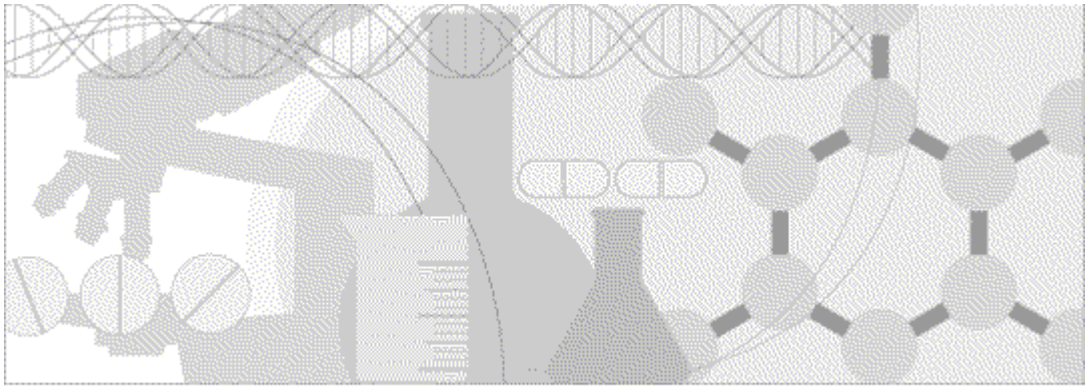
Study and Reporting Setup Guide

Oracle® Health Sciences InForm 6.1.1



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CHAPTER 1

Setting up and configuring a study

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About setting up and configuring a study

Setting up and configuring a study requires a series of steps performed with multiple products. For an illustration of the setup process, see *Study setup workflow* (on page 2).

1 Ensure all of the required set up tasks, which are performed with multiple products, are complete.

- **Central Designer application**—Use to define the study forms and visits, system configuration parameters, and study administration parameters.

  For more information, see *Central Designer—Study setup requirements* (on page 4).

- **InForm application**—Use to install the InForm software, Central Designer certificates, and Central Designer rule engine, and to create deployment users.

  For more information, see *InForm—Study setup requirements* (on page 4).

- **User management tool**—Use to create the InForm users, define the rights, rights groups, and sites.

  For more information, see *User management tool—Study setup requirements* (on page 5).

2 Use the Central Designer application to deploy your study to the InForm application.

  For more information, see *Study package deployment to the InForm application* (on page 5).

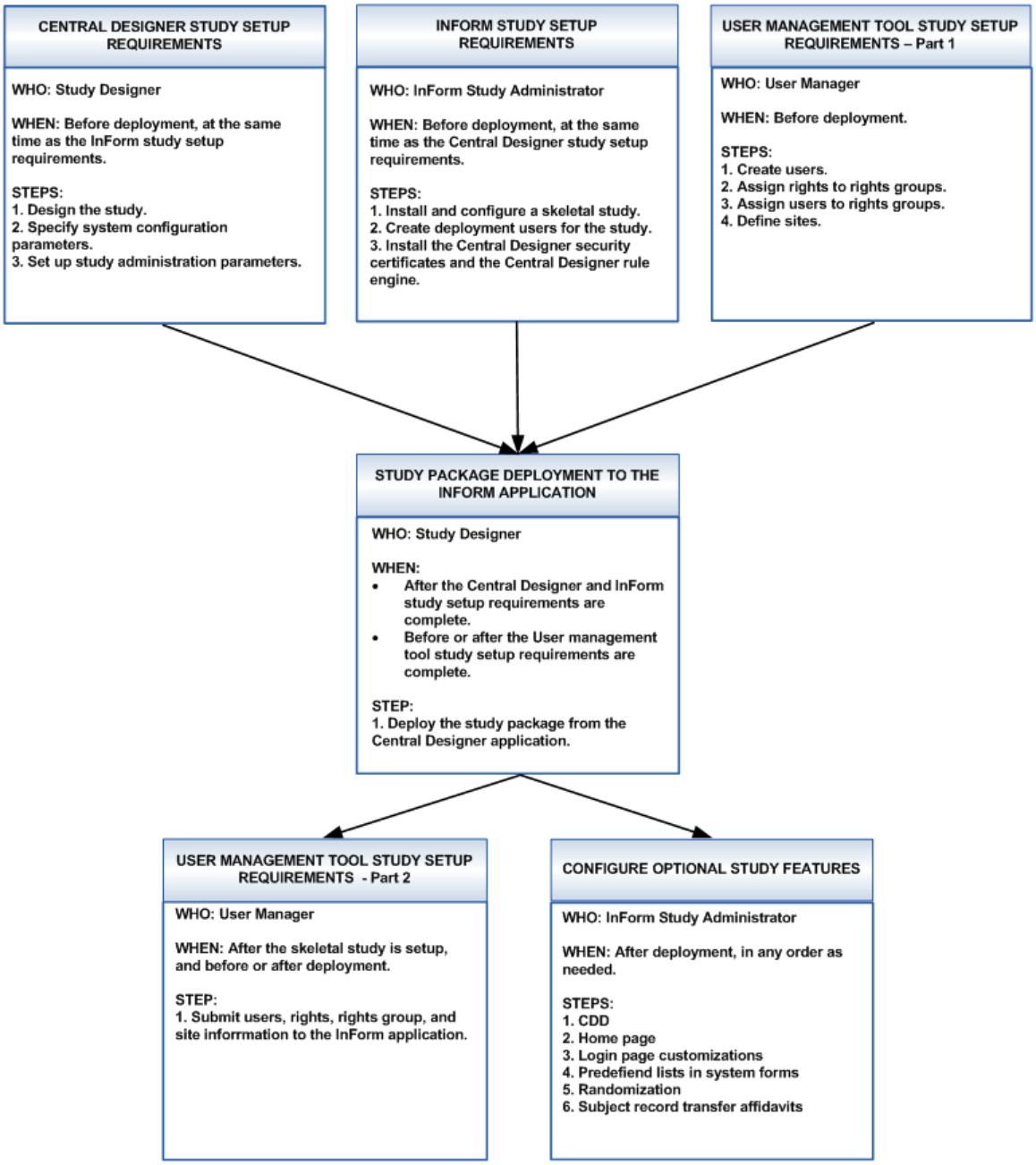
3 Use the InForm application to configure any optional study features that are required by your study.

  For more information, see *Optional study features* (on page 6).

4 Use your user management tool to transmit the users, rights, rights groups, and site information to the InForm application.

Study setup workflow

The study setup workflow is a cross-product process that includes requirements from the Central Designer application, the InForm application, and a user management tool.


CENTRAL DESIGNER STUDY SETUP REQUIREMENTS
WHO: Study Designer
WHEN: Before deployment, at the same time as the InForm study setup requirements.
STEPS:
1. Design the study.
2. Specify system configuration parameters.
3. Set up study administration parameters.
INFORM STUDY SETUP REQUIREMENTS
WHO: InForm Study Administrator
WHEN: Before deployment, at the same time as the Central Designer study setup requirements.
STEPS:
1. Install and configure a skeletal study.
2. Create deployment users for the study.
3. Install the Central Designer security certificates and the Central Designer rule engine.
USER MANAGEMENT TOOL STUDY SETUP REQUIREMENTS – Part 1
WHO: User Manager
WHEN: Before deployment.
STEPS:
1. Create users.
2. Assign rights to rights groups.
3. Assign users to rights groups.
4. Define sites.
STUDY PACKAGE DEPLOYMENT TO THE INFORM APPLICATION
WHO: Study Designer
WHEN:
• After the Central Designer and InForm study setup requirements are complete.
• Before or after the User management tool study setup requirements are complete.
STEP:
1. Deploy the study package from the Central Designer application.
USER MANAGEMENT TOOL STUDY SETUP REQUIREMENTS - Part 2
WHO: User Manager
WHEN: After the skeletal study is setup, and before or after deployment.
STEP:
1. Submit users, rights, rights group, and site inforrmation to the InForm application.
CONFIGURE OPTIONAL STUDY FEATURES
WHO: InForm Study Administrator
WHEN: After deployment, in any order as needed.
STEPS:
1. CDD
2. Home page
3. Login page customizations
4. Predefiend lists in system forms
5. Randomization
6. Subject record transfer affidavits

Central Designer—Study setup requirements

A study designer typically performs the Central Designer study setup tasks. For more information, see the Central Designer *InForm Design Guide*.

The Central Designer study setup tasks can be performed at same time as the InForm study setup tasks.

1 Design the study, including the forms and visits.

2 Specify the system configuration parameters.

   System configuration parameters are global settings that specify customizable, system-wide InForm behaviors for how the InForm application handles a study.

3 Set up the study administration parameters, including display overrides and rights groups.

   Study administration parameters specify configuration parameters for a study, who is running a study, and how the InForm application distributes the workload.

InForm—Study setup requirements

An InForm study administrator typically performs the InForm study setup tasks.

The InForm study setup tasks can be performed at same time as the Central Designer study setup tasks.

1 Install and configure a skeletal study.

   Before you can deploy a study, you must set up the basic framework to hold your study design and data. This framework is called a skeletal study. A skeletal study is required for automated deployment.

   Skeletal studies are created and configured to communicate with the Central Designer application using pfadmin commands during the InForm software installation. For more information, see the *Installation Guide*.

2 Create Deployment users for the study.

   A deployment user is any sponsor user with the Study Deployment right.

   You create deployment users in the InForm user interface or with the MedML Installer utility. For more information, see the *User Guide* or *Utilities Guide*.

3 Install the Central Designer security certificates and the Central Designer rule engine.

   For more information, see the *Installation Guide*.

User management tool—Study setup requirements

A User Manager typically performs the user management tool study setup tasks.

You can perform the following tasks at any time.

1 Create users.

2 Assign rights to rights group.

3 Assign users to rights groups.

4 Define sites.

You perform the following tasks after the skeletal study is set up, and before or after the study deployment.

- Submit users, rights, rights group, and site information to the InForm application.

Study package deployment to the InForm application

A study designer typically deploys the study package to the InForm application.

1 Ensure that all the Central Designer and InForm study setup requirements are complete.

2 Deploy a Central Designer study package from the Central Designer user interface.

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

Optional study features

Depending on the requirements of your study, you might need to set up some optional features that are not available through the InForm user interface.

This guide provides instructions for configuring these features, which can be configured in any order, and include:

- A customer-defined database (CDD).
- Login page customizations.
- Predefined lists in system forms.
- Randomization.
- Text of a subject record transfer affidavit.

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 data mapping 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.

Configuring a CDD

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

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

```
pfadmin view service
```

2 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
```

3 Make the online CDD functionality transactional:

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

For example:

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

4 Enable online CDD functionality for the study:

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

For example:

```
pfadmin config cdd pfst60 enable
```

5 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 99).

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 **ExternalLoginForm.aspx** file, located in **<***cognos_installation_directory***>\InForm\pfexternallogin**.

2 Edit **div id= "TechSupportInfo" text=** attribute, and save the file.

3 Clear the browser cache.

Any information you enter is visible on the External Reporting Login page as soon as you save the file, and then access the External Reporting Login page.

The contact information appears at the bottom of the External Reporting Login page.

Note: Customized files are overridden when you upgrade Reporting. If you upgrade Reporting, you must update the ExternalLoginForm.aspx file again.

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	• Resources\Enu\pfscript.js • Resources\Enu\Templates\PDFPage.xsl • Resources\Enu\resources.xml • Resources\Jpn\pfscript.js • Resources\Jpn\Templates\PDFPage.xsl • 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.

5 Save your changes.

6 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 12).

1 Make a backup copy of each **pfscript.js** and **PDFPage.xsl** file.

2 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 pfscript.js files with the MedML Installer utility:

```
<RESOURCEDATA xmlns="PhaseForward-MedML-Inform4">
<RESOURCE
 FILENAME="pfscript.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="pfscript.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 pfscript.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.

Identifier	Default strings	When used
[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 14).

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

For more information, see *Randomization source manager configuration* (on page 15).

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

For more information, see *Randomization sequence format configuration* (on page 16).

6 Configure the study to use the randomization data source.

For more information, see *Randomization source database setup* (on page 16).

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 21).

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 pfdamin 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 22).

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 the Central Designer *InForm Design Guide*.

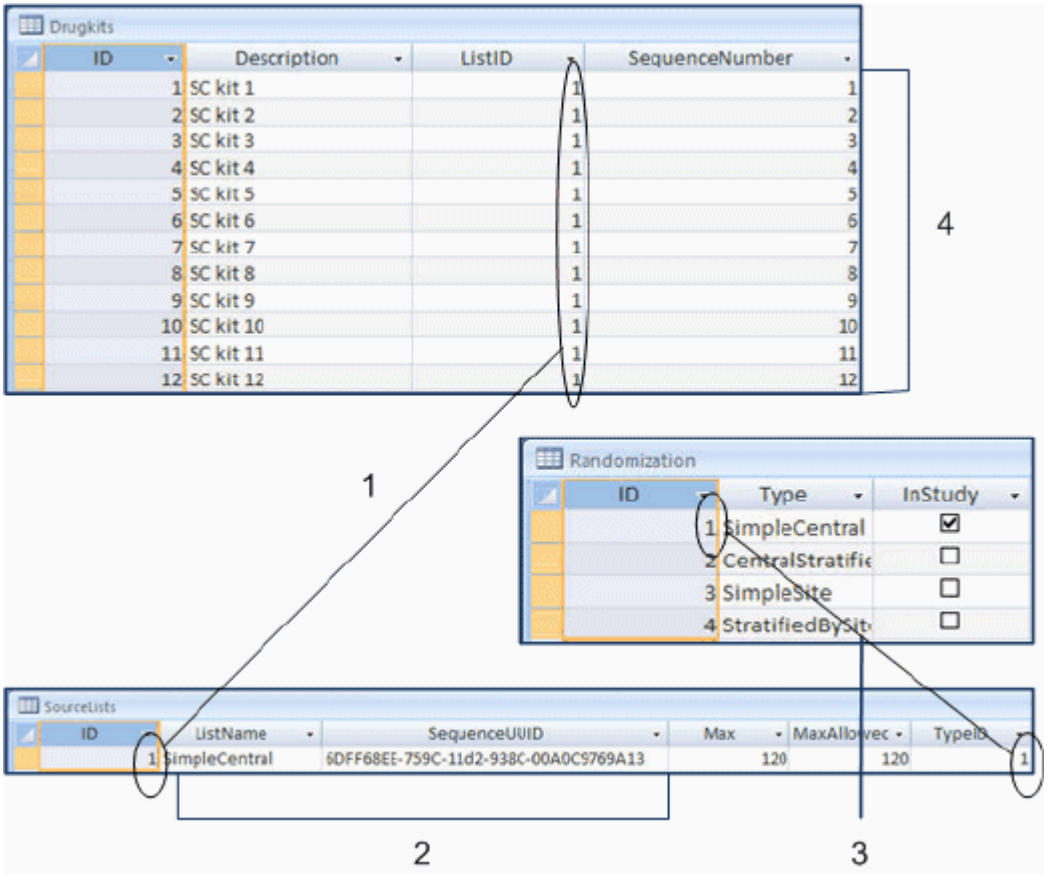
Randomization source database setup

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 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 SOURCELISTS table: • **1**—Simple Central • **2**—Central Stratified • **3**—Simple Site • **4**—Stratified by Site
Type	Text	Name of the randomization type; one of the following: • 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.
SequenceUUID	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.

Column name	Data type	Description
TypeID	Number	Identification code of the randomization type. This value maps to the ID column in the Randomization table: • **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 20).

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 sample study and provides a template for the randomization source database. The MDB file for the sample database is located in the \InForm\SampleStudy\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 randomization data source do one of the following:

- Manually create the DSN using the Microsoft Windows and ODBC Data Source Administrator.

  For more information, see:

  - *Creating an ODBC connection using the Windows ODBC Manager* (on page 21).
  - *Configuring the trial to use the randomization DSN* (on page 22).

  Use this method for both an Oracle randomization data source or a Microsoft Access randomization data source.

- Use the pfadmin command to create and configure the DSN.

  Use this method for a Microsoft Access randomization data source.

  For more information, see *Creating an ODBC connection with the pfadmin utility* (on page 22).

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

Creating an ODBC connection using the Windows ODBC Manager

1 Click **Start > Administrative Tools > Data Sources (ODBC)**.

2 Select the **System DSN** tab.

3 Click **Add**.

4 In the Create New Data Source window:

- For a Microsoft Access randomization source database, select **Microsoft Access Driver**.
- For an Oracle randomization source database, select **Oracle in OraClient_**<*version_home*> driver.

5 Click **Finish**.

6 Configure the data source.

For more information, see *Configuring a randomization data source* (on page 21).

Configuring a randomization data source

- For a Microsoft Access data source, the ODBC Microsoft Access Setup dialog box appears:

  1 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.

  Click **OK** in each dialog box.

- For an Oracle data source, the Oracle ODBC Driver Configuration dialog box appears:
  1 Enter the DSN of the randomization database as the **Data Source Name**.
  2 Select the TNS name for the randomization database from the **TNS Service Name** drop-down list.
  3 Enter the owner of the randomization database in the **User ID** field.

Creating an ODBC connection with the pfadmin utility

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 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:\InForm\Sample_PFST60\Rand\RndPFST60.mdb
```

Note: You must manually create a DSN for an Oracle randomization source database. You cannot use the pfadmin command. For more information, see ***Creating an ODBC connection using the Windows ODBC Manager*** (on page 21).

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 21).

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 either the:
  - **Name of the randomization source DSN**—When the randomization tables are in a separate database from the study database.
  - **Name of the study DSN**—When the randomization tables are part of the study database.

  For more information, see *ODBC connection for the randomization database* (on page 21).

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
  ```

Migrate a randomization source to an Oracle database

Use the **RandomizationMigration** command (located in the <*Installation_Directory*>\InForm\bin folder) to migrate a trial randomization source database from Microsoft Access to an Oracle database.

When you run the command, you can specify whether to:

- Store the randomization tables in the existing study database.
- Store the randomization tables in a new randomization source database.

Migrating the randomization source to the study database

1 To migrate trial randomization to the InForm study database, use the following syntax:

```
RandomizationMigration.exe <trialname> /UseTrialSchema /prompt <outfile>
```

where:

- *trialname*—The name of the trial for which you are migrating randomization to an Oracle database.
- *outfile*—The name of the log file used to record the results of the RandomizationMigration command.

When prompted, enter the following parameters:

- OracleSysUID—The name of the Oracle system user.
- OracleSysPID—The password for the Oracle system user.

The results of the command are recorded in the output file you specify with the command.

- If the migration is successful, the output file will include the word **SUCCESS**.
- If the migration fails, the first line of the output file will be **ERROR**, followed by one or more error messages that indicate the cause of the failure.

2 Restart the trial after the migration is complete.

Migrating the randomization source to a new database

1 To migrate trial randomization to a new randomization source database, use the following syntax:

```
RandomizationMigration.exe <trialname> /NewRNDSchema <dbserver> /prompt
<outfile>
```

where:

- *trialname*—The name of the trial for which you are migrating randomization to an Oracle database.
- *outfile*—The name of the log file used to record the results of the RandomizationMigration command.
- *dbserver*—The TNS name for the Oracle server to store the new randomization schema.

The name of the data file and tablespace for the randomization use the InFormRND_<*trialname*> format. For example, InFormRND_pfst461.dbf for the data file name, and InFormRND_pfst461 for the tablespace name.

When prompted, enter the following parameters:

- OracleSysUID—The name of the Oracle system user.
- OracleSysPID—The password for the Oracle system user.
- NewRNDSchemaUID—The name of the owner of the new randomization schema.
- NewRNDSchemaPID—The password for the owner of the new randomization schema.

The results of the command are recorded in the output file you specify with the command.

- If the migration is successful, the output file will include the word **SUCCESS**.
- If the migration fails, the first line of the output file will be **ERROR**, followed by one or more error messages that indicate the cause of the failure.

2 Restart the trial after the migration is complete.

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-b48f-8e034a28a349"
NOTE="&lt;TABLE BORDER=&quot;0&quot;CELLPADDING=&quot;4&quot;
CELLSPACING=&quot;0&quot;
 WIDTH=&quot;100%%&quot; ID=&quot;Table1&quot;&gt;
&lt;TR&gt;
&lt;TD CLASS=&quot;ttl&quot;&gt;&lt;B&gt;Subject Record Transfer
Affidavit:&lt;/B&gt;&lt;/TD&gt;
&lt;/TR&gt;
&lt;TR&gt;
&lt;TD&gt;&lt;TABLE CLASS=&quot;tbl&quot; BORDER=&quot;1&quot;
CELLPADDING=&quot;4&quot;
 CELLSPACING=&quot;0&quot; WIDTH=&quot;100%%&quot;
 BORDERCOLOR=&quot;#003366&quot;ID=&quot;Table2&quot;&gt;
&lt;TR&gt;
&lt;TD&gt;&lt;TABLE BORDER=&quot;0&quot; CELLPADDING=&quot;4&quot;
CELLSPACING=&quot;0&quot;
 WIDTH=&quot;100%%&quot; ID=&quot;Table3&quot;&gt;
&lt;TR&gt;
&lt;TD&gt;
&lt;P&gt;
The sponsor takes responsibility for and has clear processes/procedures
in place around the handling of subject transfers and coordinating across
sites to ensure that:
&lt;/P&gt;
&lt;P&gt;
1. The originating site produces or receives a certified copy of the current
CRF data created for all transferred subjects prior to the transfer.
&lt;/P&gt;
&lt;P&gt;
2. The target site accepts responsibility for the management of any
outstanding queries and data cleaning following the subject record transfer,
since the originating site will no longer have modification access.
&lt;/P&gt;
&lt;P&gt;
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 subject record transfer.
&lt;/P&gt;
&lt;P&gt;
4. The subject(s) being transferred are fully enrolled and a Case Book
has been created for each subject.
&lt;/P&gt;
&lt;/TD&gt;
&lt;/TR&gt;
&lt;/TABLE&gt;
&lt;/TABLE&gt;
&lt;/TABLE&gt;"
TITLE="Subject Record Transfer Form" MNEMONIC="PSC_FORM"
QUESTIONWIDTH="30" CONTROLWIDTH="70" TYPE="CUSTOMTRIAL" LANGUAGE="English">
. . .
<SECTIONREF REFNAME="PSC_SECT2" />
. . .
<SECTIONREF REFNAME="PSC_SECT" />
</FORM>
```

CHAPTER 2

Managing a study

In this chapter

About managing a study 28
Common pfadmin commands 29
Common Integration Manager commands 30

About managing a study

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.

You can configure your InForm study to connect to additional applications. The Integration Manager is the application that manages these integrations. Use the Integration Manager commands to register, unregister, and monitor activity of integrated applications.

Common pfadmin commands

The following table lists the most commonly used pfadmin command options. For a complete description of all pfadmin command options, see ***pfadmin*** (on page 99).

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

Common Integration Manager commands

The integration manager is used to safely start and stop integration applications during the automated deployment process. The following lists common commands used by administrators.

Action	Command, issued from a Command Prompt window
List all the integrated applications registered for a study.	IntegrationManager Query [-TRIAL] <study_name>
Register an integration application for a study.	IntegrationManager Register [-TRIAL] <study_name> Application <application_name> [application_parameters]
Unregister an integration application from a study.	IntegrationManager Unregister [-TRIAL] <study_name> Application <application_name>
Display IntegrationManager command help.	IntegrationManager /?

CHAPTER 3

Using in-place revision for study versions

In this chapter

About in-place revision of study versions....32
Supported in-place revision changes....33

About in-place revision of study versions

In-place revision (IPR) is the process of automating changes to non-clinical data in your study without changing the study version.

In-place revision changes are defined and initiated in the Central Designer application, and can be run at any time on a study that has been deployed to the InForm application. In the Central Designer application, item, itemset, or section selections can be made by study version (rather than by revision number). For more information, see the Central Designer *InForm Design Guide*.

If you want to migrate a deployed study to this release after you used MedML to make changes to non-clinical data without changing the study version, you must update the affected study objects in the Central Designer application for in-place revision to work as expected. If the study designs do not match, when you migrate and deploy the study, the changes made using MedML may be overwritten, or the deployment may fail.

Supported in-place revision changes

The Central Designer and InForm applications support many types of in-place revision changes. Any in-place revision changes not explicitly listed in the Central Designer or InForm documentation are not supported.

In-place revision changes may have no form or regulatory impact, may affect the meaning of data on a form, or may affect regulatory compliance.

The InForm MedML has been updated to support the in-place revision changes made in the Central Designer application. For more information, see the *Utilities Guide*.

Supported in-place revision changes with no regulatory or data impact

- Expand the year ranges in a date control.
- Change item properties to not required or SDV not required.
- Increase the length of a text, integer, or float field.
- Add hidden items to manage rule modifications.
- Add a new checkbox option for a control used to trigger forms in an Unscheduled Visit.

Supported in-place revision changes that may affect the meaning of data on a form

- Update item text to correct spelling or punctuation errors, provided the meaning is not changed.
- Add options to radio, pull down, or checkbox controls to allow sites to enter data accurately.
- Add items to an existing section.

Supported in-place revision changes that may affect regulatory compliance

- Remove items that contain data.
- Reduce the length of text, integer, or float fields.
- Decrease the precision of a float field.
- Reduce the maximum limit or increase the minimum limits on integer or float fields.
- Remove selections from pull down lists, radio controls, or checkbox controls.
- Decrease the date range for a date control.
- Change codelist selection labels.
- Remove UNK or NREQ in date controls.
- Remove date parts, such as hours and minutes.
- Change in control structure, such as adding levels of nesting.

CHAPTER 4

Configuring the Reporting and Analysis module

In this chapter

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Setting up reporting in a study 38

Configuring a study for the Reporting and Analysis module 43

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 *Installation Guide*.

Setting up reporting in a study

If your study and reporting schemas are installed in the same database instance (SameDB), you do not need to set up communication between the two schemas. However, for an environment where the study schema and reporting schema are installed on different database instances (DiffDB), you must perform the following tasks to set up the reporting in a study:

- *Granting privileges to the study user* (on page 38).
- *Edit and test reporting configuration variables* (on page 39).
- *Create the streams between the InForm study schema and the Reporting schema, and install the Reporting schema* (on page 42).

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, <*Installation_Directory*>\Inform\bin\DBOra\Reporting.

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 87).

Edit and test reporting configuration variables

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, <*Installation_Directory*>\InForm\bin\DBOra\Reporting.

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

- There are some variables that are preset. You must not try to change them. These variables are indicated with a **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*.

I/S	Variable	Value	Comments
	I=Set one time 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	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, <*Installation_Directory*>\Inform\bin\DBOra\Reporting.

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
```

You are prompted for the following parameters:

- **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.

For more information, see *configandcheckdiffdb* (on page 73).

Create the streams between the InForm study schema and the Reporting schema, and install the Reporting schema

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

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-<studyname>.sql** script. For more information, see *Configuring the reporting variables for a study—Different database instances* (on page 39).

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
```

You are prompted for the following parameters:

- **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 study database who has read-only access to the specified study schema.

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 52)**.

For more information, see *install_reporting_diffdb* (on page 95).

Configuring a study for the Reporting and Analysis module

About configuring a study for the Reporting and Analysis module

Configuring a study for Cognos involves establishing communications between the InForm study and the Cognos 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 44).

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 44).

3 Run the pfrinit utility.

For more information, see *Running the pfrinit utility* (on page 46).

4 Authorize users for the Reporting and Analysis module.

For more information, see *Authorizing users for the Reporting and Analysis module* (on page 47).

5 Specify a logo for InForm standard reports.

For more information, see *Specifying a logo for InForm standard reports* (on page 50).

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.
- **Wizard location**—Start > All Programs > Oracle® Health Sciences > InForm 6.1 > 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 6.1 > 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, and click **Next**.

The Cognos parameters page appears.

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

Cognos parameter	Description
Cognos Namespace	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 in lower case (informcap). informcap is the namespace created by the InForm CRN wizard. The namespace can be shared by many studies, and it should not typically need to be changed. If you have created additional namespaces manually with the Cognos Configuration utility, use the name of the newly created namespace in this field.
Gateway URI	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 Business Intelligence Gateway Customization for InForm wizard. The parameter setting is stored in the cogstartup.xml file. Example: http://www.example.com/cognos
Dispatcher URI	Internal URI that the InForm server uses to communicate with the Cognos 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. Example: http://www.example.com:9300/p2pd/servlet/dispatch.
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.

Field	Description
Password	Reporting study 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 for the CAP.
User	The user name for the CAP database schema owner.
Password	Password for the CAP database schema owner.
Name of Trusted User	Optional. The name of the user that is trusted for InForm Clinical Model Generation. By default, it is populated with pfreportinguser. This field can be left blank.

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**—<*InstallationDirectory*>\InForm\Bin
  - **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
```

You are prompted for the following parameters:

- **sysadmin_namespace**—Oracle Directory Server admin namespace.
- **sysadmin_uid**—User name for the Oracle Directory Server admin namespace.
- **sysadmin_pass**—Password you chose when creating the crnsysadmin user.
- **publisher_namespace**—Custom Authentication Provider (CAP) namespace.
- **publisher_uid**—InForm study user who is a member of the following Reporting groups:
  - Publishers.
  - Either Sponsor Users or Site Users.
- **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.
- **trial_name**—Name of the InForm study.
- **in_place_upgrade**—Y/N. Indicate if the PFRInit command is being run as part of an in-place upgrade (required for an in-place upgrade).

For more information, see *pfrinit* (on page 113).

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 48).

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 namespace

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

Default reporting groups

As part of the initial Reporting and Analysis setup, the pfrinit utility imports the PFRsetupTrial_<*lang*>.xml file, which loads the following predefined reporting groups into the Cognos 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 namespace. The groups are added to the Cognos namespace by the pfrinit utility.

InForm reporting group	Cognos 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 Reporting 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 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.

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

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 (named logo.gif) 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:

`<c10 install directory>\webcontent\<TrialName>`

For example: e:\Cognos\c10\webcontent\pfst61\logo.gif.

If there is no image file available in the *<c10 install directory>*\webcontent*<TrialName>* folder, reports that contain images might crash when exporting to Microsoft Excel or PDF.

To prevent this from happening, make sure that communications between the Report Servers and the Gateway Server use the same the protocol (both servers must use either HTTP or HTTPS).

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 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 53).

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 54).

4 Delete study-specific information from the Cognos environment.

For more information, see *Deleting study-specific information from the Cognos environment* (on page 55).

5 Remove the InForm study.

For more information, see *Removing an InForm study* (on page 57).

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 39).

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
```

You are prompted for the following parameters:

- **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. Y/N. Optional.

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 79).

Deleting stream information from the study database and reporting database

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

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
```

You are prompted for the following parameters:

- **streams_admin_user_rep_passwd**—Password for the reporting streams admin user.
- **streams_admin_user_trial_pwd**—Password for the study streams admin user.

For more information, see ***remove_streams_setup_info_diffdb*** (on page 117).

Deleting study-specific information from the Cognos environment

To remove study information from the Cognos environment, you must be an InForm user with the following credentials:

- Access to the study to be removed.
- Member of a rights group that includes the Reports right.
- Member of the following Reporting groups:
  - Either Site Users or Sponsor Users.
  - Directory Administrators.
  - Either Report Administrators or Server Administrators.

To remove study information from the Cognos environment:

1 Log in to the Cognos server using a Private Gateway.

For more information about Private Gateways, see the *Installation Guide*.

2 Click **Reporting**.

3 Log on to the Reporting and Analysis module as a System Administrator:

a Select **Logon**.

b In the **User** field, type crnsysadmin.

c In the **Password** field, type the password for the crnsysadmin user.

d Click **OK**.

4 Select **Launch > Reporting Administration**.

5 Select the **Configuration** tab.

6 Click **Data Source Connections**.

The connection for the study appears (for example, pfst61 Connection).

7 In the list of Actions icons, click **More**.

The Perform an action page appears.

8 Click **Delete**, and when the confirmation dialog box appears, click **Yes**.

9 Click **Return**.

10 On the **Public Folders** tab, select the folders that are related to the study (for example, **InForm Trial Management for PFST61**).

11 For each study-related folder:

a In the list of Actions icons, click **More**.

The Perform an action page appears.

b Click **Delete**, and when the confirmation dialog box appears, click **Yes**.

c Click **Return**.

12 Select **Logoff**.

Note: If you log out and attempt to log in again, an Authentication Failed error appears. If this occurs, you must log out of the InForm study and log in again. You can then log in to the Reporting and Analysis module as a System Administrator by performing Step 2 and Step 3 of this procedure.

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.

CHAPTER 6

Performance tuning

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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 6.1 > 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\PFMngrTrial\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

To ensure satisfactory performance, Oracle recommends that you do the following:

- Analyze all tables and indexes.
- Refresh database statistics periodically.

  In a production environment, refreshing one time per day during the maintenance window is usually sufficient. However, Oracle recommends that you also refresh the database statistics if you add a large amount of data or metadata to a study.

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

```
sqlplus <pfdbadmin_uid>@<connect_string> @updatestats.cmd <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 *n* 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 =>
'STGTAB_SQLPROF_DB006');
```

4 Import the data to the destination database.

```
imp <user>/<pwd>@<instance> tables=('STGTAB_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 => 'STGTAB_SQLPROF_DB006');
```

6 Verify that the profiles imported correctly.

```
Select name, created from dba_sql_profiles;
```

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*]

Command line prompts

You are prompted for the following parameters:

- **pfdbauid**—*pfdbadmin user*
- **pfdbapid**—*pfdbadmin password*
- **admindbuid**—*informadmin user*
- **admindbpid**—*informadmin password*

For legacy purposes, you can also pass the parameters by using the **/accountparams:***"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.

Example

admindb trial1

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

Command line prompts

You are prompted for the following parameters:

- **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.

For legacy purposes, you can also pass the parameters by using the **/accountparams:***"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.

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.

create_cap_table.sql

Purpose

Creates the TRIAL_URLS table for the PFCAPAdmin user.

Location

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

Usage

@create_cap_table.sql

Notes

Run from SQL*Plus with /nolog.

Errors are recorded in the create_cap_table.log file.

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.

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*>]]

Option	Parameter
SysAdminNamespace	Oracle Directory Server admin namespace.
SysAdminUsername	User name for the Cognos system administrator.
TrialNamespace	Custom Authentication Provider (CAP) namespace.
TrialUsername	InForm study user who is a member of the following Reporting groups: • Publishers. • Either Sponsor Users or Site Users.
CognosDispatcherURI	Internal URI that the InForm server uses to communicate with the Cognos 10 BI server.
TrialName	Name of the InForm study.
company_code	The organization ID. Optional. This parameter is required only for Oracle-hosted studies in a single sign-on environment.

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.

Note: You are always prompted for the System Administration password and Trial user passwords when you run DecomTrial.

For legacy purposes, you can also pass the parameters by using the **/accountparams:***"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

DeleteObject

Purpose

Deletes obsolete reports from a Reporting and Analysis module that has been migrated to Cognos 10.2.2:

- CRF Reports/CRF Cycle Time Detail by User
- CRF Reports/CRF Site Performance Summary by User
- CRF Reports/CRF Aging by User
- Subject Reports/Case Book Completion and Query Summary by User
- Subject Reports/Subject Enrollment Status by User
- Query Reports/Query Volume by Month by User

Location

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

Usage

DeleteObject [sysadmin_namespace=*SysAdminNamespace* sysadmin_uid=*SysAdminUsername* dispatcher_url=*CognosDispatcherURI* trial_name=pfst [cognos_version=[8.2 | 8.4 | 10.2.1 | 10.2.2]] ["path_to_parameter_file"]

Option	Parameter
sysadmin_namespace	Oracle Directory Server admin namespace.
sysadmin_uid	User name for the Cognos system administrator.
dispatcher_url	Internal URI that the InForm server uses to communicate with the Cognos 10 BI server.
trial_name	Name of the InForm study.
cognos_version	The Cognos version you are migrating from. Options are: • 8.2 • 8.4 • 10.2.1 • 10.2.2

Option	Parameter
path_to_parameter_file	• 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 parameter=value. 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 DeleteObject command, you are prompted for the following parameters:

- **sysadmin_namespace**—Oracle Directory Server admin namespace.
- **sysadmin_uid**—User name for the Cognos system administrator.crnsysadmin
- **sysadmin_pid**—Password for the Cognos system administrator.crnsysadmin
- **dispatcher_url**—Internal URI that the InForm server uses to communicate with the Cognos 10 BI server.
- **cognos_version**—The Cognos version you are migrating from.

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.
- sysadmin_pid=Password for the Cognos system administrator.
- dispatcher_url=Internal URI that the InForm server uses to communicate with the Cognos 10 BI server.
- cognos_version=The Cognos version you are migrating from.

Example

DispatchAPI sysadmin_namespace=OHSI sysadmin_uid=crnsysadmin dispatcher_url=http://host:9300/p2pd/servlet/dispatch cognos_version=10.2.1

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

Command line prompts

You are prompted for the following parameters:

- **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.

For legacy purposes, you can also pass the parameters by using the **/accountparams:***"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.

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.
- 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.

DeployBackup.cmd

Purpose

Backs up a study under a custom archive file name and path. If the operation is successful, the command returns 0. Otherwise, it returns 1 to signal the error.

Location

Deployment root folder, as defined in the DeployRoot registry value under HKEY_LOCAL_MACHINE\SOFTWARE\OracleHS\InForm. By default, it is the InFormDeploy folder on the drive where the InForm application is installed. For example: E:\InFormDeploy.

Usage

DeployBackup <*Study_Name*> <*Archive_File_Name*> <*TNS_Service_Name*> <*Archive_Path*> <*Parameters_File_Name*>

Option	Parameter
Study_Name	Name of the study to be backed up.
Archive_File_Name	Name of the backup file.
TNS_Service_Name	Local Net Service Name for the remote database service.
Archive_Path	Path on the database server where the backup file is saved.

Parameters_File_Name	Name of the parameters file that contains database credentials.
	The parameters file must contain the following values:
	`trial_user=<study_schema_user_name>`
	`trial_user_pass=<study_schema_user_password>`
	`orasystem_user=<admin_user_name>`
	`orasystem_user_pass=<admin_user_password>`

DeployEnd.cmd

Purpose

Applies custom system tasks after a successful or failed study deployment. If the operation is successful, the command returns 0. Otherwise, it returns 1 to signal the error.

Location

Deployment root folder, as defined in the DeployRoot registry value under HKEY_LOCAL_MACHINE\SOFTWARE\OracleHS\InForm. By default, it is the InFormDeploy folder on the drive where the InForm application is installed. For example: E:\InFormDeploy.

Usage

DeployEnd <*Study_Name*> <*Deployment_Status*>

Option	Parameter
Study_Name	Name of the deployed study.
Deployment_Status	• 0 for successful study deployment • 1 for failed study deployment

DeployRestore.cmd

Purpose

Restores a backed up study from a specified archive file. If the operation is successful, the command returns 0. Otherwise, it returns 1 to signal the error.

Location

Deployment root folder, as defined in the DeployRoot registry value under HKEY_LOCAL_MACHINE\SOFTWARE\OracleHS\InForm. By default, it is the InFormDeploy folder on the drive where the InForm application is installed. For example: E:\InFormDeploy.

Usage

DeployRestore <*Study_Name*> <*Archive_File_Name*> <*TNS_Service_Name*> <*Archive_Path*> <*Parameters_File_Name*>

Option	Parameter
Study_Name	Name of the study to be restored.
Archive_File_Name	Name of the backup file.
TNS_Service_Name	Local Net Service Name for the remote database service.
Archive_Path	Path on the database server where the backup file is saved.

Parameters_File_Name	Name of the parameters file that contains database credentials.
	The parameters file must contain the following values:
	`trial_user=<study_schema_user_name>`
	`trial_user_pass=<study_schema_user_password>`
	`orasystem_user=<admin_user_name>`
	`orasystem_user_pass=<admin_user_password>`

ExportMigrationFiles

Purpose

Modifies the InForm study database for migration, creates a dump file of the modified database, backs up the InForm registry, and records the InForm server information in a text file that you can use to migrate an InForm study to a new environment.

Location

The InForm\InstallSupport folder on the product image.

Usage

ExportMigrationFiles.cmd <*TNS_Service_Name*>

Command line prompts

You are prompted for the following parameters:

- **Trial user ID**—Owner of the study database schema.
- **Trial user password**—Password for the owner of the study database schema.
- **Oracle system uid**—Oracle database system user.
- **Oracle system user password**—Password for the Oracle database system user.
- **Oracle sys uid**—Oracle database sys user.
- **Oracle sys password**—Password for the Oracle database sys user.
- **Dump file directory path**—Directory on the InForm database server to store the dump file.
- **Dump file name**—Name of the DMP file to export.

> **Note:** Do not include spaces in the dump file name or the directory path to the dump file.

For legacy purposes, you can also pass the parameters by using the **/accountparams:***"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:

- trial_user=Owner of the study database schema. **Note:** This name should not change.
- trial_user_pass=Password for the owner of the study database schema.
- orasystem_user=Oracle database system user.
- orasystem_user_pass=Password for the Oracle database system user.
- orasys_user=Oracle database sys user.
- orasys_user_pass=Password for the Oracle database sys user.
- dump_file_dir_path=Directory on the InForm database server where the database dump file will be created.
- dump_file_name=Database dump file name.

Notes

The ExportMigrationFiles command creates the following files:

- <*dump_file_name*>**.dmp**—The dump file name specified on the command line. The dump file is located in the specified directory on the InForm database server.
- **pfadmin_view_service.txt**—Text file containing the information for the servers and studies running on the InForm application server.
- **InForm.reg**—A registry file that contains the contents of the exported from:
  - HHKEY_LOCAL_MACHINE\SOFTWARE\PhaseForward (InForm 4.6, 5.0 , or 5.5 studies)
  - HHKEY_LOCAL_MACHINE\SOFTWARE\OracleHS (InForm 6.0 studies)

Note: If error messages indicating that the system cannot find the paths specified for the System Product Locale and the System Study Locale appear, disregard the messages and continue with the migration.

Example

ExportMigrationFiles.cmd trial1

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.

ImportMigrationFiles

Purpose

Imports an InForm study database dump file that was created by the ExportMigrationFiles command into a new database instance, and creates and configures the InForm study based on command parameters supplied when the command runs.

Location

<InstallationDirectory>\InForm\Bin\DBOra

Usage

ImportMigrationFiles.cmd <*TNS_Service_Name*>

Command line prompts

You are prompted for the following parameters:

- **InForm study name**—Enter the name of the InForm study you will create to import the dmp file.
- **InForm server name**—Enter the name of the InForm server to run the study.
- **Trial user ID**—Owner of the study database schema.
- **Trial user password**—Password for the owner of the study database schema.
- **Study locale ISO name**—For InForm 4.6 studies, enter en-US; for other InForm versions, enter an available study locale.
- **Oracle system uid**—Oracle database system user.
- **Oracle system user password**—Password for the Oracle database system user.
- **Oracle sys uid**—Oracle database sys user.
- **Oracle sys password**—Password for the Oracle database sys user.
- **InForm database administrator name**—The name for the InForm database administrator.
- **InForm database administrator password**—The password for the InForm database administrator.
- **Dump file directory path**—Location of the directory that you created on the InForm database server.
- **Dump file name**—Name of the DMP file to export.
- **Was dump file created with Oracle 9 or 10?**—Enter **Y** or **N**.
- **Upgrade from InForm version?**—Enter the version of the study you are migrating Options are 4.6, 5.0, 5.5, 6.0, or 6.1.
- **Study type**—Enter a trial type for your study. Options are LIVE, UAT, TRN, DEV, or QA.

- **Study approval**—Enter TRUE if you require approval for any deployment package, FALSE if your study does not require deployment package approval.

  Note: By default, Live and UAT studies require study approval.

- **Deployment backup folder**—Enter a path on the InForm database server that will be used for database recovery during study deployment. For example /u01/app/deploybackup.

  Note: The physical must exist before you run the ImportMigrationFiles command.

- **Deployment service port**—Enter a port number for the Central Designer application to communicate with the InForm application server to transmit deployment packages.
- **Authentication service port**—Enter a port number for the InForm application server to authenticate users for the Reporting and Analysis module.
- **ODMSubmit service port**—Enter a port number for the Clinical Data API to exchange SOAP requests.

For legacy purposes, you can also pass the parameters by using the **/accountparams:***"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:

- InForm_trial_name=InForm studyname.
- InForm_server_name=InForm server name.
- trial_user=Owner of the study database schema.
- trial_user_pass=Password for the owner of the study database schema.
- study_locale_ISO_name=Study locale.
  - For InForm 4.6 studies, enter **en-US**.
  - For InForm 5.0, 5.5, 6.0, and 6.1 studies, enter one of the available study locales.
- orasystem_user=Oracle database system user.
- orasystem_user_pass=Password for the Oracle database system user.
- orasys_user=Oracle database sys user.
- orasys_user_pass=Password for the Oracle database sys user.
- pfdbauid=InForm Database Administrator Username (pfdbadmin).
- pfdbapid=InForm database administrator password.
- dump_file_dir_path=Database dump file directory.
- dump_file_name=Database dump file name.

- dump_created_with_exp=(Y or N) Was the dump file created with exp.exe (Oracle 9 or 10) or with expdp.exe (Oracle 11)?
- UpgradeFromInFormVersion=4.6, 5.0, 5.5, 6.0, or 6.1.
- trial_type=UAT, LIVE, TRN, DEV, or QA.
- trial_approval=TRUE or FALSE.
- deployment_backup_folder=The path on the InForm database server that will be used for database recovery during study deployment.
- deployment_service_port=The port number for the Central Designer application to communicate with the InForm application server to transmit deployment packages.

  Recommended port is 14040, however any port other than 80 or 443 can be used.
- auth_service_port=The port number for the InForm application to authenticate users for the Reporting and Analysis module.

  Recommended port is 14041, however any port other than 80 or 443 can be used.
- odm_service_port=The port number for the Clinical Data API to exchange SOAP requests.

  Recommended port is 14042, however any port other than 80 or 443 can be used.

Notes

Based on the parameters submitted when the command runs, the ImportMigrationFiles command imports the InForm study database dump file, and performs study configuration tasks, including:

- Creates the InForm server and study.
- Upgrades the study schema.
- Updates study statistics.
- Sets the MedML Installer server.
- Upgrades resources.
- Terminate obsolete users.
- Sets the deployment web service port.

Example

ImportMigrationFiles.cmd TRIAL1

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	• 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	• 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	• 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	• 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 the 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.

- **company_code**—The organization ID. Optional.

  This parameter is required only for Oracle-hosted studies in a single sign-on environment.

For legacy purposes, you can also pass the parameters by using the **/accountparams:***"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.

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 "E\scripts\import.txt"

informprepora

Purpose

Creates the pfdbadmin 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 <*oracle_connection_string*>

Command line prompts

You are prompted for the following parameters:

- **orasys_user**—Name of the Oracle sys user.
- **orasys_user_pass**—Oracle sys user password.
- **pfdbauid**—Name of the InForm Admin database user.
- **pfdbapid**—InForm Admin database user password.

For legacy purposes, you can also pass the parameters by using the **/accountparams:***"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.

Example

informprepora trialdb

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

Command line prompts

You are prompted for the following parameters:

- **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 study database who has read-only access to the specified study schema.

For legacy purposes, you can also pass the parameters by using the **/accountparams:***"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.

Notes

Before running the installation script, make sure that you have updated the study-specific variable settings with the configdiffdb.sql script.

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

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 command enables you to set it up manually, during or after the Oracle installation.

The mtsora102 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 <*oracle_connection_string*> <*oracle_client_home_key*>

Command line prompts

You are prompted for the following parameters:

- **orasys_user**—Name of the Oracle sys user.
- **orasys_user_pass**—Oracle sys user password.

For legacy purposes, you can also pass the parameters by using the **/accountparams:***"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.

Example

mtsora102 dev1 KEY_OraClient11g_CLIENT1 /accountparams:"E:\scripts\mtsora.txt"

Notes

When setting up Oracle XA transaction support manually, run both the mtsora102 and the oramtsadmin.sql script. For more information, see *oramtsadmin.sql* (on page 98).

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 command.

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 | RULESCANPROCESS | RULESCANVIEW | SETSERVER | SETUP | SETLANGUAGE | START | STOP | UNINSTALL | UPDATEWORKFLOW| VIEW]

Option	Purpose and Syntax
CHECKREG [/Del] [/DelAll]	Displays the current InForm Server COM and MTS components in the NT registry. **WARNING**: Be careful to remove the server(s) or uninstall the service before using either of the delete options: • [/Del]—Removes obsolete settings. • [/DelAll]—Removes the settings of all servers.

Option	Purpose and Syntax
CONFIG Service [/AdminDB *DBServer*] | [/AdminDSN *DsnName*] | [/*AdminDN*] | [/EmailSender *valid_email_address*] | [/PfUser] | [/SysDBA]	Configures an existing service. • [/AdminDB *DBServer* [SQL]]—Sets the ODBC DSN for the InformAdmin database. Make sure that *DBServer*, *UID*, and *PID* are the same ones that were used to create the InformAdmin database. Use alphabetic or alphanumeric characters for the UID and PID, and begin them with a letter; do not use all numeric characters. • [/AdminDSN *DsnName*]—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 UID and PID, and begin them with a letter; do not use all numeric characters. • [/EmailSender *valid_email_address*]—Creates the PFMngrExecutionPlan registry key and populates the EmailSender subkey with an email address to use during autodeployment notifications. • [/PfUser]—Creates the PfUser_*computername* account during the InForm 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. 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. Use alphabetic or alphanumeric characters for the UID and PID, and begin them with a letter; do not use all numeric characters.
CONFIG Server *ServerName* [Automatic|Manual]	Configures the startup mode for an existing server as either Automatic or Manual.

Option	Purpose and Syntax
CONFIG Trial *TrialName* [Automatic | Manual] | [/TriDSN *DSN* | [/RndDSN *DSN*] | [/RndDSN *DSN*] | [/Rnd [*MDBFilePath*]] | [/Rnd [*MDBFilePath*]] | [/Host *ServerName*] | [/TrialType [UAT | LIVE | TRN | DEV | QA]] | [/TrialApproval [TRUE | FALSE]] | [/TrialMaintenance [ON | OFF]] | [/DeployBackupFolder <"path_to_a_database_server_folder" >]	Configures an existing study. • [Automatic | Manual]—Configures the study startup mode. • [/TriDSN *DSN*]—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 *DSN*]—Configures the study randomization source dataset name. Use when setting up a Microsoft randomization source database. • [/RndDSN *DSN*]—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 [*MDBFilePath*]]—Creates a study randomization source dataset name to use the given Microsoft Access database file. • [/Rnd [*MDBFilePath*]]—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 *ServerName*]—Moves the study from current host server to another server in the InForm Service. • [/TrialType [UAT | LIVE | TRN | DEV | QA]]—Specify the type of study. Live studies are for production environments, UAT studies are for user acceptance testing, Training, Dev, and QA are for internal use. • [/TrialApproval [TRUE | FALSE]]—Specify whether a deployment package needs approval before it can be deployed to the InForm application. By default, Live and UAT studies are set to TRUE. Training, Dev, and QA studies are set to false. • [/TrialMaintenance [ON | OFF]]—Specify that a study is in Maintenance mode and is unavailable to users. This is set during study deployment. • [/DeployBackupFolder <"path_to_a_database_server_folder">]—Specify the path to an existing folder on the database server. This folder is the location used to store copies of the study database during deployment package processing.

Option	Purpose and Syntax
CONFIG CDD *TrialName* [Enable | Disable] | [*DSN* [Active | Inactive]] | [*DSN StudyLocale*]	Configures an existing CDD: • [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 StudyLocale*]—Specifies the study locale used for the unit symbol translation that is stored in the CDD column for the unit symbol. • *path_to_dsn_password_file*—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.
CONFIG WEBSERVICE *TrialName* [AuthService | DeploymentService | ODMSubmitService] [Add [HTTP:*port* | HTTPS:*port* cert:*thumbprint*] | Remove]	Associates a web service with a study and specifies the port number each service should use. • [AuthService | DeploymentService | ODMSubmitService]—The type of service • [Add [HTTP:*port* | HTTPS:*port* cert:*thumbprint*] | Remove]—Creates or removes an association between a study and a web service
CREATEREPORTINGMODEL *TrialName*	Creates the Reporting model from scratch.
HELP	Lists all the options of the pfdamin command.
KILLSERVER *ServerName*	Stops server MTS packages without stopping studies on the server.
PING *MachineName* 1 | 2 | 3:*ServerName* | *4*:*ServerName* | 5:*ServerName* [Port#]	Pings the InForm Service or a particular server. The ping levels are: • 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.

Option	Purpose and Syntax
PUBLISHREVIEWSCHEMA *TrialName* [/FORCE]	Applies all study version changes to the review schema clinical tables. 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. **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. This operation is synchronous. The study is unavailable during the operation.
RECREATEREVIEWSCHEMA [*TrialName StudyLocale_ISO_name*]	Recreates the review schema database tables from the InForm schema. Depending on the size of the study, this can take a long time to run. The Review schema study locale is chosen automatically when a study is first installed, but can be changed using this command.
REMOVE [Server *ServerName*] | [Trial *TrialName* [/DSN]] | [CDD *TrialName* [/All | *DSN*]	Removes an existing server, study, or CDD. • [Server *ServerName*]—Removes an InForm server from the InForm Service. Studies should be either reconfigured to other servers or removed before this command is run. • [Trial *TrialName* [/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 *TrialName* [/All | *DSN*]—Removes either all CDD DSNs in the specified study or the given CDD by DSN. **Note:** Before using the PFADMIN REMOVE command, verify that IIS is running.
RULESCANPROCESS *StudyName*	Scans existing rules and execution plans, and outputs a list of rules that violate the allowed rule objects list and marks the rules as valid or invalid.
RULESCANVIEW *StudyName*	Scans existing rules and execution plans, and outputs a list of rules that violate the allowed rule objects list. This is an informational scan only; it does not mark rules as valid or invalid.

Option	Purpose and Syntax
SETSERVER [Site *TrialName MachineName*] | [MedMLInstaller *TrialName MachineName*] | [Reporting *TrialName ReportingUrl*] | [ReportingAN *TrialName AuthenticationNamespace*] | [ReportingUR *TrialName UserRoot*] | [ReportingInt *TrialName ReportingInternalURI]* | [pfreportinguserpw *TrialName*] | [systempw *TrialName*]	Changes the MedML and Site servers and sets the Reporting configuration settings. • [Site *TrialName MachineName*]—Not supported. • [MedMLInstaller *TrialName MachineName*]—Not supported. • [Reporting *TrialName ReportingUrl*]—Set Cognos URL for study. • [ReportingAN *TrialName AuthenticationNamespace*]—Set Cognos AuthenticationNamespace for study. • [ReportingUR *TrialName UserRoot*]—Set Cognos UserRoot for study. • [ReportingInt TrialName ReportingInternalURI]—Set the internal URI that the InForm server uses to communicate with the Cognos server. • [pfreportinguserpw *TrialName*]—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. pfreportinguser is the preferred studyuser to run pfrinit to configure Cognos for each study. • [systempw *TrialName*]—Set the password for the system user for the specified study. The command also activates the system user. **Note:** The SETSERVER command requires that you set the Default Authentication Level property of the InForm server to Connect: To set this property: 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 *ServerName* [Automatic]	Creates a new InForm server in the InForm Service. • [Automatic]—The server is automatically started with the InForm Service. Manual startup is the default.

Option	Purpose and Syntax
SETUP Trial *TrialName ServerName* [/DB *OracleConnStr]* | [/DSN *TriDSN* [Automatic]	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. • [/DB *OracleConnStr UID PID*]—Creates an ODBC DSN *TrialName* with the given *ServerName*, *UID*, and *PID*. Use alphabetic or alphanumeric characters for the UID and PID, and begin them with a letter; do not use all numeric characters. • [/DSN *TriDSN UID PID* [Automatic]]—Configures the created study *TrialName* to use the given study dataset name *TriDSN*, *UID*, and *PID*. The study must be present in the ODBC DSN. Use alphabetic or alphanumeric characters for the UID and PID, and begin them with a letter; do not use all numeric characters. **Note:** Before using the /DSN command, verify that IIS is running.
SETUP CDD *RefName TrialName* /DB *OracleConnStr DSN* [/TBSP *OraTBSP*] [Active] [NoSchema]	Sets up a new CDD DSN associated with the given CDD refname. Use alphabetic or alphanumeric characters for the UID and PID, and begin them with a letter; do not use all numeric characters. • [/TBSP *OraTBSP*]—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 RefName that defines the schema. **Note:** To execute this command successfully, the study must be started.

Option	Purpose and Syntax
SETUP CDD *RefName TrialName* /DSN *DSN* [/TBSP *OraTBSP*] [Active] [NoSchema]	Sets up an existing DSN associated with the given CDD RefName. Use alphabetic or alphanumeric characters for the UID and PID, and begin them with a letter; do not use all numeric characters.[/TBSP *OraTBSP*]—Defines the Oracle tablespace for the CDD schema. • [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 RefName that defines the schema. **Note:** To execute this command successfully, the study must be started.
SETLANGUAGE *[IsoLanguageName]* | en-US | ja-JP |	Sets the InForm product locale language. en-US and ja-JP are currently supported.
START [Server *ServerName*] | [Trial *TrialName*]	Starts an existing InForm server or study. • [Server *ServerName*]—Starts an existing InForm server by server name. • [Trial *TrialName*]—Starts an existing study by study name.
START [Trial *TrialName* [/Design]]	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.
STOP [Server *ServerName* [/Trials]] | [Trial *TrialName* [/Anyway]]	Stops an existing InForm server or study. • [Server *ServerName* [/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 Trials keyword stops all running studies, and then stops the server. • [Trial *TrialName* [/Anyway]]—Stops the named study. The Anyway keyword stops a study regardless of any connections or HTTP requests.
UNINSTALL	Removes all InForm servers and studies, and then removes the InForm service settings PfUser_*computername* and the MTS library package. **Note:** The InForm service must be running for the command to work.

Option	Purpose and Syntax
UPDATEWORKFLOW *StudyName*	Triggers the update workflow process for the specified study.
VIEW [Languages] | [Service] | [Server *ServerName*] | [Trial *TrialName*] | [CDD *TrialName*] | [Reporting *TrialName*]	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. • [Languages]—Lists installed languages without starting the InForm Service. • [Service] ▪ Lists all the servers and studies in the InForm service. ▪ Lists installed product languages as well as the actual installed product language. • [Server *ServerName*]—Lists each server by server name and studies hosted on that server. • [Trial *TrialName*]—Lists a study by its name. • [CDD *TrialName*]—Lists the RefNames for each CDD DSN configured for the specified study. • [Reporting *TrialName*]—Lists the current status of Reporting. ▪ 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).

Command line prompts

Depending on the options you specify, you are prompted for the following parameters:

For **pfadmin setup** or **pfadmin config** commands:

- **uid**—InForm study database user.
- **pid**—InForm study database user password.

For **pfadmin setserver** commands:

- **pid**—InForm study database user password.

Examples

Check the status of InForm Reporting:

```
pfadmin view reporting pfst61
```

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 sample study:

```
pfadmin start study sample
```

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 pfst61
```

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 does not need to specify all of the parameters; only the changed parameters need to be specified.

Location

<*Installation_Directory*>\InForm\bin folder.

Usage

```
pfcognosconfig ["path_to_password_file"]
```

Option	Parameter
path_to_password_file	When specified, includes the path to a text file that contains the user name and passwords required to run the command. If the parameter file 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.

Command line prompts

You are prompted for the following parameters:

- **trialname**—Name of the InForm study.
- **log_file**—Name of output log.
- **namespace**—Custom Authentication Provider (CAP) namespace.
- **gateway_uri**—External public URI that communicates with the Cognos 10 BI Gateway Services from an end user's browser.
- **dispatcher_uri**—Internal URI that the InForm server uses to communicate with the Cognos 10 BI server.
- **root_folder**—The top-level reporting folder for the company.
- **reporting_samedb**—True if the study and the Reporting database are on the same server.
- **reporting_diffdb_server**—Reporting database connection string (TNS Name).
- **reporting_diffdb_pass**—Reporting Trial password (reporting database study username must be the same as the InForm database study username, so the username need not be specified).
- **trial_web_service**—InForm authentication web service URL.
- **register_db_server**—Study database user registered with Cognos.
- **register_db_user**—Password for the database user registered with Cognos.
- **remove**—When set to **true**, reporting is turned off for the specified study and clears all reporting settings for the study.

Parameter file contents

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

Option	Description
trialname=<*studyname*>	Name of the InForm study. **Note:** Use the same case as when the study was created by the Central Designer deployment package.
log_file=<*outputlog*>	Name of output log. **Example:** nocreatorgcap.log. (Optional).
namespace=<*cap_namespace*>	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. Users can create additional namespaces manually in the Cognos Configuration utility. In this case, the name of the newly created namespace should be used in this field.

Option	Description
gateway_uri=<*gateway_uri*>	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. **Example:** http:www.example.com/cognos10
dispatcher_uri=<*dispatcher_uri*>	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. **Example:** http://www.example.com:9300/p2pd/servlet/dispatch.
root_folder=/<*content*>/<*folder*>[@name='<*studyname*>']	The top-level reporting folder for the company. Default: /content/folder[@name='<*studyname*>']
reporting_samedb=<true | false>	True if the study and the Reporting database are on the same server.
reporting_diffdb_server=<*servername*>	Reporting database connection string (TNS Name). Use if Reporting and the InForm study are in different databases.
reporting_diffdb_pass=<*rptpid*>	Reporting study 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.
trial_web_service=<*URL*>	InForm authentication web service URL. This is a required parameter.
register_db_server=<*ServerName*>	Name of the server in which the study is registered with Cognos.
register_db_user=<*UserName*>	Study database user registered with Cognos.
register_db_pass<*UserPassword*>	Password for the database user registered with Cognos.
remove=<*true*>	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: • study_name • register_db_server • register_db_user • register_db_pass

Example

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

```
pfcognosconfig "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 package present in the InForm folder and renames it as a study-specific 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

Command line prompts

You are prompted for the following parameters:

- **sysadmin_namespace**—Oracle Directory Server admin namespace.
- **sysadmin_uid**—User name for the Oracle Directory Server admin namespace.
- **sysadmin_pass**—Password you chose when creating the crnsysadmin user.
- **publisher_namespace**—Custom Authentication Provider (CAP) namespace.
- **publisher_uid**—InForm study user who is a member of the following Reporting groups:
  - Publishers.
  - Either Sponsor Users or Site Users.
- **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.
- **trial_name**—Name of the InForm study.

- **in_place_upgrade**—Y/N. Indicate if the PFRInit command is being run as part of an in-place upgrade (required for an in-place upgrade).

For legacy purposes, you can also pass the parameters by using the **/accountparams:***"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.

Note

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 99).

Example

pfrinit "E:\scripts\init.txt"

PostDeployWorkaround.cmd

Purpose

Applies a workaround after a study deployment. If the operation is successful, the command returns 0. Otherwise, it returns 1 to signal the error.

Location

Deployment root folder, as defined in the DeployRoot registry value under HKEY_LOCAL_MACHINE\SOFTWARE\OracleHS\InForm. By default, it is the InFormDeploy folder on the drive where the InForm application is installed. For example: E:\InFormDeploy.

Usage

PostDeployWorkaround <*Study_Name*> <*TNS_Service_Name*> <*Deployment_ID*>

Option	Parameter
Study_Name	Name of the study requesting deployment.
TNS_Service_Name	Local Net Service Name for the remote database service.
Deployment_ID	Unique identifier for the deployment request.

Note: **Workarounds should be used as a last resort during automated deployments, in order to keep human intervention to a minimum.**

PreDeployWorkaround.cmd

Purpose

Applies a workaround before a study deployment. If the operation is successful, the command returns 0. Otherwise, it returns 1 to signal the error.

Location

Deployment root folder, as defined in the DeployRoot registry value under HKEY_LOCAL_MACHINE\SOFTWARE\OracleHS\InForm. By default, it is the InFormDeploy folder on the drive where the InForm application is installed. For example: E:\InFormDeploy.

Usage

PreDeployWorkaround <*Study_Name*> <*TNS_Service_Name*> <*Deployment_ID*>

Option	Parameter
Study_Name	Name of the study requesting deployment.
TNS_Service_Name	Local Net Service Name for the remote database service.
Deployment_ID	Unique identifier for the deployment request.

Note: **Workarounds should be used as a last resort during automated deployments, in order to keep human intervention to a minimum.**

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

Command line prompts

You are prompted for the following parameters:

- **streams_admin_user_rep_passwd**—Password for the reporting streams admin user.
- **streams_admin_user_trial_pwd**—Password for the study streams admin user.

For legacy purposes, you can also pass the parameters by using the **/accountparams:***"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.

Example

remove_streams_setup_info_diffdb

RequestTime.cmd

Purpose

Indicates if a future study deployment time conflicts with any conditions on the production environment. If the system is not available or if resource intensive tasks are scheduled on the production environment during the requested timeframe, the requested time is rejected (the command returns 1). Otherwise, it is accepted (the command returns 0).

Location

Deployment root folder, as defined in the DeployRoot registry value under HKEY_LOCAL_MACHINE\SOFTWARE\OracleHS\InForm. By default, it is the InFormDeploy folder on the drive where the InForm application is installed. For example: E:\InFormDeploy.

Usage

RequestTime <*Study_Name*> <*Requested_Time*> <*Study_Type*>

Option	Parameter
Study_Name	Name of the study to be deployed.
Requested_Time	Local time on the InForm server when the deployment is requested, in the format MM/DD/YYYY HH:MM. For example: 05/18/2016 15:30.
Study_Type	Type of the study to be deployed. Options are: • LIVE • UAT • TRAINING • QA • DEV

Note: The RequestTime command helps planning deployments that do not conflict with scheduled maintenance windows or expected peak system usage periods. However, it cannot prevent conflicts caused by conditions that were unexpected or unscheduled at the time the request was made, such as emergency maintenance operations.

APPENDIX B

Troubleshooting

In this appendix

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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 and mtsora102 commands.
- If the installation window has been closed, run the following commands, located in the InstallSupport folder of the InForm installation image:
  - *mtsora102.exe* (on page 96)
  - *oramtsadmin.sql* (on page 98)

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 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 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** command 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.

About the documentation

Where to find the product documentation

The product documentation is available from the following locations:

- **My Oracle Support** (https://support.oracle.com)—*Release Notes* and *Known Issues*.
- **Oracle Technology Network** (http://www.oracle.com/technetwork/documentation/hsgbu-154445.html)—The most current documentation set, excluding the *Release Notes* and *Known Issues*.

If the software is available for download, the complete documentation set is available from the Oracle Software Delivery Cloud (https://edelivery.oracle.com).

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

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.

Access to Oracle Support

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

Documentation

Document	Description	Part number	Last updated
Release Notes	The *Release Notes* document describes enhancements and issues fixed in the current release, and other late-breaking information.	E61316-01	6.1.1
Known Issues	The *Known Issues* document provides detailed information about the known issues in this release, along with workarounds, if available.	E61318-01	6.1.1

Document	Description	Part number	Last updated
Secure Configuration Guide	The *Secure Configuration Guide* 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.	E61320-01	6.1.1
Upgrade and Migration Guide	The *Upgrade and Migration Guide* 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.	E61321-01	6.1.1
Installation Guide	The *Installation Guide* describes how to install the software and configure the environment for the InForm application and Cognos software.	E61322-01	6.1.1
Study and Reporting Setup 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.	E61323-01	6.1.1
User Guide	The *User Guide* provides an overview of the InForm application including details on multilingual studies, how to navigate through the user interface, how to manage a study-specific Home page with the InForm Portal application, and how to accomplish typical tasks you perform while running a clinical study. This document is also available from the user interface.	E61324-01	6.1.1
Reporting and Analysis Guide	The *Reporting and Analysis Guide* 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 InForm Ad Hoc Reporting workspace, and describes the study management and clinical data packages available for creating reports. It also provides detailed descriptions of each standard report that is included with your installation.	E61326-01	6.1.1
Reporting Database Schema Guide	The *Reporting Database Schema Guide* describes the Reporting and Analysis database schema, and provides information on creating Reporting Database Extracts (RDEs).	E61327-01	6.1.1

Document	Description	Part number	Last updated
Utilities Guide	The *Utilities Guide* provides information about and step-by-step instructions for using the following utilities: • PFConsole utility • MedML Installer utility • InForm Data Import utility • InForm Data Export utility • InForm Performance Monitor utility • InForm Report Folder Maintenance utility 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.	E61328-01	6.1.1
MedML Installer utility online Help	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. 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. This document is also available from the user interface.	NA	NA
InForm Data Export utility online Help	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: • Customer-defined database (CDD) • Name value pairs This document is also available from the user interface.	NA	NA

Document	Description	Part number	Last updated
InForm Data Import utility online Help	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. This document is also available from the user interface.	NA	NA
Clinical Data API Guide	The *Clinical Data API Guide* provides information about submitting data to the InForm application in InForm ODM format.	E61329-01	6.1.1
Third Party Licenses and Notices	The *Third Party Licenses and Notices* document includes third party technology that may be included in or distributed with this product.	E61330-01	6.1.1
Secure Development Guide	The *Secure Development Guide* provides an overview of common security risks for developers using Application Programming Interfaces (APIs) with the Oracle® Health Sciences InForm application, and information on how to address those risks.	E72493-01	6.1.1