility does not validate the item metadata against any existing subject data.

Updating an item without revising the study version

To update an item within a section without modifying the study version, use the UPDATE_ITEM_SECTION MedML element. This element is used to modify an existing item. It cannot be used to add a new item. If subject data already exists for this item, it is linked to the old version of the item. Data entered after the update is linked to the newer version of the item.

Note: To determine the RefNames for the section and item to update, it is recommended that you run the InForm RefName Report in the Central Designer application. For more information, see the Central Designer *InForm Design Guide*.

UPDATE_SECTION_ITEM syntax

```
<UPDATE_SECTION_ITEM
  SECTION_REFNAME="name"
  SECTION_REVISION="number"
  ITEM_REFNAME="name"
  ITEM_REVISION="number"/>
```

Attribute	Description
SECTION_REFNAME	The RefName of the section to modify. Required.
SECTION_REVISION	The revision number of the section to modify. Required.
ITEM_REFNAME	The RefName of the item to modify. If the modified item is contained in an itemset, this RefName is the RefName of the itemset. Required.
ITEM_REVISION	The revision number of the item to modify. If the modified item is contained in an itemset, this revision number is the revision number of the itemset. Required.

Using the UPDATE_SECTION_ITEM element to update an item definition

- 1 Stop the study and make sure that no one can access the study or modify the study data.
- 2 Make the necessary changes to the XML for the item you want to modify.
- 3 Install the new version of the item using the MedML Installer utility.
- 4 Generate the XML for the "UPDATE_SECTION_ITEM." You can use SQL to retrieve the revision numbers for the new and old items or you can look in the database directly.
- 5 For the SECTION_REVISION number, open the PF_SECTION table and look up the latest (highest number) SECTIONREVISIONNUMBER for the corresponding SECTIONREFNAME. For the ITEM_REVISION number, open the PF_ITEM table and look up the most recent (highest number) ITEMREVISIONNUMBER for the corresponding ITEMREFNAME.

Note: If the item you are modifying is contained in an itemset, the RefName and revision number you enter here must be for the itemset. Itemset RefNames and revision numbers are also stored in the PF_ITEM table.

- 6 Run the MedML Installer utility and apply the "UPDATE_SECTION_ITEM" XML. The MedML Installer utility validates that the CRF RefName and revision is correct, and that the CRF contains the item you updated.
- 7 Restart the study.
- 8 Test the updated form version after applying this change. The MedML Installer utility does not validate the item metadata against any existing subject data.

CHAPTER 2

Installing the Reporting and Analysis module in a study

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About configuring the Reporting and Analysis module

The procedures for installing and configuring the Reporting and Analysis module vary according to the way your environment is set up.

- **Study and reporting schemas installed in the same database instance (SameDB)**—This is the recommended configuration. The InForm database and the InForm reporting database are installed on a single database instance.
- **Study and reporting schemas installed in different database instances (DiffDB)**—The InForm database and the InForm reporting database are installed on separate database instances.

For more information, see the *Installation Guide*.

Comparison of configuration scenarios

Characteristic	Single database instance (SameDB)	Different database instance (DiffDB)
Oracle Streams	Oracle Streams is not required, because there is no need to replicate study data.	Oracle Streams is required. When you install the Reporting and Analysis module into a different database from the study, data is replicated using Oracle Streams. For more information about streams, streams operations, and monitoring, see the Oracle database documentation about streams.
Schema ownership	The study schema owner owns all study and reporting objects.	Different schema owners own study or reporting objects (and each schema is in a separate instance).
Archive log mode	Running in archive log mode is not required.	Running in archive log mode is required. For more information, the <i>Installation Guide</i> .

Installing the Reporting and Analysis module—Study and reporting in different database instances

Granting privileges to the study user

Purpose	Grants database user privileges to the user that owns the study schema.
Script	grant_user_privs.sql
Where to run	Database instance for the study schema, from the folder in which the reporting software is located, for example, <i><Installation_Directory>\Inform\bin\DBOra\Reporting</i>

- 1 Open a Command Prompt window.
- 2 Change to the *<Installation_Directory>\Inform\bin\DBOra\Reporting* folder, for example, **e:\OracleHS\InForm\bin\DBOra\Reporting**.
- 3 Log on to SQL*Plus with /nolog.
- 4 Connect to the study database as a user with the privilege to grant user database privileges.
- 5 Type the following at the SQL*Plus prompt:

```
@grant_user_privs.sql <study schema owner>
```

Where:

<study schema owner>—Database user name that holds the study schema.

This script should run to completion without further prompts. The script produces a log called `grant_user_privs.log`. A size of 0 bytes indicates that the script was successful.

For more information, see *grant_user_privs.sql* (on page 106).

Configuring the reporting variables for a study—Different database instances

Purpose	Configure reporting variables in an environment in which the study and reporting schemas are located in different database instances.
File to edit	configdiffdb.sql
File location	Folder in which the reporting software is located, for example, <i><Installation_Directory>\InForm\bin\DBOra\Reporting.</i>

To configure reporting variables, you edit the **configdiffdb.sql** script. The installation and uninstallation scripts use the configdiffdb.sql file for user name, password, tablespace, and connection information.

- There are some variables that are preset. You must not try to change them. These variables are indicated with an **P** in the table that follows.
- When you set up the InForm environment to support the Reporting and Analysis module, you edited the configdiffdb.sql script to set the values of variables that remain constant for the database instance in the environment. These variables are indicated with an **I** in the table that follows.
- Before you install the Reporting and Analysis module for a specific study, you must verify or update the configdiffdb.sql variables that are specific to the study. These variables are indicated with an **S** in the table that follows. When you finish updating the variables, rename the file *ConfigDiffDB-<studyname>.sql*.

For more information, see **configdiffdb.sql** (on page 100).

I/S	Variable	Value	Comments
I=Set once for the database instance; S=Set for each study; P= Do not change.			
I	trialdb_tnsnames_alias	Tnsnames alias for the study database.	Used for connection to the study database. Also used as a part of the PUBLIC database link.
P	trialdbstring	@&&trialdb_tnsnames_alias	Preset variable. Do not change. Used for connection to the study database.
S	trial_schema_owner	InForm study schema owner.	Oracle user name of the study schema owner in the study database.
S	rep_proxy_user	New user. Prepend RP to the InForm study schema owner.	Oracle user name in the study database that serves as a proxy user for reporting database connections.

I/S	Variable	Value	Comments
I=Set once for the database instance; S=Set for each study; P= Do not change.			
I	trial_to_rep_dblink_name	Global name of the reporting database.	Name of all database links in the study database. Connect to the reporting database and run the command: Select global_name from global_name; Use the value returned from this command for this variable.
P	trial_dblink_name_select	@&&trial_to_rep_dblink_name	Preset variable. Do not change. Used for connection to remote objects in the reporting database.
I	repdb_tnsnames_alias	Tnsnames alias for the reporting database.	Used for connection to the reporting database. Also used as a part of the PUBLIC database link.
P	repdbstring	@&&repdb_tnsnames_alias	Preset variable. Do not change. Used for connection to the reporting database.
P	rep_schema_owner	&&trial_schema_ow	Preset variable. Do not change.
I	rep_to_trial_dblink_name	Global name of study database.	Name of all database links in the reporting database. Connect to the study database and run the command: Select global_name from global_name; Use the value returned from this command for this variable.
P	rep_dblink_name_select	@&&rep_to_trial_dblink_name	Preset variable. Do not change. Used for connection to remote objects in the study database.

Checking the variable settings for a study—Different database instances

Purpose	Checks the variable settings in an environment where the study and reporting databases are in different database instances.
Script	configandcheckdiffdb
Where to run	Folder in which the reporting software is located, for example, <i><Installation_Directory>\Inform\bin\DBOra\Reporting</i> .

Use the `configandcheckdiffdb.sql` script to check the variable settings. The installation calls this script to check the environment and variables before the installation. No logon is required to run this script, because the script uses information provided in the `configdiffdb.sql` file to log on.

Note: Before running the `configandcheckdiffdb.sql` script, make sure that archive log mode is set for the instance. For more information, see the *Installation Guide*.

- 1 Open a Command Prompt window.
- 2 Change to the directory where the reporting software is located.
- 3 Run the script using the command:

```
configandcheckdiffdb [/accountparams:path_to_password_file]
```

If the script passes with no errors, the variables are correct. If there is an error, make corrections and then rerun the script. Do not proceed with the installation until errors have been resolved.

For more information, see *configandcheckdiffdb* (on page 99).

Installing the Reporting and Analysis module—Different database instances

Purpose	Installs the Reporting and Analysis module in an environment where the study and reporting databases are in different database instances.
Script	<code>install_reporting_diffdb</code>
Where to run	Folder in which the reporting software is located, for example, <code><Installation_Directory>\Inform\bin\DBOra\Reporting</code> .

Use the `install_reporting_diffdb.sql` script to install the Reporting and Analysis module in a multiple database environment. Before running the installation script, make sure that you have updated the study-specific variable settings with the `configdiffdb.sql` script. For more information, *Configuring the reporting variables for a study—Different database instances* (on page 65).

- 1 Open a Command Prompt window.
- 2 Change to the directory where the reporting software is located.
- 3 Run the script using the command:

```
install_reporting_diffdb [/accountparams "path_to_password_file"]
```

The script should run to completion without prompts.

- 4 Search the logs for the word Error. If the installation is successful, you should find no errors.
- 5 After the installation is complete, copy the `configdiffdb.sql` file to a different location with a different name.

You will need this file in the future if you want to uninstall or re-install the Reporting and Analysis module.

Note: If the installation process fails, run the `deinstall_reporting_diffdb.sql` script to remove all components associated with the Reporting and Analysis module for a single study schema and reporting schema. For more information, see *About removing reporting elements and an InForm study* (on page 92).

For more information, see *install_reporting_diffdb* (on page 111).

CHAPTER 3

Configuring a study for the Reporting and Analysis module

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About configuring a study for the Reporting and Analysis module

Configuring a study for Cognos 10 BI involves establishing communications between the InForm study and the Cognos 10 BI Server and setting up the objects that are needed for reporting. To establish communications so that users can generate reports with the Reporting and Analysis module:

- 1 Make sure that an InForm study user exists with sufficient rights and reporting group membership.
For more information, see *Giving an InForm study user reporting rights* (on page 71).
- 2 Run the InForm Reporting Configuration utility.
For more information, see *Configuring a study for the Reporting and Analysis module using the InForm Reporting Configuration utility* (on page 72).
- 3 Run the pfrinit utility.
For more information, see *Running the pfrinit utility* (on page 74).
- 4 Authorize users for the Reporting and Analysis module.
For more information, see *Authorizing users for the Reporting and Analysis module* (on page 75).
- 5 Specify a logo for InForm standard reports.
For more information, see *Specifying a logo for InForm standard reports* (on page 78).

Clinical reporting package considerations

After the clinical reporting package is generated, you can use the Reporting and Analysis Ad Hoc Reporting module to view the reporting tree.

Text controls in an InForm study can be set to accept more than 4000 characters. However, be aware that text stored in clinical views generated for reporting are truncated. If the text is longer than 4000 characters, the first 3986 characters are shown, and ****TRUNCATED**** appears at the beginning of the text in Ad Hoc Reporting.

Giving an InForm study user reporting rights

- 1 Log in to the InForm study as a user who can update InForm user information.
- 2 Click **Admin**, and click the link for a user.
The User details page appears.
- 3 Click the **Group** tab.
- 4 On the Group page:
 - a Select a **Rights Group** that includes the Reports right.
 - b Associate the user with one or more sites.
 - c In the **Reporting** list, select Publishers and either Site Users or Sponsor Users.
- 5 Click **Submit**, click **OK** in the confirmation dialog box, and then click **Return**.
- 6 Log out of the study.

Configuring a study for the Reporting and Analysis module using the InForm Reporting Configuration utility

Purpose	Configure a study to work with Cognos 10 BI.
Wizard location	Start > All Programs > Oracle® Health Sciences > InForm 6.0 > InForm Reporting Configuration
Where to run	Server where the InForm core software is installed.

- 1 On the server where the InForm core software is installed, select **Start > All Programs > Oracle® Health Sciences > InForm 6.0 > InForm Reporting Configuration**.
The wizard title page appears.
- 2 Click **Next**.
The Select Study page appears.
- 3 Use the drop-down list to choose the study you want to configure for Cognos 10 BI, and click **Next**.
The Cognos parameters page appears.
- 4 Fill out the information as described in the table below, and click **Next**.

Cognos Namespace	<p>Custom Authentication Provider (CAP) namespace. The default is informcap. The case of the value you enter here must be the same case as the entry in the Cognos Configuration utility. For example, if the entry in the Cognos Configuration utility is in lower case (informcap), the <namespace> option must also be informcap.</p> <p>informcap is the namespace created by InForm CRN wizard. The namespace can be shared by many studies, and it should not typically need to be changed.</p> <p>If you have created additional namespaces manually with the Cognos Configuration utility, use the name of the newly created namespace in this field.</p>
Gateway URI	<p>External public URI that communicates with the Cognos 10 BI Gateway Services from an end user's browser. This Cognos parameter is set in the Cognos 10 BI Gateway Customization for InForm wizard. The parameter setting is stored in the cogstartup.xml file.</p> <p>Example: http://example.north.com/cognos10</p>
Dispatcher URI	<p>Internal URI that the InForm server uses to communicate with the Cognos 10 BI server. This Cognos parameter is set in the InForm CRN wizard. The parameter setting is stored in the cogstartup.xml file and corresponds to the Reporting internal URI value on the Admin > System Configuration page of the InForm application.</p> <p>Example: http://appsru02.north.com:9300/p2pd/servlet/dispatch.</p>

Root Folder	The top-level reporting folder for the study. Default: /content/folder[@name='<studyname>']
-------------	--

The Reporting database parameters page appears.

- 5 Fill out the information as described in the table below, and click **Next**.

Field	Description
Reporting uses trial database	Use if the study and the Reporting database are on the same server.
Reporting uses separate database	Select if the Reporting database and the study database are in separate servers.
Database Connection String	Reporting database connection string (TNS Name). Use if Reporting and the InForm study are in different databases.
User name (same as trial user)	Reporting database study username must be the same as the InForm database study username.
Password	Reporting Trial password. Use if the study and the Reporting database are in different databases.

The Study URL and database connection information page appears.

- 6 Fill out the information as described in the table below, and click **Next**.

Field	Description
Trial URL	The URL for the InForm study.
Database Connection String	The connection string for the CAP.
User	The user name for the CAP database schema owner.
Password	Password for the CAP database schema owner.

The Verification page appears.

- 7 Verify that the information on the page is correct and click **Next**.

The study is configured according to the information provided.

The Reporting configuration is complete page appears.

- 8 Click **Finish**.

Running the pfrinit utility

Purpose	Configures Cognos for each study.
Location of file	<p><InstallationDirectory>\InForm\Bin</p> <ul style="list-style-type: none"> • pfrsetuptrial.xml—Supplies database connection information used by the pfrinit utility. • pfrinit—Sets up connection information, permissions, and folder structures needed for accessing the Reporting and Analysis module from the InForm application.
Where to perform	The InForm application server.

- 1 On the InForm application server, open the pfrsetuptrial.xml file, located in the <Installation_Directory>\InForm\bin directory folder, and make the following changes:
 - **connectionstring**—Oracle connection string for the reporting database (in a single database configuration, use the study database connection string).
 - **dbuid**—Update the DBUID parameter with the UserID of the study owner.
- 2 Save and close the PFRsetupTrial.xml file.
- 3 Open a Command Prompt window, and type the following command:


```
pfrinit "path_to_password_file"
```

The text file format is **parameter=value**. Each parameter is on a separate line in the text file and there are no spaces in the parameter=value pair.

For more information, see *pfrinit* (on page 130).

Authorizing users for the Reporting and Analysis module

InForm access rights for reporting

Data access rights in the Reporting and Analysis module are inherited from the InForm study and adhere to the site associations and item blinding permissions that are in place for each user.

Additionally, to access the Reporting and Analysis module, an InForm user must be:

- Assigned to a rights group that includes the InForm **Reports** right. The InForm **Reports** right gives users access to the Reporting and Analysis module.
- A member of either the **Sponsor Users** or **Site Users** reporting group. This conveys the Cognos 10 BI Consumer permissions that allow users only to run reports.

You can give users access to additional reporting rights by making sure that the users are assigned to one of the default reporting groups installed with the InForm software. For more information, see *Default reporting groups* (on page 76).

Authorization on the reporting server

Reporting authorizations on the reporting server rely on permissions that are defined in authorization namespaces on the reporting server.

All rights to create or run reports are governed by reporting authorizations in the InForm study, which is referenced by the Cognos Custom Authentication Provider (CAP).

The Cognos 10 BI namespace

Each reporting server references one master namespace that controls authorization for all studies. This namespace, the Cognos 10 BI namespace, contains the Cognos 10 BI objects, such as groups, roles, distribution lists, and contacts. During the Cognos 10 BI Content Store initialization, predefined security entries that control access to specific Cognos 10 BI features are created in this namespace.

Default reporting groups

As part of the initial Reporting and Analysis setup, the pfrinit utility imports the PFRsetupTrial.xml file, which loads the following predefined reporting groups into the Cognos 10 BI namespace for an InForm study.

In the following table, some groups are described as custom groups added by the InForm application. By default, these groups have no corresponding group or role in the Cognos 10 BI namespace. The groups are added to the Cognos 10 BI namespace by the pfrinit utility.

InForm reporting group	Cognos 10 BI namespace group or role	Provides these permissions
Ad Hoc Users	Query Users	Can run the Ad Hoc Reporting utility. Users also have the same rights as members of the Cognos 10 BI Consumers namespace role.
Authors	Authors	Can use Cognos 10 BI Report Studio. Users have the same rights as members of the Cognos 10 BI Consumers namespace role.
No equivalent group	Consumers	Can run reports in the Public folders. These reports can be Standard Reports or custom reports that users create. Every user that has the InForm Reports rights group right is by default a member of the Consumers group. This group is visible only as a Cognos 10 BI namespace role.
Directory Administrators	Directory Administrators	Can perform administration in the Cognos and in Oracle Directory Server namespaces. Can administer roles, groups, accounts, contacts, distribution lists, data sources, and printers.
Publishers	Publishers	Can create, change, schedule, or delete all content, including reports (Ad Hoc or Report Studio) to a Public folder. When users in the Publishers group run a report in a Public folder, their prompt selections are saved with the report.
Report Administrators	Report Administrators	Can administer permissions for all public content including folders and reports.
Server Administrators	Server Administrators	Can administer servers, dispatchers, and jobs.

InForm reporting group	Cognos 10 BI namespace group or role	Provides these permissions
Site Users	Site Users	<p>Access to all Standard Reports except for by User reports. Users are automatically assigned to this group based on their user type.</p> <p>Custom group added by the InForm application.</p>
Sponsor Users	Sponsor Users	<p>Access to all InForm standard reports. Users are automatically assigned to this group based on their user type.</p> <p>Custom group added by the InForm application.</p>
No equivalent group	System Administrator	<p>The superuser role in Cognos 10 BI. This user has full control of every setting for every trial that can be set in a given Cognos 10 BI server. There is no equivalent InForm reporting group. At initial setup, all users have this right.</p> <p>You should identify a small group of highly trusted users and directly assign them to the Cognos 10 BI namespace System Administrator role. Then, remove the Everyone group from this role.</p>
User Admin Info Data Users	User Admin Info Data Users	<p>Access to user data including password related data.</p> <p>Custom group added by the InForm application.</p>
User Info Data Users	User Info Data Users	<p>Access to user data except password related data.</p> <p>Custom group added by the InForm application.</p>

Specifying a logo for InForm standard reports

You can specify a company logo to appear in your standard reports. If you do not want a logo to appear in the standard reports, you must place a blank image in the location that is specified.

Note: If you do not include the blank graphic file, a missing graphic icon appears on your standard reports.

- 1 Create a file called logo.gif.
- 2 Copy the logo.gif file to the following location on the server where the Cognos 10 BI Gateway Services software is installed:

`<Cognos_Installation_Directory>\webcontent\<StudyDesign>`

For example: e:\ibm\cognos\c10\webcontent\StudyDesign\logo.gif

CHAPTER 4

Performance tuning

In this chapter

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About performance tuning

Perform the performance tuning steps in any order, as needed.

Controlling the load behavior

Studies with a very large number of subjects can take a long time to start up, because all subjects are loaded into memory cache. To confirm whether this problem is occurring, check the InForm Performance Monitor utility.

- 1 Select **Start > All Programs > Oracle® Health Sciences > InForm 6.0 > InForm Performance Monitor**.
- 2 Start the study.

If load behavior is being affected by the number of subjects, the InForm Performance Monitor utility shows many 'select * from DCV_PatientCRF where PatientID=xxxx' SQL statements.

You can modify registry settings to help alter the load behavior to make study startup more efficient. The settings are in HKEY_LOCAL_MACHINE\SOFTWARE\ORACLEHS\InForm\PFMgrTrial\PatientCacheLoadingMode.

The following registry setting values control load behavior:

- **ondemand**—The study starts immediately and the subject data is loaded into cache only when an InForm user tries to access data for that subject. This option provides the fastest study startup, but results in slow performance the first time a subject is accessed. Subjects who are not accessed are not cached at all, which means they do not consume memory or require other server resources to load them.
- **async**—The study starts immediately and the subject cache continues to load in the background. When an InForm user tries to access data for a subject that is not yet loaded, the subject is loaded on demand. Performance may be slow the first time the subject is accessed.
- **sync**—Default. Standard InForm behavior. At start up, all subjects are loaded into memory cache.

Updating statistics in a production environment

It is recommended that you analyze all tables and indexes for better performance. The study setup process creates statistics for your study. As you add subject data to the study, it is important to refresh these statistics periodically. In a production environment, refreshing one time per day during the maintenance window is usually sufficient.

To update the statistics, you can run the `updatec.sql` script, located in the `<Installation_Directory>\bin\dbora` directory. Type the following in a Command Prompt window:

```
sqlplus <pfdbadmin_uid>@<connect_string> @updatec.sql <trialUID>
```

When prompted, enter the password for the `pfdbadmin` database user.

Do not use the `dbms_utility.analyze_schema` procedure with the `COMPUTE` or the `FOR TABLES` option on any production servers. The recommended procedure is to analyze each table and index with the `ESTIMATE` option (35 percent is adequate).

Configuring an ODBC connection

You can configure Oracle ODBC connection pooling to provide a longer connection time by changing the Timeout value.

- 1 Select **Start > All Programs > Administrative Tools > Data Sources (ODBC)**.

The ODBC Data Source Administrator window appears.

- 2 Select the **Connection Pooling** tab.
- 3 Double-click **Oracle in <Oracle_Client_Home>**.

Note: Be careful *not* to double-click Microsoft ODBC for Oracle.

The Set Connection Pooling Attributes dialog box appears.

- 4 Make sure that the **Pool connections to this driver** radio button is selected.
- 5 In the **Time that unused connections remain in the pool in seconds** field, set the pooling timeout value. The recommended pooling timeout is 1.5 x MSDTC Timeout Value (about 450 seconds).

If the pooling timeout value is too short, the connection refreshes too frequently. If the pooling timeout value is too long, the connection consumes too many resources.

- 6 Click **OK** in each dialog box.

Resizing virtual memory

The InForm software uses virtual memory (disk space simulated as memory) aggressively. It is recommended that you create a large paging file in a location that is different from the default location, particularly on a drive with lots of disk space.

- 1 Click **Start > Control Panel > System > Advanced system properties**.

The System Properties dialog box appears.

- 2 Click the **Advanced** tab.
- 3 In the **Performance** section, click **Settings**.

The Performance Options dialog box appears.

- 4 Click the **Advanced** tab.
- 5 Click **Change**.

The Virtual Memory dialog box appears.

- 6 In the **Drive (Volume Label)** section, select a drive in which to place the virtual memory.
- 7 Type a value in the **Initial Size (MB)** field. The sum of physical RAM plus 11 is recommended, or you can use the Recommended size.
- 8 Type a value in the **Maximum Size (MB)** field. The Initial Size (MB) x 1.5 or 2 is recommended.
- 9 Click **Set**.
- 10 Click **OK** in each dialog box.

Removing preferential treatment from foreground applications

To provide more resources for background applications in Windows 2008, you can remove preferential treatment from foreground applications.

- 1 Click **Start > Control Panel > System > Advanced system properties**.

The System Properties dialog box appears.

- 2 Click the **Advanced** tab.
- 3 In the **Performance** section, click **Settings**.

The Performance Options dialog box appears.

- 4 Click the **Advanced** tab.
- 5 Select **Background services**.
- 6 Click **OK** in each dialog box.

Optimizing Windows for network applications

- 1 Click **Start > Control Panel > Network and Sharing Center > Local Area Connection**.
The Local Area Connection Status dialog box appears.
- 2 Click **Properties**.
The Local Area Connection Properties dialog box appears.
- 3 On the Networking tab, select **File and Print Sharing for Microsoft Networks**, and click **Properties**.
The File and Printer Sharing for Microsoft Networks Properties dialog box appears.
- 4 Click **Maximize Throughput for Network Applications**.
- 5 Click **OK**, and in the Local Area Connection Status dialog box, click **Close**.

Monitoring the Windows Event Logs

The InForm application logs events to the Application Event log. For optimum performance, make sure to manually clear the log periodically, or wrap events so that the oldest events are overwritten when the log's capacity is reached.

- 1 Click **Start > Administrative Tools > Event Viewer**.

The Event Viewer window appears.

- 2 Right-click the **Application** node, and select **Properties**.

The Application Properties dialog box opens.

- 3 Set the **Log size** options according to your event log monitoring policy. You can:

- Overwrite events as needed.
- Overwrite events older than # days.
- Clear the log manually.

It is recommended that you overwrite events as needed.

Note: The Application Event log holds a record of all InForm login attempts. If you do not want to lose any of the InForm login information, set the Log Settings accordingly.

For production servers, it is recommended that you save event logs periodically.

Moving locations for MS DTC logs

The MS DTC logs are generated by default in the %SYSTEMROOT%\SYSTEM32\DTClog folder. It is recommended that you place the logs on a different disk, and increase the log file size.

To move locations for MS DTC logs in Windows 2008:

- 1 In Windows Explorer, create a new folder for the DTC logs.
- 2 In a Command Prompt window, stop the MS DTC service.
- 3 Open Microsoft Component Services by selecting **Start > All Programs > Administrative Tools > Component Services**.
- 4 Expand **Component Services**.
- 5 Expand **Computers**.
- 6 Expand **Distributed Transactions**.
- 7 Right-click **LocalDTC**, and select **Properties**.
- 8 Select the **Logging** tab.
- 9 In the **Log Information** section, change the **Capacity** to 16 MB or higher.
- 10 Specify the location for the log file, and click **OK**.
- 11 Start the MS DTC service.
- 12 Delete the original MS DTC directory through Windows Explorer.

Clearing and enlarging MS DTC logs

If you experience an MS DTC log problem, for example if you receive the following error message, you can reset the log size:

```
The MS DTC log file is full and cannot accept new log records.
```

- 1 Open a Command Prompt window.
- 2 Stop the InForm study by typing:

```
pfadmin stop trial
```
- 3 Stop the MS DTC service by typing:

```
net stop msdtc
```
- 4 Click **Start > Programs > Administrative Tools > Component Services**.
- 5 Expand **Component Services**.
- 6 Expand **Computers**.
- 7 Expand **Distributed Transactions**.
- 8 Right-click **LocalDTC**, and select **Properties**.
- 9 Select the **Logging** tab.
- 10 In the **Capacity** field, increase the capacity of the log file to 100 MB.
- 11 Click **OK**.
- 12 Right-click **My Computer**, and select **Start MS DTC**.
- 13 Close the **Component Services** window.

Deploying SQL profiles

SQL profiles can be used to improve performance.

To create a SQL Profile, a user must have the following privileges:

- ADVISOR role
- CREATE ANY SQL PROFILE PRIVILEGE
- ALTER ANY SQL PROFILE PRIVILEGE
- DROP ANY SQL PROFILE PRIVILEGE
- EXECUTE PRIVILEGE ON DBMS_SQLTUNE

To deploy SQL profiles:

- 1 Unzip **InForm_SQLProfiles.zip**.(located in the <Installation_Directory>\InForm\Bin\DBOra\ReviewSchema folder).
- 2 Connect to SQLPlus as a user with the proper privileges.
- 3 Create a staging table in the destination database.

```
EXEC DBMS_SQLTUNE.CREATE_STGTAB_SQLPROF (table_name =>
'SGTAB_SQLPROF_DB006');
```
- 4 Import the data to the destination database.

```
imp <user>/<pwd>@<instance> tables=('SGTAB_SQLPROF_DB006') file=
InForm_SQLProfiles.dmp log=imp.log ignore=y
```
- 5 Create SQL Profiles in the destination database using the data stored in the staging table.

```
EXEC DBMS_SQLTUNE.UNPACK_STGTAB_SQLPROF(replace => TRUE,
staging_table_name => 'SGTAB_SQLPROF_DB006');
```
- 6 Verify that the profiles imported correctly.

```
select name, created from dba_sql_profiles;
```


CHAPTER 5

Removing reporting objects and an InForm study

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About removing reporting objects and an InForm study

Perform the following steps to remove the Reporting and Analysis infrastructure components in all study and reporting databases within a study or reporting database instance.

Note: Be sure to perform these steps only on the databases on which you are completely removing the Reporting and Analysis module.

Note: For information about how to uninstall the core InForm software, the Cognos 10 BI software, and the customizations for the Reporting and Analysis module, see the *Installation Guide*.

- 1 Stop your study.
- 2 Remove the reporting schema.
For more information, see *Removing a reporting schema* (on page 93).
- 3 Delete stream information from the study database and reporting database.
For more information, see *Deleting stream information from the study database and reporting database* (on page 94).
- 4 Delete study-specific information from the Cognos 10 BI environment.
For more information, see *Deleting study-specific information from the Cognos 10 BI environment* (on page 95).
- 5 Remove the InForm study.
For more information, see *Removing an InForm study* (on page 96).

Removing a reporting schema

Purpose	Removes a single reporting schema when the study and reporting schemas are located in different database instances.
Script	deinstall_reporting_diffdb
Where to run	Folder where the reporting software is located, for example, \Oracle\InForm\bin\DBORA\Reporting.

Before you start, review the parameters in the **configdiffdb.sql** file to make sure that they contain the same values that you used to install the reporting schema. For more information, see *Configuring the reporting variables for a study—Different database instances* (on page 65).

- 1 Open a Command Prompt window, and change to the folder where the reporting software is located, for example, \Oracle\InForm\bin\DBORA\Reporting.
- 2 Run the script using the command:


```
deinstall_reporting_diffdb [/accountparams:path_to_password_file]
```
- 3 Check for any errors by searching for the word **Error** in the deinstall_reporting_diffdb.log file. If any errors are found, correct the problem and run the script again.
- 4 Rerun the script until it does not find anything to remove and does not have any errors. The log shows all steps with the message **No object... was found.**
- 5 Run the configandcheckdiffdb.sql script to make sure everything has been removed. If the script completes successfully, the uninstall succeeded.

For more information, see *deinstall_reporting_diffdb* (on page 103).

Deleting stream information from the study database and reporting database

Purpose	Deletes stream information from the study database and reporting database.
Script	<code>remove_streams_setup_info_diffdb</code>
Where to run	Folder where the reporting software is located, for example, <code><Installation_Directory>\InForm Reporting\DBOra</code> .

- 1 Open a Command Prompt window, and change to the folder where the reporting software is located, for example, `<Installation_Directory>\InForm Reporting\DBOra`.
- 2 At the command prompt, type:

```
remove_streams_setup_info_diffdb [/accountparams "path_to_password_file"]
```

For more information, see *remove_streams_setup_info_diffdb* (on page 132).

Deleting study-specific information from the Cognos 10 BI environment

Use the `DecomTrial` (located in `<Installation_Directory>\InForm\bin` on the InForm application server) command to securely remove study information from the Cognos 10 BI environment by entering the following command at the command prompt:

```
DecomTrial .Sys.AdminNamespace Sys.AdminUsername TrialNamespace TrialUsername CognosDispatcherURI TrialName
```

For more information, see ***DecomTrial*** (on page 101).

Removing an InForm study

Purpose	Removes an InForm study and server.
----------------	-------------------------------------

Where to perform	Server where the InForm core software is installed.
-------------------------	---

- 1 Stop the study, using the following command:

```
pfadmin stop trial <studyname>
```

- 2 Remove the study, using the following command:

```
pfadmin remove trial <studyname>
```

or

To remove the DSNs from ODBC data source administration at the same time, use the following command

```
pfadmin remove trial <studyname> /DSN
```

- 3 If you did not remove the study DSN with the pfadmin utility, remove it through the Windows Data Sources (ODBC) utility:

- a Select **Start > Administrative Tools > Data Sources (ODBC)**.
- b Select the **System DSN** tab.
- c Select the study DSN, and click **Remove**.
- d If the study has a randomization or CDD DSN, remove those, as well.
- e Click **OK**.

- 4 After removing all studies from an InForm server, remove the server with the following command:

```
pfadmin remove server <servername>
```

- 5 Back up the study database.
- 6 Remove the study user from the database. As the pfdbadmin user, issue the following SQL*Plus command:

```
drop user <study_uid> cascade;
```

Caution: When you perform this step, all study data is removed. Make sure that the backup is complete before you drop the study user.

APPENDIX A

Command and script reference

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admindb

Purpose

Creates the InForm Admin database if you did not set it up during the InForm core software installation by selecting the **Install Admin DB** checkbox.

Location

<Installation_Directory>\InForm\bin\DBOra folder.

Usage

admindb [*connection string*] [/accountparams:"*path_to_password_file*"]

Option	Description
/accountparams " <i>path_to_password_file</i> "	When specified, includes the path to a text file that contains the user name and passwords required to run the command.
	If the accountparams option is not specified, the command prompts for the required user names and passwords.
	The format of the parameter file is parameter=value. There is a new line for each parameter, and there are no spaces on a line.

Parameter file contents

The following parameters are required for the admindb command password file:

- pfdbauid=*pfdadmin user*
- pfdbapid=*pfdadmin password*
- admindbuid=*informadmin user*
- admindbpid=*informadmin password*

Example

admindb trial1 /accountparams:"E:\scripts\adminpwd.txt"

configandcheckdiffdb

Purpose

Checks the variable settings in an environment where the study and reporting databases are in different database instances.

Location

Folder where the reporting software is located, for example, *<Installation_Directory>\InForm Reporting\DBOra*.

Usage

```
configandcheckdiffdb [/accountparams:"path_to_password_file"]
```

Option	Parameter
<i>/accountparams "path_to_password_file"</i>	<p>When specified, includes the path to a text file that contains the user name and passwords required to run the command.</p> <p>If the accountparams option is not specified, the command prompts for the required user names and passwords.</p> <p>The format of the parameter file is parameter=value. There is a new line for each parameter, and there are no spaces on a line.</p>

Parameter file contents

The following parameters are required for the configandcheckdiffdb command password file:

- trial_schema_owner_password=Password for the study schema owner.
- dbauser_trial_password=Password for the study DBA user.
- dbauser_rep_password=Password for the reporting DBA user.
- streams_admin_user_rep_passwd=Password for the reporting streams admin user.
- streams_admin_user_trial_pwd=Password for the study streams admin user.

If the script passes with no errors, the variables are correct. If there is an error, make corrections and then rerun the script. Do not proceed with the installation until errors have been resolved.

Note: The InForm database installation and administration scripts are designed to be run using the InForm Application Server. The scripts can also be run from the Oracle database home on an InForm Reporting Server. Running them from a different Windows Oracle client or from a non-Windows Oracle client or database home may work, but is not supported.

configdiffdb.sql

Purpose

Contains reporting variables in an environment where the study and reporting databases are in different database instances. The reporting installation and uninstallation scripts use the configdiffdb.sql file for user name, password, tablespace, and connection information.

Location

Folder where the reporting software is located, for example, *<Installation_Directory>\InForm\bin\DBOra\Reporting*.

Notes

Before running a command that uses the configdiffdb.sql file (for example, configandcheckdiffdb), evaluate each user-defined variable, and change the values as needed to reflect your environment.

Note: The configdiffdb.sql file cannot contain any passwords.

DecomTrial

Purpose

Securely removes InForm study components (study folders, clinical package, operational package, DSN entries, and InForm study user accounts) from the Reporting and Analysis module.

Location

The InForm application server folder on the InForm application server. For example, `<Installation_Directory>\InForm\bin`.

Usage

```
DecomTrial [SysAdminNamespace SysAdminUsername TrialNamespace TrialUsername CognosDispatcherURI TrialName [<company_code>]] | ["path_to_parameter_file"]
```

Option	Parameter
<i>SysAdminNamespace</i>	Oracle Directory Server admin namespace.
<i>SysAdminUsername</i>	User name for the Cognos system administrator.
<i>TrialNamespace</i>	Custom Authentication Provider (CAP) namespace.
<i>TrialUsername</i>	InForm study user who is a member of the following Reporting groups: <ul style="list-style-type: none"> • Publishers. • Either Sponsor Users or Site Users.
<i>CognosDispatcherURI</i>	Internal URI that the InForm server uses to communicate with the Cognos 10 BI server.
<i>TrialName</i>	Name of the InForm study.
<i>company_code</i>	The organization ID. Optional. This parameter is required only for Oracle-hosted studies in a single sign-on environment.
<i>path_to_parameter_file</i>	<ul style="list-style-type: none"> • When specified, includes the path to a text file that contains the parameters required to run the command. • You will always be prompted to enter required passwords on the command line. • If the parameter file is not specified, the command prompts for the required parameters. • The format of the parameter file is <code>parameter=value</code>. There is a new line for each parameter, and there are no spaces on a line.

Command line prompts

Depending on the syntax used with the DecomTrial command, you are prompted for the following parameters:

- **System Administrator namespace**—Oracle Directory Server admin namespace.
- **System Administrator username**—User name for the Cognos system administrator.
- **Trial namespace name**—Custom Authentication Provider (CAP) namespace.
- **Trial user username**—InForm study user who is a member of the following Reporting groups:
 - Publishers.
 - Either Sponsor Users or Site Users.
- **Cognos dispatcher URL**—Internal URI that the InForm server uses to communicate with the Cognos 10 BI server.
- **Trial name**—Study name.
- **Company Code**—The organization ID.
Optional. Reserved for Oracle-hosted studies in a single sign-on environment.
- **System Administrator password**—Password for the Cognos system administrator.
- **Trial user password**—Password for the InForm study user.

With the exception of the System Administration password and Trial user password parameters, you can pass parameters by using the "*path_to_parameter_file*" command option.

When specified, this option includes the path to a text file that contains the values required to run the command. The format of the parameter file is *parameter=value*. There is a new line for each parameter, and there are no spaces on a line.

Parameter file contents

You can pass the following parameters in a parameter file:

- *sysadmin_namespace*=Oracle Directory Server admin namespace.
- *sysadmin_uid*=User name for the Cognos system administrator.
- *trial_namespace*=Custom Authentication Provider (CAP) namespace.
- *trial_user*=Study user.
- *dispatcher_url*=Internal URI that the InForm server uses to communicate with the Cognos 10 BI server.
- *trial_name*=Study name.
- *company_code*=OrgID assigned for an single sign-on study.

Example

```
DecomTrial OHSI crnsysadmin informcap mmartin  
http://server.example.com:9300/p2pd/servlet/dispatch pfstcardio blank
```

deinstall_reporting_diffdb

Purpose

Removes a single reporting schema when the study and reporting schemas are located in different database instances. This script:

- Removes all components associated with the Reporting and Analysis module for a single study and reporting schema combination.
- Uninstalls only one reporting schema at a time. To uninstall multiple reporting schemas, you can run the script as many times as necessary.
- Does not remove the underlying reporting infrastructure, including reporting tablespaces.

Location

Folder where the reporting software is located, for example, `<Installation_Directory>\InForm\bin\DBOra\Reporting`.

Usage

```
deinstall_reporting_diffdb [/accountparams "path_to_password_file"]
```

Option	Parameter
<code>/accountparams "<i>path_to_password_file</i>"</code>	<p>When specified, includes the path to a text file that contains the user name and passwords required to run the command.</p> <p>If the accountparams option is not specified, the command prompts for the required user names and passwords.</p> <p>The format of the parameter file is <code>parameter=value</code>. There is a new line for each parameter, and there are no spaces on a line.</p>

Parameter file contents

The following parameters are required for the `configandcheckdiffdb.sql` command password file:

- `trial_schema_owner_password=Password` for the study schema owner.
- `dbauser_trial_password=Password` for the study DBA user.
- `dbauser_rep_password=Password` for the reporting DBA user.
- `streams_admin_user_rep_passwd=Password` for the reporting streams admin user.
- `streams_admin_user_trial_pwd=Password` for the study streams admin user.

Notes

Before running the `deinstall_reporting_diffdb.sql` script:

- Review the parameters in the `configdiffdb.sql` file to make sure that they contain the same values that you used to install the reporting schema. For more information, see *`configdiffdb.sql`* (on page 100).
- Stop the study.

Note: The InForm database installation and administration scripts are designed to be run using the InForm Application Server. The scripts can also be run from the Oracle database home on an InForm Reporting Server. Running them from a different Windows Oracle client or from a non-Windows Oracle client or database home may work, but is not supported.

grant_dba_privs.sql

Purpose

Grants DBA privileges to the rptinstall user, which is used for install and uninstall operations.

Location

Folder where the reporting software is located, for example,
<Installation_Directory>\InForm\bin\DBOra\Reporting.

Usage

```
@grant_dba_privs.sql rptinstall
```

Notes

Log on to the study database as SYSDBA.

The name of the DBA user must be **rptinstall**.

Note: The InForm database installation and administration scripts are designed to be run using the InForm Application Server. The scripts can also be run from the Oracle database home on an InForm Reporting Server. Running them from a different Windows Oracle client or from a non-Windows Oracle client or database home may work, but is not supported.

grant_user_privs.sql

Purpose

Grants database user privileges to the user that owns the study schema.

Location

Folder where the reporting software is located, for example,
<Installation_Directory>\InForm\bin\DBOra\Reporting.

Usage

```
@grant_user_privs.sql <study schema owner>
```

<study schema owner>—Database user name that holds the study schema.

Example

```
@grant_user_privs.sql pfst60uid
```

Notes

Run from SQL*Plus with /nolog.

Connect to the study database as a user with the privilege to grant user database privileges.

The script produces a log called grant_user_privs.log.

Note: The InForm database installation and administration scripts are designed to be run using the InForm Application Server. The scripts can also be run from the Oracle database home on an InForm Reporting Server. Running them from a different Windows Oracle client or from a non-Windows Oracle client or database home may work, but is not supported.

ImportUtility

Purpose

Securely import reporting content you export using Cognos commands to a new instance of the InForm Reporting server.

Location

The InForm application server folder on the InForm application server. For example, `<Installation_Directory>\InForm\bin`.

Usage

ImportUtility [-all | -import | -nopwd | -pfmtr]

Option	Parameter
-all	<ul style="list-style-type: none"> Creates a secure staging folder on the Reporting server accessible to system administrators. The name of the staging folder is SecureImport_<timestamp>. Creates the import specification object on the Reporting server accessible to system administrators. Imports the content from a password-protected deployment package to the SecureImport_<timestamp> folder and makes it accessible only to system administrators. Copies the imported content to the Public folders on the Reporting server. Deletes the SecureImport_<timestamp> folder, all its content, and the import specification object.
-import	<ul style="list-style-type: none"> Creates a secure staging folder on the Reporting server accessible to system administrators. The name of the staging folder is SecureImport_<timestamp>. Creates the import specification object on the Reporting server accessible to system administrators. Imports the content from a password-protected deployment package to the SecureImport_<timestamp>. Deletes the import specification object.

Option	Parameter
-nopwd	<ul style="list-style-type: none"> Creates a secure staging folder on the Reporting server accessible to system administrators. The name of the staging folder is SecureImport_<timestamp>. Creates the import specification object on the Reporting server accessible to system administrators. Imports the deployment package content to the SecureImport_<timestamp> folder and makes it accessible only to system administrators. Copies the imported content to the Public folders on the Reporting server. Deletes the SecureImport_<timestamp> folder, all its content, and the import specification object.
-pfmtr	<ul style="list-style-type: none"> Creates a secure staging folder on the Reporting server accessible to system administrators. The name of the staging folder is SecureImport_<timestamp>. Creates the import specification object on the Reporting server accessible to system administrators. Imports the content to the SecureImport_<timestamp> folder. Deletes the import specification object.

Command line prompts

Depending on the option you specify with the ImportUtility, you are prompted for following parameters:

- **sysadmin_namespace**—Cognos system administrator user namespace.
- **sysadmin_uid**—User name for the Cognos system administrator.
- **sysadmin_pass**—Cognos system administrator password.
- **dispatcher_url**—Internal URI that the InForm server uses to communicate with the Cognos 10 BI server.

This Cognos 10 BI parameter is set in the InForm CRN wizard. The parameter setting is stored in the cogstartup.xml file and corresponds to the Reporting internal URI value on the Admin > System Configuration page of the InForm application. For example, <http://example.com:9300/p2pd/servlet/dispatch>.

- **archive_name**—Name of the deployment package containing the reporting content you want to import into the Reporting server.
- **archive_pass**—Password for the deployment package.

Note: The **archive_pass** parameter is not required for the **-nopwd** or the **-pfmtr** option.

Notes

- The **-import** and **-pfmtr** command options should be used to stage custom reports before distributing them to multiple studies.

To move the content from the staging folder to the study folders and set study-specific permissions, use the **pfmtrsetuputil** command.

- The **-nopwd** and **-pfmtr** command options are used when you are importing a deployment package that is not password protected.

These options should be used only when there is no clinical data present in the deployment package.

Example

```
ImportUtility -all
```

informprepora.vbs

Purpose

Creates the pfdbadm user if you did not set it up during the InForm core software installation by selecting the **Prep Oracle** checkbox.

Location

<Installation_Directory>\InForm\bin\DBOra folder.

Usage

informprepora.vbs <oracle_connection_string> [/accountparams:"path_to_password_file"]

Option	Parameter
/accountparams "path_to_password_file"	<p>When specified, includes the path to a text file that contains the user name and passwords required to run the command.</p> <p>If the accountparams option is not specified, the command prompts for the required user names and passwords.</p> <p>The format of the parameter file is parameter=value. There is a new line for each parameter, and there are no spaces on a line.</p>

Parameter file contents

The following parameters are required for the informprepora.vbs command password file:

- orasys_user=<sys_userid>
- orasys_user_pass=<password_for_sys_user>
- pfdbauid=<pfdadmin_userid>
- pfdbapid=<pfdadmin_password>

Example

```
informprepora trialdb /accountparams:"E:\scripts\prep.txt"
```

Notes

Set scripting to cscript to suppress popup messages. Type:

```
cscript //H:cscript
```

install_reporting_diffdb

Purpose

Installs the Reporting and Analysis module in an environment where the study and reporting databases are in different database instances.

Location

Folder where the reporting software is located, for example, *<Installation_Directory>\InForm\bin\DBOra\Reporting*.

Usage

```
install_reporting_diffdb [/accountparams "path_to_password_file"]
```

Option	Parameter
<i>/accountparams "path_to_password_file"</i>	<p>When specified, includes the path to a text file that contains the user name and passwords required to run the command.</p> <p>If the accountparams option is not specified, the command prompts for the required user names and passwords.</p> <p>The format of the parameter file is parameter=value. There is a new line for each parameter, and there are no spaces on a line.</p>

Parameter file contents

The following parameters are required for the `install_reporting_diffdb.sql` command password file:

- `trial_schema_owner_password`=Password for the study schema owner.
- `rep_schema_owner_password`=Password for the reporting schema owner
- `dbauser_trial_password`=Password for the study DBA user.
- `dbauser_rep_password`=Password for the reporting DBA user.
- `streams_admin_user_rep_passwd`=Password for the reporting streams admin user.
- `streams_admin_user_trial_pwd`=Password for the study streams admin user.
- `rep_proxy_user_password`=The password for the user that exists in the trial database who has read-only access to the specified trial schema.

Notes

Before running the installation script, make sure that you have updated the study-specific variable settings with the `configdiffdb.sql` script. For more information, see *`configdiffdb.sql`* (on page 100).

Note: The InForm database installation and administration scripts are designed to be run using the InForm Application Server. The scripts can also be run from the Oracle database home on an InForm Reporting Server. Running them from a different Windows Oracle client or from a non-Windows Oracle client or database home may work, but is not supported.

mtsora102.vbs

Purpose

Sets up Oracle XA transaction support. During the InForm core software installation, if you check the Prep Oracle checkbox, the installation process sets up Oracle XA transaction support. If you do not set up Oracle XA transaction support during the installation, the mtsora102.vbs script enables you to set it up manually, during or after the Oracle installation.

The mtsora102.vbs file does the following:

- 1 Runs the XAVIEW.sql script as SYS to create the V\$XATrans\$ view:

```
%ORACLE_HOME%\RDBMS\ADMIN\XAVIEW.SQL
```

- 2 Grants SELECT access to the public on these views:

```
Grant Select on V$XATrans$ to public
Grant Select on sys.dba_pending_transactions to public
```

Note: This example grants SELECT access to public, however in your environment SELECT access should be granted to the profile associated with your database.

- 3 Modifies the following Registry keys in
HKEY_LOCAL_MACHINE\SOFTWARE\Microsoft\MSDTC\Security

```
"NetworkDtcAccess"=dword:00000001
"NetworkDtcAccessAdmin"=dword:00000001
"NetworkDtcAccessTransactions"=dword:00000001
"XaTransactions"=dword:00000001
"NetworkDtcAccessOutbound"=dword:00000001
"NetworkDtcAccessInbound"=dword:00000001
```

- 4 Modifies the following Registry key in
HKEY_LOCAL_MACHINE\SOFTWARE\Microsoft\MSDTC\XADLL

```
"mtxoci.dll"="C:\WINDOWS\system32\mtxoci.dll"
```

Location

<Installation_Directory>\InForm\bin\DBOra folder.

Usage

```
mtsora102.vbs <oracle_connection_string> <oracle_client_home_key>
[/accountparams:"path_to_password_file"]
```

Option	Parameter
<code>/accountparams "path_to_password_file"</code>	<p>When specified, includes the path to a text file that contains the user name and passwords required to run the command.</p> <p>If the <code>accountparams</code> option is not specified, the command prompts for the required user names and passwords.</p> <p>The format of the parameter file is <code>parameter=value</code>. There is a new line for each parameter, and there are no spaces on a line.</p>

Parameter file contents

The following parameters are required for the `mtsora102.vbs` command password file:

- `orasys_user=<sys_userid>`
- `orasys_user_pass=<password_for_sys_user>`

Example

```
cscript mtsora102.vbs dev1 KEY_OraClient10g_CLIENT1 /accountparams:"E:\scripts\mtsora.txt"
```

Notes

When setting up Oracle XA transaction support manually, run both the `mtsora102.vbs` script and the `oramtsadmin.sql` script. For more information, see *oramtsadmin.sql* (on page 115).

Set scripting to **cscript** to suppress popup messages. Type:

```
cscript //H:cscript
```

For a more complete description, refer to one of the following articles:

- **Microsoft Knowledge Base**—Q193893 – Info: Using Oracle with Microsoft Transaction Server and COM+.
- **MSDN Online Library**—Setting up MTS to Access Oracle.
- Microsoft KB Article 899191.
- Microsoft KB Article 817066 and 891801

oramtsadmin.sql

Purpose

Creates the MTS administrative user and schedules automatic transaction recovery. You need to run oramtsadmin.sql only if you do not set up Oracle XA transaction support during installation of the InForm core software by selecting the **Prep Oracle** checkbox. If you set up Oracle XA transaction support manually, run oramtsadmin.sql after you run the mtsora102.vbs script.

Location

%ORACLE_CLIENT_HOME%\oramts\admin folder

Usage

@oramtsadmin.sql

Notes

Run as the SYS user as SYSDBA.

Run the script against all Oracle instances connected to the InForm application server.

Note: The InForm database installation and administration scripts are designed to be run using the InForm Application Server. The scripts can also be run from the Oracle database home on an InForm Reporting Server. Running them from a different Windows Oracle client or from a non-Windows Oracle client or database home may work, but is not supported.

pfadmin

Purpose

Sets up the InForm server environment. The parameters are stored in the registry. Therefore, you need local administrator privileges to run the utility.

Location

<Installation_Directory>\InForm\bin\DBOra folder.

Usage

```
pfadmin [ CHECKREG | CONFIG | CREATEREPORTINGMODEL | HELP | KILLSERVER
| PING | PUBLISHREVIEWSCHEMA | RECREATEREVIEWSCHEMA | REMOVE |
RECREATEREPORTINGSCHEMA | SETSERVER | SETUP | SETLANGUAGE | START |
STOP | UNINSTALL | VIEW ] [/accountparams:"path_to_password_file"]
```

pfadmin command options

Option	Purpose and Syntax
CHECKREG [/Del] [/DelAll]	<p>Displays the current InForm Server COM and MTS components in the NT registry.</p> <p>WARNING: Be careful to remove the server(s) or uninstall the service before using either of the delete options:</p> <ul style="list-style-type: none"> • [/Del]—Removes obsolete settings. • [/DelAll]—Removes the settings of all servers.

pfadmin command options

Option	Purpose and Syntax
CONFIG Service [/AdminDB <i>DBServer</i>] [/AdminDSN <i>DsnName</i>] [/AdminDN] [/PfUser] [/SysDBA]	Configures an existing service. <ul style="list-style-type: none"> • [/AdminDB <i>DBServer</i> [SQL]]—Sets the ODBC DSN for the InFormAdmin database. Make sure that <i>DBServer</i>, <i>UID</i>, and <i>PID</i> are the same ones that were used to create the InFormAdmin database. Use alphabetic or alphanumeric characters for the <i>UID</i> and <i>PID</i>, and begin them with a letter; do not use all numeric characters. • [/AdminDSN <i>DsnName</i>]—Creates the ODBC DSN InForm software with the default database server, using the specified user name and password. Use alphabetic or alphanumeric characters for the <i>UID</i> and <i>PID</i>, and begin them with a letter; do not use all numeric characters. • [/PfUser]—Creates the PfUser_ <i>computername</i> account during the InForm software installation. The account is for Microsoft MTS packages used by InForm servers. In general, you do not need to configure the account. If you change the password through NT User Manager, you must reconfigure the InForm Service with the new password. • [/SysDBA]—Sets the InForm Service DBA user name and password. You can use this command to change the pfdbadmin password as needed. <p>If you want to change the InForm Service DBA name, modify the provided SQL script InFormPrepORA.sql with the new user name and password, then run the script as SYS. After running the script, use this command option to configure the InForm Service to use the new InForm Service DBA.</p> <p>Use alphabetic or alphanumeric characters for the <i>UID</i> and <i>PID</i>, and begin them with a letter; do not use all numeric characters.</p>
CONFIG Server <i>ServerName</i> [Automatic Manual]	Configures the startup mode for an existing server as either Automatic or Manual.

pfadmin command options	
Option	Purpose and Syntax
CONFIG Trial <i>TrialName</i> [Automatic Manual] [/TriDSN <i>DSN</i> [/RndDSN <i>DSN</i>] [/RndDSN <i>DSN</i>] [/Rnd [<i>MDBFilePath</i>] [/Rnd [<i>MDBFilePath</i>] [/Host <i>ServerName</i>]	Configures an existing study. <ul style="list-style-type: none"> • [Automatic Manual]—Configures the study startup mode. • [/TriDSN <i>DSN</i>]—Configures the study ODBC DSN. Use alphabetic or alphanumeric characters for the UID and PID, and begin them with a letter; do not use all numeric characters. • [/RndDSN <i>DSN</i>]—Configures the study randomization source dataset name. Use when setting up a Microsoft randomization source database. • [/RndDSN <i>DSN</i>]—Configures the study randomization source dataset name. Use when setting up an Oracle randomization source database. Use alphabetic or alphanumeric characters for the UID and PID, and begin them with a letter; do not use all numeric characters. • [/Rnd [<i>MDBFilePath</i>]]—Creates a study randomization source dataset name to use the given Microsoft Access database file. • [/Rnd [<i>MDBFilePath</i>]]—Creates a study randomization source dataset name to use the given Oracle database file. Use alphabetic or alphanumeric characters for the UID and PID, and begin them with a letter; do not use all numeric characters. • [/Host <i>ServerName</i>]—Moves the study from current host server to another server in the InForm Service.
CONFIG CDD <i>TrialName</i> [Enable Disable] [DSN [Active Inactive]] [DSN <i>StudyLocale</i>]	Configures an existing CDD: <ul style="list-style-type: none"> • [Enable Disable]—Enables or disables the CDD for a particular study. • [DSN [Active Inactive]]—Makes a CDD DSN active or inactive for a particular study. • [DSN <i>StudyLocale</i>]—Specifies the study locale used for the unit symbol translation that is stored in the CDD column for the unit symbol. • <i>path_to_dsn_password_file</i>—Configures an existing CDD DSN with the User ID and password specified. Use alphabetic or alphanumeric characters for the UID and PID, and begin them with a letter; do not use all numeric characters.

pfadmin command options	
Option	Purpose and Syntax
CONFIG WEBSERVICE <i>TrialName</i> <i>WebServiceName</i> [Add Remove]	<p>Associates a web service with a study.</p> <ul style="list-style-type: none"> <i>WebServiceName</i>—ODMSubmitService [Add Remove]—Creates or removes an association between a study and a web service
CREATEREPORTINGMODEL <i>TrialName</i>	Creates the Reporting model from scratch.
HELP	Lists all the options of the pfadmin command.
KILLSERVER <i>ServerName</i>	Stops server MTS packages without stopping studies on the server.
PING <i>MachineName</i> 1 2 3: <i>ServerName</i> 4: <i>ServerName</i> 5: <i>ServerName</i> [Port#]	<p>Pings the InForm Service or a particular server. The ping levels are:</p> <ul style="list-style-type: none"> 1—Ping the InForm Service. 2—Ping the InForm Service and all InForm server(s). 3—Ping the specified server. 4—Ping and get information about the specified server. 5—Ping the specified server and dump the user session to a server-side file. [Port#]—Allows you to specify the port number the echo server is listening on, if you changed it.
PUBLISHREVIEWSCHEMA <i>TrialName</i> [/FORCE]	<p>Applies all study version changes to the review schema clinical tables.</p> <p>If you use the /FORCE option, the InForm application does not check to see if there are study version changes that are not applied, and makes sure all study version changes are applied.</p> <p>Note: The /FORCE option does not drop and re-create the clinical tables. It makes the clinical tables match the study version. The /FORCE option should only be used if recommended by Oracle.</p> <p>This operation is synchronous. The study is unavailable during the operation.</p>
RECREATEREVIEWSCHEMA [<i>TrialName StudyLocale_ISO_name</i>]	<p>Changes the Review Schema study locale.</p> <p>The Review schema study locale is chosen automatically when a trial is first installed, but can be changed using this command.</p>

pfadmin command options	
Option	Purpose and Syntax
REMOVE [Server <i>ServerName</i>] [Trial <i>TrialName</i> [/DSN]] [CDD <i>TrialName</i> [/All <i>DSN</i>]]	<p>Removes an existing server, study, or CDD.</p> <ul style="list-style-type: none">• [Server <i>ServerName</i>]—Removes an InForm server from the InForm Service. Studies should be either reconfigured to other servers or removed before this command is run.• [Trial <i>TrialName</i> [/DSN]]—Deletes the named study from the InForm Service. The Web virtual directories and folders for the study are physically removed. Use the /DSN option to remove the study-related DSNs.• [CDD <i>TrialName</i> [/All <i>DSN</i>]]—Removes either all CDD DSNs in the specified study or the given CDD by DSN. <p>Note: Before using the PFADMIN REMOVE command, verify that IIS is running.</p>

pfadmin command options	
Option	Purpose and Syntax
SETSERVER [Site <i>TrialName MachineName</i>] [MedMLInstaller <i>TrialName MachineName</i>] [Reporting <i>TrialName ReportingUrr</i>] [ReportingAN <i>TrialName AuthenticationNamespace</i>] [ReportingUR <i>TrialName UserRoot</i>] [ReportingInt <i>TrialName ReportingInternalURI</i>] [pfreportinguserpw <i>TrialName</i>] [systempw <i>TrialName</i>]	<p>Changes the MedML and Site servers and sets the Reporting configuration settings</p> <ul style="list-style-type: none"> • [Site <i>TrialName MachineName</i>]—Not supported. • [MedMLInstaller <i>TrialName MachineName</i>]—Not supported. • [Reporting <i>TrialName ReportingUrr</i>]—Set Cognos 10 BI URL for study. • [ReportingAN <i>TrialName AuthenticationNamespace</i>]—Set Cognos 10 BI AuthenticationNamespace for study. • [ReportingUR <i>TrialName UserRoot</i>]—Set Cognos 10 BI UserRoot for study. • [ReportingInt <i>TrialName ReportingInternalURI</i>]—Set the internal URI that the InForm server uses to communicate with the Cognos 10 BI server. • [pfreportinguserpw <i>TrialName</i>]—Run this pfadmin command after the password for the pfreportinguser is changed in the InForm user interface to set a property used by Reporting when it needs the credentials of the pfreportinguser user for building the model. <p>pfreportinguser is the preferred studyuser to run pfrinit to configure Cognos for each study.</p> <ul style="list-style-type: none"> • [systempw <i>TrialName</i>]—Set the password for the system user for the specified study. The command also activates the system user. <p>Note: The SETSERVER command requires that you set the Default Authentication Level property of the InForm server to Connect:</p> <p>To set this property:</p> <ol style="list-style-type: none"> 1 Select Administrative Tools > Component Services > My Computer - Properties. 2 Set the Default Properties - Default distributed communication properties - Default Authentication Level value to Connect.
SETUP Server <i>ServerName</i> [Automatic]	<p>Creates a new InForm server in the InForm Service.</p> <ul style="list-style-type: none"> • [Automatic]—The server is automatically started with the InForm Service. Manual startup is the default.

pfadmin command options	
Option	Purpose and Syntax
SETUP Trial <i>TrialName</i> <i>ServerName</i> [/DB <i>OracleConnStr</i>] [/DSN <i>TriDSN</i> [Automatic]	<p>Creates a study on the given InForm server with the option to either create a new ODBC DSN or use an existing one. The server has to be created. The study startup mode is Manual by default. Use the Automatic option to automatically start the study when the InForm server that hosts the study is started.</p> <ul style="list-style-type: none"> • [/DB <i>OracleConnStr</i> <i>UID</i> <i>PID</i>]—Creates an ODBC DSN <i>TrialName</i> with the given <i>ServerName</i>, <i>UID</i>, and <i>PID</i>. Use alphabetic or alphanumeric characters for the <i>UID</i> and <i>PID</i>, and begin them with a letter; do not use all numeric characters. • [/DSN <i>TriDSN</i> <i>UID</i> <i>PID</i> [Automatic]]—Configures the created study <i>TrialName</i> to use the given study dataset name <i>TriDSN</i>, <i>UID</i>, and <i>PID</i>. The study must be present in the ODBC DSN. Use alphabetic or alphanumeric characters for the <i>UID</i> and <i>PID</i>, and begin them with a letter; do not use all numeric characters. <p>Note: Before using the /DSN command, verify that IIS is running.</p>
SETUP CDD <i>RefName</i> <i>TrialName</i> /DB <i>OracleConnStr</i> <i>DSN</i> [/TBSP <i>OraTBSP</i>] [Active] [NoSchema]	<p>Sets up a new CDD DSN associated with the given CDD refname. Use alphabetic or alphanumeric characters for the <i>UID</i> and <i>PID</i>, and begin them with a letter; do not use all numeric characters.</p> <ul style="list-style-type: none"> • [/TBSP <i>OraTBSP</i>]—Defines the Oracle tablespace for the CDD schema. • [Active]—Specifies that the DSN is transactional. • [NoSchema]—Indicates that no new CDD schema should be created during setup. The existing database is not touched. By default, the user is dropped and the Oracle database destroyed. Then, a new schema is created and populated based on the <i>RefName</i> that defines the schema. <p>Note: To execute this command successfully, the study must be started.</p>

pfadmin command options	
Option	Purpose and Syntax
SETUP CDD <i>RefName TrialName</i> /DSN <i>DSN</i> [/TBSP <i>OraTBSP</i>] [Active] [NoSchema]	<p>Sets up an existing DSN associated with the given CDD <i>RefName</i>. Use alphabetic or alphanumeric characters for the UID and PID, and begin them with a letter; do not use all numeric characters. [/TBSP <i>OraTBSP</i>]—Defines the Oracle tablespace for the CDD schema.</p> <ul style="list-style-type: none"> • [Active]—Makes the DSN transactional. • [NoSchema]—Indicates that no new CDD schema should be created during setup. The existing database is not touched. By default, the user is dropped and the Oracle database destroyed. Then, a new schema is created and populated based on the <i>RefName</i> that defines the schema. <p>Note: To execute this command successfully, the study must be started.</p>
SETLANGUAGE [<i>IsoLanguageName</i>] en-US ja-JP	<p>Sets the InForm product locale language. en-US and ja-JP are currently supported.</p>
START [Server <i>ServerName</i>] [Trial <i>TrialName</i>]	<p>Starts an existing InForm server or study.</p> <ul style="list-style-type: none"> • [Server <i>ServerName</i>]—Starts an existing InForm server by server name. • [Trial <i>TrialName</i>]—Starts an existing study by study name.
START [Trial <i>TrialName</i> [/Design]]	<p>Starts the study in design mode. This means you can install study components that are not completely designed (strict checking is not in force). By default, the study starts in production mode.</p>
STOP [Server <i>ServerName</i> [/Trials]] [Trial <i>TrialName</i> [/Anyway]]	<p>Stops an existing InForm server or study.</p> <ul style="list-style-type: none"> • [Server <i>ServerName</i> [/Trials]]—Stops an existing InForm server by server name. By default, a running server can be stopped if there is no study running and no other application connected to it. The <i>Trials</i> keyword stops all running studies, and then stops the server. • [Trial <i>TrialName</i> [/Anyway]]—Stops the named study. The <i>Anyway</i> keyword stops a study regardless of any connections or HTTP requests.

pfadmin command options	
Option	Purpose and Syntax
UNINSTALL	<p>Removes all InForm servers and studies, and then removes the InForm service settings PfUser_<i>computername</i> and the MTS library package.</p> <p>Note: The InForm service must be running for the command to work.</p>
VIEW [Languages] [Service] [Server <i>ServerName</i>] [Trial <i>TrialName</i>] [CDD <i>TrialName</i>] [Reporting <i>TrialName</i>]	<p>Displays a monitoring list of all servers in the InForm service, all studies in servers, or all RefNames for CDD DSNs configured for a study.</p> <ul style="list-style-type: none"> • [Languages]—Lists installed languages without starting the InForm Service. • [Service] <ul style="list-style-type: none"> ▪ Lists all the servers and studies in the InForm service. ▪ Lists installed product languages as well as the actual installed product language. • [Server <i>ServerName</i>]—Lists each server by server name and studies hosted on that server. • [Trial <i>TrialName</i>]—Lists a study by its name. • [CDD <i>TrialName</i>]—Lists the RefNames for each CDD DSN configured for the specified study. • [Reporting <i>TrialName</i>]—Lists the current status of Reporting. <ul style="list-style-type: none"> ▪ States whether the study is configured for Reporting. ▪ Specifies the type of reporting setup: samedb or diffdb. ▪ Specifies the reporting username. ▪ Gives the date of the last Cognos model update. ▪ Reports if the Reporting database is up-to-date. ▪ States whether Oracle streams are working properly (if applicable).

pfadmin command options

Option	Purpose and Syntax
<code>/accountparams "path_to_password_file"</code>	<p>When specified, includes the path to a text file that contains the user name and passwords required to run the command.</p> <p>If the accountparams option is not specified, the command prompts for the required user names and passwords.</p> <p>The format of the parameter file is parameter=value. There is a new line for each parameter, and there are no spaces on a line.</p>

Parameter file contents

The following parameters are required for the pfadmin command password file:

Command	Parameters
• pfadmin setup trial	uid= <i>user name</i>
• pfadmin setup cdd	pid= <i>password</i>
• pfadmin config cdd	
• pfadmin config service /sysdba	
• pfadmin config service /admindsn	
• pfadmin config service /pfuser	
• pfadmin config trial	
• pfadmin setserver reportingdiffdbpw	pid= <i>password</i>
• pfadmin setserver pfreportinguserpw	
• pfadmin setserver systempw	

Examples

Check the status of InForm Reporting:

```
pfadmin view reporting pfst60
```

Check the status of InForm servers and studies on an InForm Service:

```
pfadmin view service
```

Start the demo InForm server:

```
pfadmin start server demo
```

Start the pfst60 study:

```
pfadmin start study pfst60
```

Stop all studies running on the demo InForm server, and then stop the demo server:

```
pfadmin stop server demo /Trials
```

Set the password and activate the system user account:

```
pfadmin setserver systempw pfst60 /accountparams:"E:\scripts\pwd.txt"
```

Notes

Any arguments containing commas, equal signs, or spaces must be enclosed within double quotes.

pfcognosconfig

Purpose

Configures an InForm study to work with Cognos 10 BI. The PFCognosConfig utility is a command-line alternative to the **InForm Reporting Configuration Wizard**.

PFCognosConfig can be run multiple times to change reporting parameters. If the reporting study user password changes, PFCognosConfig.exe must be run to tell InForm about the new password.

When PFCognosConfig is run multiple times for a study, each run after the first need not specify all the parameters – only the changed parameters need be specified.

Location

<Installation_Directory>\InForm\bin\DBOra folder.

Usage

```
pfcognosconfig "path_to_password_file"
```

Option	Parameter
path_to_password_file	<p>When specified, includes the path to a text file that contains the user name and passwords required to run the command.</p> <p>If the parameter file is not specified, the command prompts for the required user names and passwords.</p> <p>The format of the parameter file is parameter=value. There is a new line for each parameter, and there are no spaces on a line.</p>

Parameter file contents

The following parameters are required for the pfcognosconfig command password file:

Option	Description
trial_name=<studyname>	<p>Name of the InForm study.</p> <p>Note: Use the same case as when the study was created by the Central Designer deployment package.</p>
log_file=<outputlog>	<p>Name of output log. Example: nocreatorgcap.log. (Optional).</p>

Option	Description
namespace=<cap_namespace>	<p>Custom Authentication Provider (CAP) namespace. The default is informcap. The case of the value you enter here <i>must</i> be the same case as the entry in the Cognos Configuration utility. For example, if the entry in the Cognos Configuration utility is in lower case (informcap), the <namespace> option <i>must</i> also be informcap.</p> <p>Users can create additional namespaces manually in the Cognos Configuration tool. In this case, the name of the newly created namespace should be used in this field.</p>
gateway_uri=<gateway_uri>	<p>External public URI that communicates with the Cognos 10 BI Gateway Services from an end user's browser. This Cognos parameter is set in the Cognos 10 BI Gateway Customization for InForm wizard. The parameter setting is stored in the cogstartup.xml file.</p> <p>Example: http:example.north.com/cognos10</p>
dispatcher_uri=<dispatcher_uri>	<p>Internal URI that the InForm server uses to communicate with the Cognos 10 BI server. This Cognos parameter is set in the InForm CRN wizard. The parameter setting is stored in the cogstartup.xml file and corresponds to the Reporting internal URI value on the Admin > System Configuration page of the InForm application.</p> <p>Example: http://example.north.com:9300/p2pd/servlet/dispatch.</p>
root_folder=/ <i><content></i> / <i><folder></i> [@name='<studyname>']	<p>The top-level reporting folder for the company. Default: /content/folder[@name='<studyname>']</p>
reporting_samedb=<true false>	<p>True if the study and the Reporting database are on the same server.</p>
reporting_diffdb_server=<servername>	<p>Reporting database connection string (TNS Name). Use if Reporting and the InForm study are in different databases.</p>
reporting_diffdb_pass=<rptpid>	<p>Reporting Trial password (reporting database study username must be the same as the InForm database study username, so the username need not be specified). Use if the study and the Reporting database are in different databases.</p>
trial_web_service=<URL>	<p>InForm authentication web service URL. This is a required parameter.</p>
register_db_server=<ServerName>	<p>TNS name for the CAP database.</p>
register_db_user=<UserName>	<p>User name for the CAP database schema owner.</p>
register_db_pass<UserPassword>	<p>Password for the CAP database schema owner..</p>

Option	Description
remove=<true>	<p data-bbox="818 212 1471 338">When specified, turns off reporting for the study and removes all reporting-related settings for the study. When you use the remove parameter, you must also specify the following:</p> <ul data-bbox="818 369 1078 548" style="list-style-type: none"><li data-bbox="818 369 987 394">• trial_name<li data-bbox="818 422 1078 447">• register_db_server<li data-bbox="818 474 1057 499">• register_db_user<li data-bbox="818 527 1057 552">• register_db_pass

Example:

Example command-line with a complete set of parameters to set up reporting DiffDB:

```
pfconfig "E:\scripts\pfconfigparams.txt"
```

pfrinit

Purpose

Performs the following tasks:

- Modifies the default Cognos 10 BI capabilities to fit the InForm reporting environment.
- Creates new Cognos 10 BI groups that match InForm reporting requirements.
- Sets Public folders permissions so that only Publishers can write to this public area.
- Maps study-specific reporting groups to the Cognos 10 BI groups and roles.
- Creates study-specific data connection and set permissions so that it is restricted for the use of study members only.
- Copies the InForm Trial Management (ITM) package present in the InForm folder and renames it as a study-specific ITM package.
- Creates a study folder that contains all the standard folders and reports that point to the study-specific package. Relative paths within reports will be modified to reflect the new location.
- Validates all copied reports so that all successfully validated reports are syntactically correct and able to run against the study-specific packages.

Location

The InForm Application Server folder of the server where the Cognos Application Tier components are installed. For example, *<Installation_Directory>\InForm\bin*.

Usage

`pfrinit "path_to_parameter_file"`

Option	Parameter
<code>path_to_parameter_file</code>	<p>When specified, includes the path to a text file that contains the user name and passwords required to run the command.</p> <p>If the parameter file is not specified, the command prompts for the required user names and passwords.</p> <p>The format of the parameter file is <code>parameter=value</code>. There is a new line for each parameter, and there are no spaces on a line.</p>

The recommended InForm study user for running pfrinit is **pfreportinguser**. You can change the password for this user using the InForm user interface as with any other user. After you change the password, however, you must run the PFADMIN command, using this syntax:

PFADMIN SETSERVER PFREPORTINGUSERPW <studyname>

When prompted, enter the pfreportinguser password.

This command sets a property used by Reporting when it needs the credentials of the

pfreportinguser.

For more information, see *pfadmin* (on page 116).

Parameter file contents

The following parameters are required for the pfrinit command password file:

- sysadmin_namespace=Oracle Directory Server admin namespace. Type **ORACLEHS** (case-sensitive).
- sysadmin_uid=User name for the Oracle Directory Server admin namespace. Type **crnsysadmin**.
- sysadmin_pass=<crnsysadmin_password> Password you chose when creating the crnsysadmin user.
- publisher_namespace=Custom Authentication Provider (CAP) namespace. The default is informcap.

Note: The case of the value you enter here must be the same case as the entry in the Cognos Configuration utility. For example, if the entry in the Cognos Configuration utility is in lower case (informcap), the <namespace> option must also be informcap.

- publisher_uid=*InForm_study_user*>InForm study user who is a member of the following Reporting groups:
 - Publishers.
 - Either Sponsor Users or Site Users.

pfreportinguser is the recommended study user to run pfrinit. This user is created during the Reporting and Analysis installation.

- publisher_pass=Password of the InForm study user.
- dispatcher_url=Internal URI that the InForm server uses to communicate with the Cognos 10 BI server. This Cognos 10 BI parameter is set in the InForm CRN wizard. The parameter setting is stored in the cogstartup.xml file and corresponds to the Reporting internal URI value on the Admin > System Configuration page of the InForm application.

Example: http://<machine_FQDN>:9300/p2pd/servlet/dispatch.
- trial_name=Name of the InForm study.

Note: Use the same case as when the study was created by the Central Designer deployment package.

- reportdb_pass=Password for the reporting schema user.

Example

```
pfrinit "E:\scripts\init.txt"
```

remove_streams_setup_info_diffdb

Purpose

Deletes stream information from the study database and reporting database.

Location

Folder where the reporting software is located, for example, *<Installation_Directory>\InForm Reporting\DBOra*.

Usage

```
remove_streams_setup_info_diffdb [/accountparams "path_to_password_file"]
```

Option	Parameter
<i>/accountparams "path_to_password_file"</i>	<p>When specified, includes the path to a text file that contains the user name and passwords required to run the command.</p> <p>If the accountparams option is not specified, the command prompts for the required user names and passwords.</p> <p>The format of the parameter file is parameter=value. There is a new line for each parameter, and there are no spaces on a line.</p>

Parameter file contents

The following parameters are required for the `remove_streams_setup_info_diffdb` command password file:

- `streams_admin_user_rep_passwd=Password` for the reporting streams admin user.
- `streams_admin_user_trial_pwd=Password` for the study streams admin user.

Example

```
remove_streams_setup_info_diffdb /accountparams:"e:\scripts\streampwds.txt"
```

APPENDIX B

Troubleshooting

In this appendix

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Uninstall issues	136

Install issues

Oracle MTS configuration is invalid

If the Oracle registry settings are not correct, you may get the following InForm core installer errors during the installation process:

- Oracle MTS configuration is invalid.
- Registry Settings: INVALID.
- XA Views: INVALID.

Possible solutions:

- If the installation wizard is still open:
 - 1 Click **Back** to display the **Database Configuration** window.
 - 2 Select the **Prep Oracle** checkbox.
 - 3 Click **Next** to proceed.

This runs the `informprepora.vbs` and `mtsora102.vbs` scripts.

- If the installation window has been closed, run `mtsora102.vbs` from the command line. The `mtsora102.vbs` file is in the `InstallSupport` folder of the InForm installation image.

XA Views: INVALID

If you have tried the solution that is recommended in *Oracle MTS configuration is invalid* and still get this error, or if you run `mtsora102.vbs` from the command line and get a warning, the `xaview.sql` file may not be installed.

Note: This can happen for some Oracle client-only installations (multi-tier setup).

Possible solution:

- 1 Copy the `xaview.sql` file from another machine (running the same Oracle version) to your Oracle `rdbms\admin` directory.
- 2 Log in as `SYS` on a machine with `xaview.sql`.
- 3 Run `xaview.sql` against your InForm core instance.
- 4 Run `mtsora102.vbs` from the command line.

Database connectivity

If you get a warning about database connectivity, make sure that:

- The connect string value is correct.
- The pfdbadmin password is valid.

If you get a message that the pfdbadmin user does not exist, create the user by doing one of the following:

- Select the **Prep Oracle** checkbox in the InForm installation wizard.
- Run the informprepora.vbs script located in the InstallSupport folder of the InForm installation image.

Password error on InForm service start up

The InForm installation wizard cannot ensure that the password entered on the Account Configuration Window for the Local Machine User (pfUSR) meets the password requirements set for the machine. If you enter a password that does not conform to the Windows password requirements, an error will prevent the InForm service from starting.

- 1 To change the pfUser password enter the following command at a DOS prompt:
pfadmin install
- 2 When prompted for the pfUSR password, enter a password that meets the password requirements.
- 3 Run the following command to start the InForm service:
new start pfservice

Use the pfadmin view service command to verify that the InForm service has started.

Uninstall issues

Errors when removing a reporting schema

If you run the **deinstall_reporting_diffdb.sql** script to remove a reporting schema, and you receive the message **Reporting deinstallation aborted**, the uninstall fails and no reporting objects are removed.

The probable cause is a problem with the settings in the **configdiffdb.sql** file.

Check the **configdiffdb.sql** file to make sure that the settings are correct for the reporting schema that you want to remove. In particular, the uninstall scripts check for the existence of a tablespace. If the **configdiffdb.sql** file contains variables that refer to nonexistent tablespaces, update the file and rerun the uninstall script.

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