

**Oracle® Health Sciences WebSDM
and Empirica Study**

Installation Instructions

Release 3.1.2.1 for Windows 2003/2008 Server

E40537-02

November 2014

Oracle Health Sciences WebSDM and Empirica Study Installation Instructions Release 3.1.2.1 for Windows
2003/2008 Server

E40537-02

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Preface

This guide describes the tasks a system administrator performs to install the WebSDM and Empirica Study application, version 3.1.2.1.

Audience

This guide is for system administrators and database administrators who are familiar with Oracle relational databases and who host the WebSDM and Empirica Study application in their own environments, rather than contracting for this service from Oracle.

This guide assumes familiarity with administrative tasks, including setting up and configuring the Oracle database, administering IIS, configuring Windows Services, and setting Windows file permissions. Most of these steps are performed on the Windows 2003 or Windows 2008 server that hosts the WebSDM and Empirica Study software.

Note: In the remainder of this guide, the product name WebSDM references both the WebSDM standalone product and WebSDM with the optional Empirica Study features that require additional licensing.

Using this Guide

Oracle recommends that you familiarize yourself with these procedures by reading all instructions before you begin the installation.

While the instructions provided in this guide are detailed, they are generic. This guide cannot, and is not intended to, cover all possible variations that might occur. An experienced administrator should read all instructions and be prepared to work through site-specific differences from the provided instructions.

Conventions

The following text conventions are used in this document:

Convention	Indicates
Courier font	A file or directory name or Command Prompt window.
boldface font	User interface controls, including menu options, buttons, and links.
<text_in_angle_brackets>	To substitute the values in the Prerequisites tables for the <text_in_angle_brackets>.
Optional	A procedure or step that is not required for all installations.

Convention	Indicates
Note:	Information of particular significance.
<u>32-bit server</u>	Server-specific alternative instructions.
<u>64-bit server</u>	
(Windows 2008 server)	Instructions that are different for Windows 2008 and 2003. Complete only the instructions for the operating system that you are running.
(Windows 2003 server)	

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Related Documents

For more information, see the following documents in the Oracle Health Sciences WebSDM and Empirica Study 3.1.2.1 documentation set:

- *Oracle® Health Sciences WebSDM and Empirica Study Known Issues*
- *Oracle® Health Sciences WebSDM and Empirica Study Release Notes*
- *Oracle® Health Sciences WebSDM and Empirica Study Upgrade Instructions*
- *Oracle® Health Sciences WebSDM and Empirica Study Third Party Licenses and Notices*

Installing WebSDM 3.1.2.1

To install WebSDM, you need to:

1. Set up the database.
2. Install the WebSDM software.
3. Install the supporting software.
4. Configure the properties files.
5. Start the application service.
6. Perform post-installation procedures.
7. Optional: Customize WebSDM.
8. Verify the WebSDM installation.

1.1 Prerequisites

1.1.1 Required Servers, Software, and Media

Before you begin the installation, ensure that you have the following servers, software, and installation media:

- A Windows 2003 or 2008 server to host the WebSDM application. Note whether the server is 32-bit or 64-bit.
- Oracle 10g (10.2.0.3 or higher) or Oracle 11g (11.2.0.2 or higher) installed on a server. The Oracle installation can be on the same or a different Windows server than the WebSDM software. If on different Windows servers:
 - The Oracle installation must be Oracle Database Enterprise Edition if you plan to encrypt the communications channel between the servers. The Windows server must have been restarted at least once since the Oracle installation.
 - Oracle Net Service must be installed on the Windows server where the WebSDM software is installed.
 - Both servers must be set to the same time zone.
- An Oracle database instance (Oracle SID or Service) to support WebSDM.
- IIS installed on the Windows server.
- SMTP mailer enabled on the Windows server.

- An installation of R for Windows (32-bit, version 2.13.2 only). See [Appendix A, "Notes on the Installation of R"](#) for installation notes.
- A file compression and extraction utility, such as WinZip.
- Internet Explorer version 7 or 8.
- MedDRA ZIP files obtained under a subscription from MSSO.
- The WebSDM 3.1.2.1 installation media. This is the product ZIP file from My Oracle Support (<https://support.oracle.com>).
- If you are enabling SSO, a server with the Oracle Access Manager (OAM) installed. See [Appendix C, "Configure WebSDM for SSO"](#).
- If you expect to load study data from an Oracle Life Sciences Data Hub (LSH) database, identifying information about that server. See [Appendix D, "Configure WebSDM to Access an Oracle Life Sciences Data Hub Instance"](#).
- If you expect to load study data from an Oracle Health Sciences InForm database, identifying information about that server. See [Appendix E, "Configure WebSDM to Access an Oracle Health Sciences InForm Instance"](#).

You must also have access to the Java jar and jarsigner utilities and to your company's jar signing process.

1.1.2 Required Information about Existing Accounts and Services

You need the following names and passwords for accounts and services, which must already exist when you start the installation. In these procedures, the values are shown in `<text_in_angle_brackets>`.

- Windows administrator account

`<win_admin_acct>` and `<win_admin_pass>`

Windows account and password on the Windows 2003 or 2008 server where you will install WebSDM. The account must be assigned the Administrator role.

- Optional: Administrator account and password for the Oracle server

`<winDB_admin_acct>` and `<winDB_admin_pass>`

If the Oracle database is not installed on the same Windows server as the WebSDM software, you also need a Windows account and password on the server where the Oracle database is installed. The account must have sufficient permissions to edit the Oracle `sqlnet.ora` file.

- Optional: Oracle root installation directory

`<oracle_root>`

If WebSDM and the Oracle database are to be installed on different Windows servers, and you plan to encrypt the communications channel between them, you must know the root directory where Oracle is installed.

- Oracle DBA account

`<ora_dba_acct>` and `<ora_dba_pass>`

This is the Oracle account and password for the Oracle instance that supports WebSDM. The account must be assigned the DBA role.

- Oracle service name or SID

`<ora_service_name>` or `<ORA_SID>`

Oracle SID or Oracle service name for the Oracle instance that supports WebSDM.

- Oracle host name

`<ora_host>`

The server host on which the Oracle SID or Oracle Service is installed. If the server host is the same one on which you are installing the WebSDM software, use the host name **localhost**. If the Oracle database is hosted on a different server, use that server name.

- Oracle port

`<ora_port>`

The port on which the Oracle SID or Oracle Service name is executing. The default is **1521**.

- First or subsequent install

`<is_first_install>`

To determine the procedures to follow for this installation, ascertain whether other related Oracle products are already installed on the server.

Use Windows Explorer to inspect all root directories on the file system for a `<root>\Lincoln` subdirectory. If this subdirectory does not exist, the value of `<is_first_install>` is true. The instructions indicate those steps that need to be completed only for the first install.

If a `<root>\Lincoln` subdirectory already exists on the application server, then `<is_first_install>` is false. Contact Oracle before proceeding with this installation.

- Installation root

`<root>`

File system root where the `\Lincoln` subdirectory was found. If it was not found, select the drive where you want to install WebSDM. The recommended location is **c:**.

- Submissions folder

`<submissions_folder>`

File system drive and directory to serve as the root where clinical data submissions (applications and study data) will be stored. The recommended location is **d:\ClinicalData**.

- Optional: OAM Server

`<oam_server>`

If you are enabling SSO and want to set a logout redirect page, you must provide the fully qualified name for the OAM server.

1.1.3 Removing and Setting the Read-only Attribute

If the installation instructions require you to edit a file, check the file properties to see if the read-only attribute has been set. If set, you must remove it before editing. To remove the read-only attribute:

1. Open Windows Explorer and navigate to the file.
2. Right-click the file name and select **Properties**.
3. Clear the **Read-only** option.

4. Click **OK**.

When you are done editing the file, reset the read-only attribute:

1. Open Windows Explorer and navigate to the file.
2. Right-click the file name and select **Properties**.
3. Select the **Read-only** option.
4. Click **OK**.

1.1.4 Saving Files

If the installation instructions require you to edit a file, be sure to save the file with the original name. Some editors by default add the TXT extension to the file name.

1.1.5 Required Information for New Accounts and Services

During installation, you provide names and passwords for accounts and services that are created. Ensure that all passwords comply with your company security policy. Database passwords must also comply with password requirements for the Oracle version that you are using.

- WebSDM instance name

<instance>

Name you provide for the WebSDM instance. The installation uses this name for several components, including a Windows service, a virtual directory, and a folder. The default name is **websdm**. Using the default name reduces the number of files you must edit during the installation. If you are installing more than one WebSDM instance on the Windows server, the <instance> name must be unique for each server.

- Oracle net service name

<ora_net_service>

Name for the Oracle net service for the WebSDM database.

- Oracle tablespace name

<ora_tablespace>

Name for the Oracle tablespace for the WebSDM database. Oracle recommends that you use the same name you used for the WebSDM instance name.

- Oracle master account and password for WebSDM

<websdm_master_acct> and <websdm_master_pass>

Name and password for the Oracle account that the installation creates to store data for the WebSDM instance. Oracle recommends that you use the same name you used for the WebSDM instance name.

- WebSDM application admin account default password

<app_admin_pass_default>

Password for the WebSDM user account with the reserved name 'admin'. Email Oracle at **safetysupport_ww@oracle.com** for the initial default password for the admin account.

- WebSDM application admin account final password

<app_admin_pass>

You must change the password of the WebSDM application admin account the first time you log into WebSDM.

- MedDRA account passwords

<meddraX_ora_pass>

You must provide passwords for the Oracle accounts that are created for each version of MedDRA.

- IIS default application

<is_IIS_default_app>

Determine whether to make WebSDM the default application for your IIS installation. If you do, then <is_IIS_default_app> is true. Otherwise, it is false. The instructions include the steps to make WebSDM the default application for your IIS installation. If WebSDM is not the default applications for IIS, you can skip these steps.

1.2 Set Up the Database

1.2.1 Setting Up the Oracle Net Service

Create an Oracle net service that points to the Oracle service or SID that WebSDM will use to store data.

Note: If <is_first_install> is false, complete this section only if the WebSDM instance you are installing uses a different Oracle Service or SID.

1. Start **Oracle > Configuration and Migration Tools > Net Manager**.
2. Click **Local** to see the options, and select **Service Naming**.
3. Create a new service name.
 - a. From the **Edit** menu, select **Create**.
 - or
 - b. Click the **Create** (green plus sign) icon.
4. For the **Net Service Name**, type the value of <ora_net_service>.
5. Click **Next**.
6. For **Protocol**, select **TCP/IP** (Internet Protocol).
7. Click **Next**.
8. For **Hostname**, if WebSDM and the Oracle database are installed on the same Windows server, enter **localhost**. If the Oracle database is installed on a different Windows server, enter the <host_name>.
9. For **Port**, accept the default **1521**, unless your DBA has supplied a different value for <ora_port>.
10. Click **Next**.

11. If you are using an **Oracle 10g** database, select the **Oracle 8 or Previous** radio button.
 - a. For **SID**, type the value of <ORA_SID>.
 - b. Click **Next**.or
if you are using an **Oracle 11g** database, for **Service Name**, type the value of <ora_service_name>.
 - c. For **Connection Type**, select **Dedicated Server**.
 - d. Click **Next**.
12. Optionally, to verify the settings, click **Test**.
 - a. If the test completes successfully, click **Close**.
 - b. If the test fails, edit the settings and try the test again.
13. Click **Finish**.

The settings for the Oracle net service appear.
14. From the **File** menu, select **Save Network Configuration**.
15. Exit Oracle Net Manager.

1.2.2 Encrypting the Database Connection

If WebSDM and the Oracle installations are on different servers, complete the following instructions to encrypt the communications channel between the servers.

If the WebSDM and Oracle installations are on the same Windows server, continue to [Section 1.2.3, "Setting Up the Oracle Master Account and Tablespaces for WebSDM"](#).

1. Log onto the <winDB_admin_acct> account on the machine where the Oracle database is installed.
2. Navigate to the <ora_root>\network\admin folder.
3. Use a text editor, such as Notepad, to open the SQLNET.ORA file and add these lines at the end:

```
SQLNET.ENCRYPTION_SERVER = accepted
SQLNET.CRYPTO_CHECKSUM_SERVER = accepted
SQLNET.ENCRYPTION_TYPES_SERVER = (RC4_256)
SQLNET.CRYPTO_CHECKSUM_TYPES_SERVER = (MD5, SHA1)
```

These settings enable both encrypted and unencrypted connections.

4. In an environment where encryption is required for all connections, change the setting of the first added line as follows:

```
SQLNET.ENCRYPTION_SERVER = required
```
5. Save your changes to the SQLNET.ORA file.
6. Log onto the <win_admin_acct> on the Windows server where you are installing WebSDM.
7. Navigate to the <ora_root>\network\admin folder.
8. Use a text editor, such as Notepad, to open the SQLNET.ORA file and add these lines at the end:

```
# This line is optional
SQLNET.CRYPTO_SEED = 'at least 10 chars'
SQLNET.ENCRYPTION_CLIENT = requested
SQLNET.CRYPTO_CHECKSUM_CLIENT = requested
SQLNET.ENCRYPTION_TYPES_CLIENT = (RC4_256)
SQLNET.CRYPTO_CHECKSUM_TYPES_CLIENT = (MD5, SHA1)
```

These settings ensure that connections from the WebSDM server always request an encrypted channel, and also work if the database does not support encrypted connections.

9. Save your changes to the `SQLNET.ORA` file.

1.2.3 Setting Up the Oracle Master Account and Tablespaces for WebSDM

Run scripts to create the Oracle master account and tablespaces for WebSDM.

1. Locate the `database-3_1_2_1_xxx.zip` file (where `xxx` represents a specific build number) on the installation media, and extract the contents of this file to a temporary location, such as `c:\install\database`.
2. Use a text editor, such as Notepad, to open the `1_create_tablespace.sql` file and review the `DEFINE` statements.
3. Verify that the `ORADATA` file path points to your preferred location for the tablespace data files.
4. If the value of `<ora_tablespace>` is something other than **websdm**, change the value of `TABSPACE_NAME` to that value.
5. Verify that the referenced `TABSPACE_NAME` and `DATAFILE` do not already exist. You can do so by executing each of these SQL queries in order:

```
select tablespace_name from dba_tablespaces;
select file_name from dba_data_files;
```

6. Review the default sizing parameter values. The default values are suited to an environment where study data is loaded into application-specific tablespaces. If, instead, you are loading all study data into a single tablespace and registering 100+ studies, it might be reasonable to double the size parameters.
7. If changes are needed, edit, save, and close the file.
8. Use a text editor to open the `2_create_oracle_user.sql` file and review the `DEFINE` statements. This script creates the **WebSDM** master account and grants permissions to it.
9. If the value of `<websdm_master_account>` is something other than **websdm**, change the value of `USER_NAME` to that value.
10. If the value of `<ora_tablespace>` is something other than **websdm**, change the value of `TABSPACE` to that value.

Note: For WebSDM to be fully functional, this script must be executed with the SQL statements it currently contains. If certain permissions are not granted to the Oracle master account for WebSDM, the application runs with some functionality disabled. Specifically:

- If the CREATE TABLESPACE permission is not granted, the **Create a new tablespace for each Application** radio button is disabled on the Site Options page. In addition, all application and study level accounts will use a common tablespace
 - If the DROP USER permission is not granted, the Action menus attached to Applications, Studies, and Study Pools on the Setup tab does not contain entries that allow properly authorized users to delete those objects.
 - If the DROP TABLESPACE permission is not granted, but CREATE TABLESPACE and DROP USER are granted, the dedicated tablespace contents are deleted when an application is deleted, but the tablespace itself is not deleted.
-

11. If changes are needed, edit, save, and close the file.
12. Open a command window and change the directory to the temporary directory.
13. From the <ora_dba_acct> account, run the 1_create_tablespace SQL script. For example:
 - a. Type this command on one line:

```
C:> sqlplus <ora_dba_acct>@<ora_net_service>
@c:\install\database\1_create_tablespace
```
 - b. When prompted for the password, enter <ora_dba_pass>.
 - c. Scroll up to review the results of running script 1_create_tablespace. There should be no errors.
14. From the <ora_dba_acct> account, run the 2_create_oracle_user SQL script. For example:
 - a. Type this command on one line:

```
C:> sqlplus <ora_dba_acct>@<ora_net_service>
@c:\install\database\2_create_oracle_user
```
 - b. When prompted for the password, enter <ora_dba_pass>.
 - c. When the script prompts you for the WebSDM master account password, type the value of <websdm_master_pass>.
 - d. When prompted to confirm the password, again type the value of <websdm_master_pass>. If confirmation fails, the script exits and you can run it again.
 - e. Scroll up to review the results of running script 2_create_oracle_user. There should be no errors.
15. From the newly created WebSDM master account, run the 3_create_all SQL script. For example:
 - a. Type this command on one line:

```
C:> sqlplus <websdm_master_acct>@<ora_net_service>
```

```
@c:\install\database\3_create_all
```

- b. When prompted for the password, enter <websdm_master_pass>.
 - c. Review the contents of the C:\install\database\3_create_all.log file created by running this script. There should be no errors.
16. Close the command window.

1.3 Install the WebSDM Software

1.3.1 Installing New Website Files

Complete these steps only if <is_first_install> is true.

1. Use Windows Explorer to view the installation media. Locate the following file:
32-bit server: Lincoln.zip
64-bit server: Lincoln_x64.zip
2. Extract the contents of this file to <root>, making sure the path names stored in the archive are used. For example, in the **WinZip Extract** dialog box, be sure to check the **Use folder names** checkbox.

1.3.2 Configuring Existing Website Files

Complete these steps only if <is_first_install> is false or if the value of <instance> is something other than **websdm**.

1. Use Windows Explorer to view the installation media. Locate the following file:
32-bit server: Lincoln.zip
64-bit server: Lincoln_x64.zip
2. Extract the contents of this file to a temporary folder on the server, such as C:\temp, making sure that the path names stored in the archive are used. For example, in the **WinZip Extract** dialog box, be sure to select the **Use folder names** checkbox.
3. If the value of <instance> is something other than **websdm**, change the name of the directory from:
C:\temp\Lincoln\apps\websdm
to:
C:\temp\Lincoln\apps\<instance>
4. Copy the <instance> folder (and all its files and subdirectories) from:
C:\temp\Lincoln\apps
to:
<root>\Lincoln\apps\
5. Navigate to the <root>\Lincoln\IIS\conf\ folder.
6. Use a text editor to open the uriworkermap.properties file.
7. Scroll to the last line of this file. Change **websdm** to the value of <instance>. For example, if the <instance> is **websdmProd**, change:


```
/*/*.jsp=websdm
```

to:

```
/*/*.jsp=websdmProd
```

8. Add the following lines to this file, substituting the value of <instance> for all six occurrences of **websdm**.

```
/*/websdm /*.jsp=websdm  
/*/websdm /servlet/*=websdm  
/*/websdm /services/*=websdm
```

Note: The file should contain the three lines for each instance of WebSDM that is installed on the machine. If Empirica Signal is also installed, there will be three slightly different lines for each instance of the Empirica Signal application.

9. Save your changes to the uriworkormap.properties file.
10. Edit the <root>\Lincoln\IIS\conf\workers.properties file to add <instance> to the end of the comma-separated list of applications for the **worker.list** property. For example, if the <instance> is **websdmProd**, the edited line is:

```
worker.list=websdm, websdmProd
```

Note: The worker.list element should contain an entry for each instance of an Oracle product (WebSDM or Empirica Signal) that is installed on the machine.

11. Add the following lines to this file, substituting the value of <instance> for all three occurrences of **websdm**:

```
worker.websdm.port=8009  
worker.websdm.host=localhost  
worker.websdm.type=ajp13
```

Note: The file should contain the three lines for each instance of an Oracle product (WebSDM or Empirica Signal) that is installed on the machine.

12. Compare the value specified for the newly added **port** property to the other port numbers already specified in this file. If this value (**8009**) is already assigned to another application, you must supply a different port number for this instance of WebSDM to use. Select a port number that is two greater than the highest port number specified elsewhere in the file and change the value for the **port** property to that value. For example, if the highest port number is **8009**, use the value **8011**.
13. Save your changes to the workers.properties file.
14. Check for the existence of the folder <root>\Lincoln\apache-tomcat-6.0.41 (earlier releases of WebSDM used other versions of tomcat, so this folder might not exist). If this folder does not exist, copy the folder named apache-tomcat-6.0.41 (and all its files and subdirectories) from C:\temp\Lincoln to <root>\Lincoln\.

For example, from:

C:\temp\Lincoln\apache-tomcat-6.0.41

to:

<root>\Lincoln\apache-tomcat-6.0.41

Note: The apache-tomcat-6.0.41 folder required for WebSDM can coexist with other Tomcat versions that have been installed for other products.

15. Check for the existence of the folder <root>\Lincoln\jdk1.6 (earlier releases of WebSDM used jdk 5, so this folder might not exist).

- a. If the <root>\Lincoln\jdk1.6 folder does not exist, copy the folder named jdk1.6 (and all its files and subdirectories) from C:\temp\Lincoln to <root>\Lincoln\.
- b. If the <root>\Lincoln\jdk1.6 folder exists, determine the specific version of the jdk by opening a command window and executing the following command:

```
<root>\Lincoln\jdk1.6\bin\java.exe -version
```

If the response indicates a version earlier than 6.0_81, replace the jdk1.6 folder in <root>\Lincoln with the one in C:\temp\Lincoln.

1.3.3 Configuring the server.xml File

Complete these steps if the value of <instance> is something other than **websdm**, or if you edited the workers.properties file to change the port number to a value other than 8009.

1. Navigate to the <root>\Lincoln\apps\<instance>\conf folder.
2. Use a text editor to open the server.xml file.
3. If the value of <instance> is **websdm**, skip to step 6.
4. Locate the **Host** element and its **appbase** attribute. Change **websdm** to the value of <instance>.

```
<Host name="localhost" appBase="C:/lincoln/apps/websdm/webapps">
```

5. Locate the **Context** element and its **path** attribute. Change **websdm** to the value of <instance>.

```
<Context path="/websdm">
```

6. Locate the **Connector** element and its **port** attribute. If you changed the value of the port element in the workers.properties file, change the value of the Connector port element to the same value. For example, if the value was changed to **8019**:

```
<Connector port="8019">
```

7. Locate the **Server** element and its **port** attribute. Change the value of the port element to one less than the value you specified for the Connector port element. For example, if you changed the Connector port element to **8019**, change the Server port element to **8018**.

```
<Server port="8018">
```

8. Save your changes to the server.xml file.

1.3.4 Setting Up Website Files

1. Locate the websdm-3_1_2_1_xxx.zip file (where xxx represents a specific build number) on the installation media. Extract the contents of this file to the <root>\Lincoln\apps\<instance>\webapps\web_root\ folder (created automatically in the previous task).
2. Locate the Oracle installation folder on the WebSDM server. For example, D:\oracle\product\11.2.0\db_1.

Note: If the database is running on a machine other than the application server, the Oracle installation folder refers to the path where Oracle client components were installed.

From within the \jdbc\lib subfolder, copy the following .jar file to the <root>\Lincoln\apps\<instance>\webapps\web_root\WEB-INF\lib folder, overwriting the existing file, if necessary. If you are using Oracle 10g, locate ojdbc14.jar. If you are using Oracle 11g, locate ojdbc6.jar.

3. Using Windows Explorer, navigate to the <root>\Lincoln\IIS\conf\ folder. Review the file paths in the iis_redirect.reg file using a text editor. Edit the file paths, if necessary, to reflect any changes you made for your installation.
4. Double-click the iis_redirect.reg file. Click **Yes**, and then click **OK**.

Note: This updates the registry. Perform this step even if you did not make any changes to the iis_redirect.reg file.

5. In the same folder, double-click the iis_cipher_configuration.reg file. Click **Yes**, and then click **OK**.

Note: This disables weak IIS ciphers.

1.3.5 Installing an Encryption Key

1. Navigate to the folder <root>\Lincoln\apps\<instance>\webapps\web_root\WEB-INF\classes.
2. Check for existence of the file license.config. If it exists, rename it to another name, such as license.old.
3. Navigate to the folder <root>\Lincoln\apps\<instance>\bin.
4. Use a text editor to open the file generate_keys.bat and review the values of INSTALL_ROOT and APPLICATION_DIR. If changes are needed, edit and save the file.
 - a. If the value of <instance> is other than **websdm**, change the value of the APPLICATION_DIR to the value of <instance>.
 - b. If the value of <root> is other than the **c drive**, change the value of the INSTALL_ROOT to the value of <root>.
5. (Windows 2008 server) Right-click the generate_keys.bat file, and then select **Run as administrator**.

or

(Windows 2003 server) Double-click the generate_keys.bat file.

6. Examine the script output. Verify that the last two lines are:

```
[INFO] Generating <root>\Lincoln\apps\<instance>\webapps\web_
root\WEB-INF\classes\license.config
[INFO] Done
```

7. When prompted, press any key.
8. If the last two lines of script output are not as indicated, correct the error condition and repeat this procedure.

1.3.6 Optional: Making WebSDM the Default Application

If <is_IIS_default_app> is true (WebSDM is to be the default IIS application), perform the following steps:

1. Open the <root>\Lincoln\apps\<instance>\webapps\web_root\index.html file in a text editor, such as Notepad.
2. Insert <instance> into the URL in this line. For example, if the value of <instance> is **websdm**, change:

```
<META HTTP-EQUIV=REFRESH CONTENT="0; URL=./login.jsp">
```

to:

```
<META HTTP-EQUIV=REFRESH CONTENT="0; URL=/websdm/login.jsp">
```

3. Save your changes.
4. Copy the <root>\Lincoln\apps\<instance>\webapps\web_root\index.html file to the C:\inetpub\wwwroot directory.

1.3.7 Configuring IIS

1.3.7.1 Configuring IIS for Windows 2008

This section is for Windows 2008 Server only.

1. Launch **Server Manager** and expand the **Roles** node.
2. Add the **Web Server (IIS)** role if it does not already exist.
3. Add **Services** to the role:
 - a. Right-click **Web Server (IIS)**, and select **Add Role Services**.
 - b. Select the following additional role services under **Application Development**:
 - ISAPI Extensions
 - ISAPI Filters
 - c. Click **Next**.
 - d. Click **Install**.
 - e. Click **Close**.
4. Click **Start > Administrative Tools > Internet Information Services Manager**.
5. Select the first node in the tree control.

6. Under IIS, in the middle pane, double click **Mime Types**. In the list of registered file types, check for the presence of the **.app** file extension.
7. If the **.app** extension is not already listed, click **Add**. For Extension, type **.app**. For MIME type, type **text/plain**. Click **OK**.
8. In the list of registered file types, check for the presence of the **.wsdl** file extension.
9. If the **.wsdl** extension is not already listed, click **Add**. For Extension, type **.wsdl**. For MIME type, type **text/plain**. Click **OK**.
10. If <is_first_install> is false, skip to step 24. If <is_first_install> is true, select your server name in the **Connections** pane.
11. Under IIS, double-click **ISAPI and CGI Restrictions**.
12. On the **Actions** pane, click **Add**.
13. On the **ISAPI or CGI Restrictions** pop-up, complete the following:
ISAPI or CGI Path: <root>\Lincoln\IIS\bin\isapi_redirect.dll
Description: jakarta
14. Select **Allow extension path to execute**, and click **OK**.
15. On the **Connections** pane under **Sites**, under your server name, select **Default Web Site**.
16. In the IIS section of the middle pane, double-click **ISAPI Filters**.
17. On the **Actions** pane, click **Add**.
18. Add a filter with the following characteristics, and click **OK**.
Filter name: jakarta
Executable: <root>\Lincoln\IIS\bin\isapi_redirect.dll
19. Right-click **Default Web Site**, and select **Add Virtual Directory**. Type the following, and then click **OK**.
Alias: jakarta
Physical Path: <root>\Lincoln\IIS\bin
20. From the **Connections** pane, select **jakarta** and, in the IIS section of the middle pane, double-click **Handler Mappings**.
21. In the **Actions** pane, select **Edit Feature Permissions**.
22. Ensure that **Read**, **Script**, and **Execute** are selected. If they are not, select them and click **OK**.
23. Right-click **Default Web Site** and select **Add Virtual Directory**. Type the following, and click **OK**.
Alias: <instance>
Physical Path: <root>\Lincoln\apps\<instance>\webapps\web_root
24. From the **Connections** pane, select <instance> and, in the IIS section of the middle pane, double-click **Handler Mappings**.
 - a. In the **Actions** pane, select **Edit Feature Permissions**.
 - b. Ensure that **Read** and **Script** are selected. If not, select them and click **OK**.
25. From the **Connections** pane, select <instance> and then, in the IIS section of the middle pane, double-click **Default Document**.

- a. From the list of documents, select **index.html** document and use the **Move Up** function until **index.html** is at the top of the list.
 - b. If prompted to confirm the changed list order, click **Yes**.
 - c. If document **index.html** is not listed, create it using the **Add** button. Move this document to the top of the list.
 - d. In the **Actions** pane, verify that **Disable** appears as an action. If **Enable** appears instead, click it and verify that **Disable** appears as an action.
26. On the **Connections** pane in the **Sites** folder under your server name, select **Default Web Site**.
- a. In the IIS section of the middle pane, double-click **Error Pages**.
 - b. On the **Actions** pane, click **Edit Feature Settings**.
 - c. On the **Edit Error Pages Settings** dialog, select **Detailed errors**.
 - d. Click **OK**.
27. Select **Start > Control Panel > System and Security > Administrative Tools / Services**.
28. Right-click the **World Wide Web Publishing Service**, and click **Restart**.
Alternatively, run the following commands at a DOS prompt:
- ```
C:\ net stop w3svc
C:\ net start w3svc
```

### 1.3.7.2 Configuring IIS for Windows 2003

This section is for Windows 2003 Server only.

1. Select **Start > Settings > Control Panel > Administrative Tools > Internet Services Manager**.
2. If `<is_first_install>` is false, (`<root>\Lincoln` already exists), expand the tree and skip to step 12 of this procedure.
3. Right-click the first node in the tree control. Select **Properties**. In the MIME types section, click **MIME Types**.
  - a. In the list of registered file types, check for the **.app** file extension. If the **.app** extension is not already listed, click **New**, type **.app** for Extension, and **text/plain** for MIME type.
  - b. In the list of registered file types, check for the **.wsdl** file extension. If the **.wsdl** extension is not already listed, click **New**, type **.wsdl** for Extension, and **text/plain** for MIME type.
4. To save your changes, click **OK**.
5. Expand the tree. Right-click **Default Web Site**, and select **Properties**.
6. On the **ISAPI Filters** tab, click **Add**.
7. Add a filter with the following characteristics:
 

**Filter Name:** jakarta

**Executable:** `<root>\Lincoln\IIS\bin\isapi_redirect.dll`
8. If `<is_IIS_default_app>` is true (WebSDM is the IIS default application), complete the following. Otherwise, continue with step 9.

- a. Select the **Documents** tab.
  - b. Select the **Enable Default Document** (or **Enable Default Content Page**) checkbox, and set **index.html** as the top-most document.
  - c. When you exit the **Properties** dialog for Default Web Site, if you do not want to keep the default document settings for other virtual directories (for example, printers), click **OK**.
9. Right-click **Default Web Site** and select **New > Virtual Directory**. Set up a virtual directory for jakarta, as follows:
 

**Alias:** jakarta

**Directory:** <root>\Lincoln\IIS\bin

**Access Permissions:** Select the **Read** and **Execute** checkboxes only.
10. Add a web service extension:
  - a. Select the **Web Services Extensions** node.
  - b. Click the **Add a new Web service extension** link.
  - c. Set **Extension name** to **jakarta**.
  - d. Add the <root>\Lincoln\IIS\bin\isapi\_redirect.dll file to the required files list.
  - e. Select the **Set extension status to Allowed** checkbox.
  - f. Click **OK**.
11. Right-click **Default Web Site** and select **New/Virtual Directory**. Use the wizard to set up a virtual directory for WebSDM, as follows:
 

**Alias:** <instance>

**Directory:** <root>\Lincoln\apps\<instance>\webapps\web\_root

**Access Permissions:** Select the **Read** checkbox only.
12. Make **index.html** the default document for the <instance> virtual directory.
  - a. Right-click the <instance> virtual directory and select **Properties**.
  - b. Select the **Documents** tab, select the **Enable default content page** checkbox, and set **index.html** as the top-most default document. (If document **index.html** is not listed, create it using the **Add** button, and move the document to the top of the list.)
  - c. Click **OK**.
13. Select **Start > Control Panel > Administrative Tools > System and Security > Services**. Right-click the **World Wide Web Publishing Service**, and then click **Restart**.
 

Alternatively, run the following commands at the DOS prompt:

```
C:\ net stop w3svc
C:\ net start w3svc
```

### 1.3.8 Optional: Setting the System Timeout Interval

By default, WebSDM user sessions automatically time out after 30 minutes of inactivity. You can change this timeout interval to another value.

1. Use a text editor, such as Notepad, to open:  
`<root>\Lincoln\apps\<instance>\webapps\web_root\WEB-INF\web.xml.`
2. Locate the `<session-timeout>` element.
3. Set the session timeout to another value (in minutes). For example:  
`<session-timeout>15</session-timeout>`
4. Save your changes to the `web.xml` file.

---

**Note:** If you are using Single Signon (SSO), the WebSDM timeout must be set to be longer than the SSO timeout.

---

### 1.3.9 Installing the websdm Service

For Windows 2003 SP2 only, update the `icacls.exe` utility by following the instructions located at <http://support.microsoft.com/kb/943043>.

1. If using a WebSDM instance name other than **websdm**, edit the file:  
`<root>\Lincoln\apps\<instance>\bin\install_service.bat`
  - a. Change the value of `SERVICE_NAME` from **websdm** to the value of `<instance>`.
  - b. Change the value of the `APPLICATION_DIR` from **websdm** to the value of `<instance>`.
2. If using a WebSDM instance name other than **websdm**, edit the file:  
`<root>\Lincoln\apps\<instance>\bin\uninstall_service.bat`  
 Change the value of `SERVICE_NAME` from **websdm** to the value of `<instance>`.
3. *(Windows 2008 server)* Right-click the  
`<root>\Lincoln\apps\<instance>\bin\install_service.bat` file, and then select **Run as administrator**.  
*(Windows 2003 server)* Double-click the  
`<root>\Lincoln\apps\<instance>\bin\install_service.bat` file.
4. After `install_service.bat` has completed, inspect the transcript. There should be no errors. When you have finished, press any key.
5. *(Windows 2008 server)* Open the **Start menu**, select **Administrative Tools**, then **Server Manager**. Expand **Configuration > Local Users and Groups > Users**.  
 or  
*(Windows 2003 server)* Right-click the server's desktop **My Computer** icon and select **Manage**. Expand **System Tools > Local Users and Groups > Users**.
6. Right-click `<instance>_app` and select **Set Password**.
7. In the **Set Password for <instance>\_app** dialog box, click **Proceed**.
8. Change the password to satisfy site password policy restrictions, and then click **OK**.
9. *(Windows 2008 server)* Click **Services**.  
 or  
*(Windows 2003 server)* Expand the **Services and Applications** directory, and then click **Services**.



10. Right-click the service named <instance> and select **Properties**.
11. On the **Log On** tab, select the **This account** radio button, and then clear the password fields and enter the password that you just changed.
12. On the **Recovery** tab, for both **First Failure** and **Second Failure**, select **Restart the Service**.
13. (*Windows 2008 server*) On the **General** tab, set **Startup type** to **Automatic (Delayed Start)**.

---

**Note:** This allows time for the database service to start before the WebSDM application service.

---

14. Click **OK**.

## 1.4 Install Supporting Software

### 1.4.1 Installing a Disk Space Monitoring Utility

To support monitoring of disk space allocated to Oracle tablespaces used by WebSDM, you install the `lt_DiskUtil.dll` utility, a standalone windows executable.

This process is required if the Oracle database is running on a Windows server and no related products were previously installed. If the Oracle database is running on a UNIX host, or if any related products are already installed on the server, continue to [Section 1.4.2, "Optional: Installing a SAS File Viewer"](#).

1. Use Windows Explorer to view the installation media and locate the appropriate file:
  - 32-bit server: `lt_DiskUtil.dll`
  - 64-bit server: `lt_DiskUtil_x64.dll`
2. Copy this file to `C:\WINDOWS\system32`.
3. 64-bit server: Rename the file from:

`lt_DiskUtil_x64.dll`

to:

`lt_DiskUtil.dll`

---

**Note:** If WebSDM and Oracle are not installed on the same server, the WebSDM and Oracle servers must map the same drive letter for the Oracle data files for the disk space monitoring utility to function correctly.

---

### 1.4.2 Optional: Installing a SAS File Viewer

The SAS System Viewer or SAS Universal Viewer application is useful for inspecting the content of the SAS transport files that constitutes the data sources for WebSDM studies. This file viewer software is distributed without charge by SAS.

1. Use a Web browser, such as Internet Explorer, to navigate to <http://support.sas.com/downloads/index.htm>.
2. Choose the **SAS System Viewer** or **SAS Universal Viewer** appropriate to your client operating system.
3. Follow the installation instructions provided for the download.

## 1.5 Configure WebSDM Application Properties Files

The `website.properties` file stores database connection information and points to the location of the executables. You review and modify this information as needed for your installation.

1. Navigate to `<root>\Lincoln\apps\<instance>\webapps\web_root\WEB-INF\classes\`.
2. Use an editor, such as Notepad, to open the `website.properties` file.
3. Review the settings for the following values in the file:

```
user=websdm
pass=<password>
connect=jdbc:oracle:oci8:@websdm
```

4. If the value of `<websdm_master_acct>` is something other than **websdm**, change the value of `user` to that value.
5. Change the password to the value of `<websdm_master_pass>`.

---

**Note:** Later, you will configure WebSDM to encrypt this password.

---

6. If the value of `<ora_net_service>` is something other than **websdm**, change the connect string **@websdm** to that value.

---

**Note:** With Oracle 10g and Oracle 11g, use `oci8`.

---

7. Examine the drive and directory specified for `logfile=` and `process_dir=`. Modify these if needed, keeping in mind that the parent directory for `\logs` and `\procs` is created as the `WORKING_DIR` by running script `set_permissions.bat` (see [Section 1.7, "Set File Permissions"](#).) The parent directory name should be set to the value of `<instance>`.
8. Review the location specified for the R executable:  

```
r_path=C:/Program Files/R/R-2.13.2/bin/R.exe
```

If necessary, modify this to match the location you specified when you installed R. For example, on a 64-bit server, the 32-bit version of R might have been installed by default to `C:/Program Files (x86)/R/R-2.13.2/bin/R.exe`.
9. Review the location specified for the Oracle `sqlldr` executable:  

```
sqlldr_path=D:/oracle/product/11.2.0/dbhome_1/BIN/sqlldr.exe
```

If necessary, modify this to the correct location.
10. Review the default path provided for `tablespace_datafileSpec`. If necessary, modify the path to match your Oracle environment.

## 1.6 Add Manifest Entries and Sign JAR Files

If you do not perform these steps, security-related dialog boxes appear for end users when they work with DataMontage graphs in applet mode, and DataMontage may even be completely blocked by a client machine's security settings. To perform these steps, you need access to the Java jar and jarsigner utilities in the Java jdk1.6\bin directory (jdk1.6\bin must be in the application server's PATH), and you must have access to your company's jar signing process.

1. From the <root>:\Lincoln\apps\<instance>\webapps\web\_root\AppJars\DataMontage23\ folder, copy files lti.jar and DataMontage.jar to a temporary folder such as C:\temp\UpdateJarManifest\.

2. Update the manifest in both JAR files:

- a. In the temporary folder where you copied the JAR files, create a text file and save it. The example later in this procedure uses the name MANIFEST.MF.
- b. Insert two lines of text in the file, supplying the fully qualified domain name of the Windows application server (or its IP address) and the connection port on each line. For example:

```
Codebase: <server_name>.example.com:80
Caller-Allowable-Codebase: <server_name>.example.com:80
```

Alternatively you can use an asterisk (\*) as a wildcard for the most specific part of the domain name, but this will result in a less secure deployment.

- c. Be sure to insert a line break after the second line of text. Then save and close the file.
- d. Open a DOS Command window and navigate to the temporary folder containing the JAR files and the text file you created.
- e. At the DOS prompt, issue the following commands, replacing MANIFEST.MF with the name of the text file you created:

```
jar -ufm DataMontage.jar MANIFEST.MF
jar -ufm lti.jar MANIFEST.MF
```

3. You must now sign the modified JAR files before they will work correctly within the WebSDM application. Use your company's jar signing process to perform this signing task, which probably includes using Java's jarsigner utility. (See <http://docs.oracle.com/javase/7/docs/technotes/tools/windows/jarsigner.html> for additional information about this utility.)
4. Copy both signed JAR files to the <root>:\Lincoln\apps\<instance>\webapps\web\_root\AppJars\DataMontage23\ folder, replacing the original files.
5. Finally, copy the signed DataMontage.jar file to the <root>:\Lincoln\apps\<instance>\webapps\web\_root\WEB-INF\lib\ folder, replacing the original file. (You do not need a copy of lti.jar in this location.)

## 1.7 Set File Permissions

1. Navigate to the folder <root>\Lincoln\apps\<instance>\bin.
2. Use a text editor to open the file set\_permissions.bat and review the values of SERVICE\_NAME, INSTALL\_ROOT, APPLICATION\_DIR, and WORKING\_DIR:

- a. If the value of <Instance> is other than **websdm**, change the values of SERVICE\_NAME, APPLICATION\_DIR, and WORKING\_DIR to the value of <instance>.
  - b. If the value of <root> is other than the C drive, change the value of the INSTALL\_ROOT to the value of <root>.
  - c. If the D drive is not an acceptable location for the working directory, change the drive for WORKING\_DIR to an acceptable drive.
  - d. Verify that CATALINA\_HOME is defined correctly.
3. Optionally, grant permissions to a Windows group of non-administrator users who might require access to the log files and \web\_root folder.
    - a. While editing the set\_permissions.bat file, locate the following lines:
 

```
REM -
REM - Local Administrators group
REM -
REM SET ADMIN_GROUP=Study Operators
```
    - b. Remove REM from the REM SET ADMIN\_GROUP line.
    - c. Replace Study Operators with the appropriate Windows user group that requires access.
  4. If changes are needed, edit, save, and close the file.
  5. (Windows 2008 server) Right-click the set\_permissions.bat file, and then select **Run as administrator**.  
(Windows 2003 server) Double-click the set\_permissions.bat file.
  6. When prompted, press any key.
  7. Examine the log file <root>\Lincoln\apps\<instance>\logs\set\_permissions.log for errors. If there are errors, contact Oracle.

## 1.8 Create the Submissions Folder

1. Create a directory, <submissions\_folder>, to serve as the root for clinical data submissions. This directory will later be specified on the Site Options page in WebSDM as the highest level directory within which users can browse for data.
  - If <submissions\_folder> will be located on the same drive as the WORKING\_DIR specified in the previous procedure, it should not be set at or below WORKING\_DIR.
  - If <submissions\_folder> will be located on the same drive as the WebSDM application software, it should not be set at or below <root>\Lincoln\apps\<instance>.
  - The recommended <submissions\_folder> location is at or below D:\ClinicalData.
2. The Windows <instance>\_app user (created in section 1.3.9) needs **Read** and **Write** permissions on the new directory. To ensure that these permissions are in place, right-click the <submissions\_folder> directory in Windows Explorer. Select **Properties**, the **Security** tab, and the <instance>\_app user.
3. Save any changes.

## 1.9 Start the websdm Service

1. In the **Services Control Panel**, right-click the <instance> Windows service, then click **Start** or, if the service is already running, click **Restart**.

Alternatively, execute the `net start` command in a Command window. For example, if the value of <instance> is the default **websdm**:

```
C:\> net start websdm
```

2. In the Services Control Panel, right-click the **World Wide Publishing Service**, then click **Start** or, if the service is already running, click **Restart**.

---

# Configure the WebSDM Application

Chapter 2 describes WebSDM configuration.

## 2.1 Prerequisites

Before you access the WebSDM application and set site options for your organization, at least one client computer must be set up. See the instructions in the `WebSDM_Client_Installation_Instructions.pdf` file supplied on the product ZIP file from My Oracle Support (<https://support.oracle.com>).

## 2.2 Setting WebSDM Site Options

Perform the following steps to prepare WebSDM for use by others at your site.

1. Open Internet Explorer. If you made WebSDM the default application for IIS, enter  
`http://<server name>`  
Otherwise, navigate to:  
`http://<server name>/<instance>`

---

**Note:** If your server is configured to require SSL connections, use `https://` instead of `http://`.

---

The WebSDM Login page appears.

2. Log into WebSDM using the default administrative account:

**Username:** admin

**Password:** <app\_admin\_pass\_default>

where <app\_admin\_pass\_default> is the password provided by Oracle.

You are prompted to change the password for the admin account.

3. Change the password for the admin account to the value of <app\_admin\_pass>.
4. After changing the password, log in again to the admin account, using the new password. The WebSDM home page appears.

---

**Note:** The username admin is predefined with maximum privileges in WebSDM, and has the special status Superuser. Log into WebSDM with this username in subsequent steps that reference a Superuser.

---

- Click **Settings**, and then click **Set Site Options**.

The Set Site Options page appears.

**Figure 2–1 Set Site Options page**

**Set Site Options**

Sponsor Name:  Submissions Can Override ☐

Custom Terminology and Labeling:

System Name:

System Description:

System Version Description:

Database Accounts and File System Structure:

Profile for new Accounts:

Default Tablespace for new Accounts: ☒ Create a new tablespace for each Application ☐ Use this tablespace for all Application and Study accounts

Temporary Tablespace for new Accounts:

Root directory of source data for all applications and studies:  [Browse](#)

Password Restrictions:

Expiration:  days

Expiration Warning:  days

Minimum Length:

Number of Attempts Allowed:

Number of Passwords Retained:

Specify minimum number of each of the following characters required in new passwords:

Alphabetic:

Numeric:

Non-alphanumeric:

Lower case:

Upper case:

**Figure 2–2 Set Site Options page (continued)**

SMTP Server:

Feedback Email:

Error Email:

Date & Time Format: ☒ 04/29/2013 19:49:19 EDT - Standard Date with 24-Hour Time and Timezone ☐ 04/29/2013 19:49:19 - Standard Date with 24-Hour Time ☐ 2013-04-29 19:49:19 - UTC Standard Format ☐ 2013-04-29 19:49:19 EDT - UTC Standard Format with Timezone ☐ 04/29/2013 07:49:19 PM - Standard Date and Standard Time

Auto-Start Local Listener: ☒ Yes ☐ No

Log Level:

Max Memory Per Report:  MB

☐ Allow data import from Oracle Health Sciences InForm

☐ Allow data import from Oracle Life Sciences Data Hub

☒ Allow Subject Comment/Review/Exclusion

☐ Enable PPD Patient Profiles

☐ Enable Advanced Tab

☐ Use FDA Look and Feel

☐ Enable Empirica Study Features

☐ Enable Second Level Drilldown on Subjects Page

☐ Enable Download Subject Details

Scrollbar Location for Tables: ☐ Right Side ☐ Left Side ☒ User's Preference

- Edit the Site Options as appropriate for your installation.

7. Set the **Profile** for new accounts.
  - Set the **Root directory of source data for all applications and studies** to the <submissions\_folder> created in [Section 1.9, "Start the websdm Service"](#).
  - Set the **SMTP Server** to the name of the server you use for outgoing email.
  - For **Error Email**, supply the address to which server error reports should be sent.
  - If you license PPD Patient Profiles, select **Enable PPD Patient Profiles**.
  - If you license Empirica Study, select **Enable Empirica Study Features**.
  - Set other options as appropriate for your installation.
8. Click **Save**.

## 2.3 Encrypt Password and Restart Listener

1. Click **Settings**, and then click **Set Database Connection**.
2. Verify that **Username** contains the value of <websdm\_master\_acct>.
3. Enter <websdm\_master\_pass> for the **Password**.
4. Enter <websdm\_master\_pass> for the **Confirm Password**.
5. Select **Encrypt Password**.
6. Click **Save**.
7. Click **Restart Listener**.
8. Click **Exit** to log out of WebSDM.





---

## Perform Post Installation Procedures

This chapter describes the activities to be performed post installation.

### 3.1 Setting Up MedDRA Accounts

#### 3.1.1 Background

Install each version of MedDRA used by the studies that you plan to load into WebSDM. Even if your own studies do not use MedDRA version 11.0, install version 11.0 because the LTI sample study uses it. The sample study serves as an anchor to the standard reports feature of WebSDM.

The process described in this section creates and loads an account named **MEDDRAx** for each MedDRA version, where x represents the two- or three-digit MedDRA version. For example, accounts **MEDDRA70** and **MEDDRA131** create and load MedDRA versions 7.0 and 13.1.

The same MedDRA account can be used by multiple WebSDM instances.

#### 3.1.2 Prerequisites

Create a folder for loading the MedDRA data (for example, `c:\meddra`). This folder is referred to as `<meddra_base>` in the instructions that follow.

For each MedDRA version that you plan to load, you need two zip files:

- WebSDM MedDRA Dictionary zip file

Locate the WebSDM MedDRA Dictionary zip file for the MedDRA version on the WebSDM Installation media.

The zip file is named `MEDDRAx.zip`

where x represents the two- or three-digit MedDRA version.

- MSSO MedDRA Dictionary zip file

Obtain the licensed MedDRA Dictionary zip file for the MedDRA version from the MedDRA MSSO (Maintenance and Support Services Organization, <http://www.meddramsso.com>).

### 3.1.3 Installing a MedDRA Version Dictionary

For each MedDRA version you need to load, complete the following steps, where x represents the two- or three-digit MedDRA version.

1. Unzip the WebSDM and MSSO Dictionary files:
  - a. Unzip MEDDRAx.zip from the WebSDM installation media into <meddra\_base>. This creates a folder named <meddra\_base>\MEDDRAx\ containing several files and two subfolders named ctrl and MedDRA.
  - b. Unzip the zip file from MSSO containing the correct MedDRA version into <meddra\_base>\MEDDRAx. This creates a folder named <meddra\_base>\MEDDRAx\MedDRA\medascii containing the \*.asc data files.
2. Edit the following files in folder <meddra\_base>\MEDDRAx using a text editor. Save and close each file after editing.
  - a. Create\_MedDRA.sql  

Review the DEFINE ORACLE statements. By default, this script stores tablespace files in a subfolder of oradata named orcl (. . \oradata\orcl). Edit the path used by the DEFINE ORACLE\_DBF\_FILE statement, if necessary, to indicate a different location.

You must specify a path that already exists on your computer. The path can be in any location, although it is typically in a subfolder of oradata.
  - b. Load\_MedDRA.imp  

Change the Oracle net service name at the end of the line  
userid=MEDDRAx@orcl from **orcl** to the value of <ora\_net\_service>.
  - c. Restore\_meddra\_terms.bat  

Change the name of the Oracle net service at the end of the ninth line:

```
SET SID=ORCL
```

from **orcl** to the value of <ora\_net\_service>.
3. Open a command window and change to the <meddra\_base>\MEDDRAx folder. Execute the following commands:
  - a. Execute the Create\_MedDRA.sql script from an account with DBA privileges.  

```
C:\> sqlplus <ora_dba_acct>@<ora_net_service> @Create_MedDRA.sql
```

When prompted for the password, enter <ora\_dba\_pass>. The script also prompts you to supply a password for the new MedDRA account. Supply the value of <meddraX\_ora\_pass>.
  - b. Execute the batch file: Load\_MedDRA.bat.  

When prompted for the password of the newly created MedDRA account, supply the value of <meddraX\_ora\_pass>.

The file imp\_MEDDRAx.log is produced. You can compare its row counts with those in the provided file exp\_MEDDRAx.log. The row counts should be the same.
  - c. Execute the batch file restore\_meddra\_terms.bat.  

You are again prompted to supply the password of the new MedDRA account. As the script completes, you can verify the row count checks displayed on the screen.

4. Clean up the file, if errors occur.

If errors occur while running the supplied MedDRA account installation scripts, you can correct the problem, clean up, and start over by running the `Drop_MedDRA.sql` script in the respective `MEDDRAx` folder. Execute the script from an account with DBA privileges, and supply `<ora_dba_pass>` when prompted for the password.

```
C:\> sqlplus <ora_dba_acct>@<ora_net_service> @Drop_MedDRA.sql
```

## 3.2 Installing the LTI Sample Studies

To enable standard report definitions that are supplied for WebSDM, you must install a sample application and study. Installation of MedDRA 11.0 is a prerequisite for this procedure. One sample study is required to enable the standard reports features of the software, and is referenced in the Operational Qualification test supplied on the installation media.

### 3.2.1 Installing the Required Sample Study

1. Locate the `LTI_Sample_Application.zip` file on the installation media, and extract the contents of this file to a location on the machine where WebSDM is installed, under the Root directory `<submissions_folder>` specified on the Site Options page. To make sure that path names stored in the archive are used, specify the appropriate option when extracting (for example, in WinZip, select the **Use folder names** checkbox).
2. Log into WebSDM as a Superuser.
3. Click the **Setup** tab, and then click **Register Application**.
  - a. For the **Name** property, specify **LTI**. The sample study requires this exact application name to function properly. Do not modify the application name.
  - b. For the application **Path**, use the **Browse** link and then locate and select the **LTI** application folder.
  - c. For **Default codelists in metadata**, use the supplied value, **Standard Codelists**.
  - d. For **Default MedDRA account**, specify **MEDDRA110**.
  - e. For **Default SDTM version**, specify **sdm312**.
4. When you click **OK**, the Auto-Register Studies page appears. Three studies, **SAMP1**, **SAMP1\_311**, and **SAMP1\_312**, are offered for automatic registration.
  - a. For **Study SAMP1** and **Study SAMP1\_311**, use the drop-down control to select **Defer study registration**.
  - b. For **Study SAMP1\_312**, keep the default value, **Generate a new metadata file with standard codelists**.
  - c. To begin automatic registration, click **OK**.
  - d. When registration is complete, click **Continue**.  
The Applications page appears, with the entry **LTI**.
5. From the **LTI actions** menu, click **Load**.
6. On the **Select Studies/Pools to Load** page, select the **Include** checkbox for study **SAMP1\_312**.

7. Click **Next**, **Next**, and **Submit** to begin the run.
8. Click **Continue**, and occasionally refresh the **Run History** page to view the run status. After a few minutes, the run completes.

The required sample study that was registered and loaded in the previous steps is compliant with CDISC SDTM version 3.1.2. You can install additional sample studies that are compliant with CDISC SDTM versions 3.1 and 3.1.1, respectively. [Section 3.2.2, "Optional: Registering Other LTI Sample Studies"](#) and [Section 3.2.3, "Optional: Loading the Optionally Registered Studies"](#) are optional.

### 3.2.2 Optional: Registering Other LTI Sample Studies

Perform the steps below to register other LTI sample studies.

1. Click the **Setup** tab, and then click **Studies > Pools**.
2. From the **Application** drop-down list, select **LTI**.
3. Click **Register Study**.
4. For the **Name** property, specify **SAMP1** (or SAMP1\_311).
5. For the **SDTM** version, specify **sdm31** (or sdm311).
6. Accept the MedDRA account, **MEDDRA110**.
7. For the **Data** location, use the **Browse** link and navigate to \crt\datasets\. On the row for SAMP1 (or SAMP1\_311), click **Select**.
8. Accept the **Metadata** value. Generate a new metadata file with standard codelists.
9. Click **Generate Metadata**, and click **OK** to confirm.

The application creates the metadata file and adds the name to the Metadata field.
10. Click **OK**.

### 3.2.3 Optional: Loading the Optionally Registered Studies

1. On the **Studies and Study Pools** page, on the **Action** menu, click **Load**.
2. Click **Next**.
3. Click **Next**.
4. Click **Submit**.
5. Click **Continue**, and occasionally refresh the **Run History** page to view the run status. After a few minutes, the run completes.
6. Repeat steps 1 through 5 to load each registered study.
7. Click **Exit** to log out of WebSDM.

## 3.3 Optional: Customize WebSDM

You can customize WebSDM by making one or more of the following alterations. For more detailed instructions, see the WebSDM Help.

### 3.3.1 Replacing the Default Home Page

A default home page appears when users log into WebSDM. Another home page file is supplied for use by installations that license the optional Empirica Study features. You can replace either of the home pages with a custom home page. You can create a single home page for all users, or specify a different customized home page for each WebSDM login group.

1. Use an HTML editor to design each new home page, and save it as an HTML file.
2. Use a text editor to remove the `<body>` tag at the beginning of the file and the `</body>` tag at the end of the file, leaving all other HTML content that occurs between those tags intact.

3. Save the edited file with the extension, `.inc.`, in the following directory:

```
<root>\Lincoln\apps\<instance>\webapps\web_root\customhomes\
```

For example, `EStudy_home.inc` is the name of the home page file that is supplied for use by installations using the Empirica Study application.

4. Log into WebSDM as a user with the Administer Users permission.
5. Click **Settings**.
6. Click **Edit Login Groups**.
7. Supply the name of the home page file in the `customhomes\` directory that should appear when the members of this login group log in to WebSDM.

---

**Note:** If more than one login group is set up in WebSDM, repeat this procedure for each login group.

---

### 3.3.2 Replacing the Default Logotype

A logotype appears in the upper left corner of WebSDM pages. An additional logotype file is supplied for use by installations that license the optional Empirica Study features. You can replace either of the logotypes delivered with WebSDM with a logotype of your own design. You can create a custom logotype for all users, or specify different logotypes for each WebSDM login group.

1. Select a `.bmp` or `.gif` file with dimensions of approximately 150x100 pixels and copy it to the `<root>\Lincoln\apps\<instance>\webapps\Web_root\image` directory. For example, `E_logo.gif` is the image file that is supplied for use by installations with the Empirica Study application.
2. Log into WebSDM as a user with the Administer Users permission.
3. Click **Settings**.
4. Click **Edit Login Groups** and supply the name of the logotype file in the `image\` directory that appears for members of this login group.

---

**Note:** If more than one login group is set up in WebSDM, repeat steps 3 and 4 for each login group.

---

### 3.3.3 Customizing the List of FDA Review Divisions

When you register an application in WebSDM, you can select an FDA review division for that application from a dropdown list. This list is populated with values from the

FDA\_REVIEW\_DIVISIONS table owned by <websdm\_master\_acct>. You can add values to the list of FDA review divisions.

If new review divisions are created, complete the following steps to add the new divisions:

1. Launch SQL\*Plus and connect using the <websdm\_master\_acct>.
2. Execute one or more SQL statements in the following form:

```
INSERT INTO FDA_REVIEW_DIVISIONS
(REVIEW_DIVISION, ORDER_BY)
VALUES('[new review division]', [sequence number]);
```

3. Commit your changes.

New values are immediately available for selection in WebSDM on the Register Application page.

4. Exit SQL\*Plus.

### 3.3.4 Specifying the Profile for New Accounts

When you register an application or study in WebSDM, WebSDM creates an Oracle database account for the application or study. These accounts are associated with the Oracle database profile named DEFAULT, unless you create an alternate profile and direct WebSDM to use that profile instead.

For guidelines on creating an alternate profile for your application and study accounts, see [Appendix B, "Optional: Creating Alternate Profiles"](#).

After you have created an alternate profile, you must specify that WebSDM is to use it for new study accounts:

1. Log in to WebSDM as an administrator.
2. Click **Settings**.
3. Click **Set Site Options**.
4. In the **Database Accounts and File System Structure** section, select the appropriate **Profile for new Accounts**.

## 3.4 Verify the WebSDM Installation

For Installation Qualification (IQ) and Operational Qualification (OQ) testing, refer to the IQ\_Test.doc and OQ\_Test.doc files supplied on the installation media.

---

## Notes on the Installation of R

The 32-bit version of R for Windows version 2.13.2 must be installed on the WebSDM application server. Licensing information for R can be found at <http://www.r-project.org>.

To install R version 2.13.2:

1. Log onto the WebSDM server as a user with administrator access.
2. Access <http://cran.r-project.org>. In the **Download and Install R** section, click **Download R for Windows**.
3. On the next page, click **base**.
4. Under **Other builds**, click **Previous releases**.
5. Click **R 2.13.2**, and then click **Download R 2.13.2 for Windows**.
6. Follow instructions in the installation wizard, or review the instructions available at **Installation and other instructions** to install R.

When running the installation wizard, even if you are installing to a 64-bit server, in the **Select Components** screen, choose the **32-bit user installation** option.





---

## Optional: Creating Alternate Profiles

WebSDM creates a database account for each application and study that is registered. The accounts associated with studies own the tables that contain the clinical data comprising a study. These tables are created and populated during loading and checking runs. The accounts associated with applications are reserved for future use.

WebSDM assigns randomly generated passwords for these accounts. The passwords satisfy the following criteria:

- The password is 16 characters long.
- The password contains at least one lowercase alphabetic character.
- The password contains at least one uppercase alphabetic character.
- The password contains at least one number.
- The password contains at least one nonalphanumeric character.

WebSDM does not support the expiration or resetting of the password for these accounts. If your site has installed a new version of WebSDM and your database is configured with a DEFAULT profile that imposes limits on the duration of passwords or that uses a password verifying function more restrictive than the criteria specified above, you must define an additional profile and use the WebSDM site options activity to associate that profile with the application and study accounts.

The following sample script creates a profile for the application and study accounts. You can modify the script to meet your company security policy requirements. Execute it while connected as the SYS user.

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

BEGIN
 digitarray:= '0123456789';
 chararray:= 'abcdefghijklmnopqrstuvwxyzABCDEFGHIJKLMNOPQRSTUVWXYZ';
 punctarray:= '!"#$%&()'``*+,-/;<=>?_';
```

---

```

-- Check for the minimum length of the password
IF length(password) < 16 THEN
 raise_application_error(-20002, 'Password length less than 16');
END IF;
-- Check if the password contains at least one letter, one digit and one
-- punctuation mark.
-- 1. Check for the digit
isdigit:=FALSE;
m := length(password);
FOR i IN 1..10 LOOP
 FOR j IN 1..m LOOP
 IF substr(password,j,1) = substr(digitarray,i,1) THEN
 isdigit:=TRUE;
 GOTO findchar;
 END IF;
 END LOOP;
END LOOP;
IF isdigit = FALSE THEN
 raise_application_error(-20003, 'Password should contain at least one digit,
one character and one punctuation');
END IF;
-- 2. Check for the character
<<findchar>>
ischar:=FALSE;
FOR i IN 1..length(chararray) LOOP
 FOR j IN 1..m LOOP
 IF substr(password,j,1) = substr(chararray,i,1) THEN
 ischar:=TRUE;
 GOTO findpunct;
 END IF;
 END LOOP;
END LOOP;
IF ischar = FALSE THEN
 raise_application_error(-20003, 'Password should contain at least one digit,
one character and one punctuation');
END IF;
-- 3. Check for the punctuation
<<findpunct>>
ispunct:=FALSE;
FOR i IN 1..length(punctarray) LOOP
 FOR j IN 1..m LOOP
 IF substr(password,j,1) = substr(punctarray,i,1) THEN
 ispunct:=TRUE;
 GOTO endsearch;
 END IF;
 END LOOP;
END LOOP;
IF ispunct = FALSE THEN
 raise_application_error(-20003, 'Password should contain at least one digit,
one character and one punctuation');
END IF;

<<endsearch>>
-- Everything is fine; return TRUE ;
RETURN(TRUE);
END;
/
show errors;

```

---

```
create profile WEBSDM_STUDIES_PROFILE limit
 COMPOSITE_LIMIT UNLIMITED
 SESSIONS_PER_USER UNLIMITED
 CPU_PER_SESSION UNLIMITED
 CPU_PER_CALL UNLIMITED
 LOGICAL_READS_PER_SESSION UNLIMITED
 LOGICAL_READS_PER_CALL UNLIMITED
 IDLE_TIME UNLIMITED
 CONNECT_TIME UNLIMITED
 PRIVATE_SGA UNLIMITED
 FAILED_LOGIN_ATTEMPTS 5
 PASSWORD_LIFE_TIME UNLIMITED
 PASSWORD_REUSE_TIME UNLIMITED
 PASSWORD_REUSE_MAX UNLIMITED
 PASSWORD_LOCK_TIME UNLIMITED
 PASSWORD_GRACE_TIME UNLIMITED
 PASSWORD_VERIFY_FUNCTION verify_websdm_acct_pw
```

After creating a profile, use **Settings > Set Site Options** in WebSDM to associate it with application and study accounts. Use the control labeled **Profile for new Accounts** in the **Database Accounts and File System Structure** section to select it.

For more information, see the *Oracle Database Security Guide*, 10g Release 2, Chapter 7 Security Policies, Section Password Complexity Verification, or *Oracle Database Security Guide*, 11g Release 2, Chapter 3, Configuring Authentication, Section Customizing Password Complexity Verification.



## Configure WebSDM for SSO

This section applies only to customers that plan to configure WebSDM for an SSO (Single Sign-On) environment.

This is optional functionality. Begin by reviewing the *Configuring Single Sign-On for WebSDM/Empirica Study* topic in the WebSDM/Empirica Study Help.

Before configuring WebSDM for SSO, you must install Oracle Access Manager (OAM) on a server and configure a Webgate agent. Contact Oracle for assistance.

### C.1 Configure WebSDM SSO

1. Navigate to `<root>\Lincoln\apps\<instance>\webapps\web_root\WEB-INF\classes`.
2. Open **website.properties** and uncomment the two lines for required SSO properties:
 

```
#sso.plugins=com.oracle.hsgbu.empirica.sso.EmpiricaSsoPlugin
#sso.EmpiricaSsoPlugin.username.header=oam-remote-user
```
3. Optionally, enter an SSO alternative logout URL. Uncomment this line and change the value of `<oam_server>` to the name for the fully qualified OAM server:
 

```
#sso.EmpiricaSsoPlugin.logoutRedirectUrl= http://<oam_server>/oam/server/logout
```

For example:

```
sso.EmpiricaSsoPlugin.logoutRedirectUrl=
http://myserver.com:14100/oam/server/logout
```
4. Configure the session timeout to be longer than the SSO timeout.
 

The default WebSDM session timeout is 30 minutes. Modify **WEB-INF/web.xml** and `<sessiontimeout>` to be longer than the SSO session timeout.
5. Configure the WebSDM server for native login:
  - a. Edit `/Lincoln/apps/<instance>/conf/server.xml`.
  - b. Under `<Service name="Catalina">`, add
 

```
<Connector address="127.0.0.1" port="8080" protocol="HTTP/1.1"
connectionTimeout="20000" redirectPort="8443" />
```
  - c. If the port 8080 is not available on the server, change the value of the port attribute to an available port.
6. Restart the WebSDM service.

## C.2 Validate WebSDM SSO

1. Open a browser window and type the WebSDM URL.
2. At the **Login** prompt, enter your SSO username and password.  
The WebSDM home page appears.
3. On the WebSDM server, start a browser and enter the WebSDM URL using the port number for native login that you set in section C.1.
4. At the **WebSDM login** prompt, enter a WebSDM username that is a Superuser and enter the password.  
The WebSDM home page appears.

---

## Configure WebSDM to Access an Oracle Life Sciences Data Hub Instance

This section applies only to customers who will load SDTM-formatted study data from an instance of the Oracle Life Sciences Data Hub (LSH), version 2.2.

To perform these steps you must know the Oracle DBA account/password and the Oracle master account name/password for WebSDM. In addition, you must have the following information pertaining to an existing LSH database instance:

- <LSH\_consumer\_acct>—LSH database account having "LSH Consumer" role.
- <LSH\_consumer\_pass>—Password for the above LSH database account.
- <LSH\_host>—LSH database server.
- <LSH\_port>—Port number where LSH database server listens for incoming connections
- <LSH\_SID>—Oracle system identifier for the LSH database instance.
- <LSH\_service\_name>—Alias for the LSH database address containing connection information.

Finally, you need access to files extracted from database-3\_1\_2\_1\_xxx.zip, as described in section 1.2.3, or access to the WebSDM installation media.

### D.1 Add Net Service Name for LSH Database

On the WebSDM database server, add an entry for the LSH database service name to the tnsnames.ora file.

```
<LSH_service_name>=
(DESCRIPTION=
 (ADDRESS=
 (PROTOCOL=TCP)
 (HOST=<LSH_host>)
 (PORT=<LSH_port>)
) (CONNECT_DATA= (SID=<LSH_SID>))
)
```



---

**Note:** The WebSDM application does not require this entry. Use it to access the LSH database and execute the SQL commands listed below.

If you do not want to modify `tnsnames.ora`, you can substitute the value of `<LSH_service_name>` directly in the SQL commands in steps D.2 and D.3. Replace `<LSH_service_name>` with:

```
(DESCRIPTION= (ADDRESS= (PROTOCOL=TCP) (HOST=<LSH_
host>) (PORT=<LSH_port>))
(CONNECT_DATA= (SID=<LSH_SID>)))
```

---

## D.2 Create a Database Link

1. Connect to WebSDM DB as `<ora_dba_acct>`.
  - a. Type this command: `C:> sqlplus <ora_dba_acct>@<ora_net_service>`
  - b. When prompted for the password, enter `<ora_dba_pass>`.
2. Grant Create DB Link privilege to the websdm master account by typing:  
`SQL>GRANT CREATE DATABASE LINK TO <websdm_master_acct>;`
3. Exit SQL\*Plus.
4. Connect to WebSDM DB as `<websdm_master_acct>`.
  - a. Type this command: `C:> sqlplus <websdm_master_acct>@<ora_net_service>`
  - b. When prompted for the password, enter `<websdm_master_pass>`.
5. Run the following command, with values substituted as appropriate. The `<DB_link_name>` is a new name that you provide.  
`SQL>CREATE DATABASE LINK <DB_link_name> CONNECT TO <LSH_consumer_acct>  
IDENTIFIED BY <LSH_consumer_pass> USING '<LSH_service_name>';`
6. Exit SQL\*Plus.
7. Repeat step 1 to connect to WebSDM DB again as `<ora_dba_acct>`.
8. Revoke Create DB Link privilege from the websdm master account by typing:  
`SQL>REVOKE CREATE DATABASE LINK FROM <websdm_master_acct>;`

## D.3 Install and Run a PL/SQL Package in the LSH Database

1. Locate the file `create_lsh_pkg.plb` either in the directory to which you extracted files from `database-3_1_2_1_xxx.zip` or from the `.zip` file on the WebSDM installation media.
2. Connect to the LSH instance as `<LSH_consumer_acct>`:  
`C:> sqlplus <LSH_consumer_acct>/<LSH_consumer_pass>@<LSH_service_name>;`
3. Run this command:  
`SQL>@create_lsh_pkg.plb`
4. Exit SQL\*Plus.

## D.4 Set Site Option to Allow LSH Import

1. Log into WebSDM using the default administrative account.
2. Click the **Settings** link at the top right corner of the page.
3. Click **Set Site Options**.
4. Select the **Allow data import from Oracle Life Sciences Data Hub** option if it is not already selected.
5. Click **Save**.
6. Click **Continue**.
7. Log out.



---

## Configure WebSDM to Access an Oracle Health Sciences InForm Instance

This section applies only to customers who will load SDTM-formatted study data from an Oracle Health Sciences InForm instance.

To perform these steps you must know the Oracle DBA account/password and the Oracle master account name/password for WebSDM. In addition you must have the following information pertaining to an existing InForm database instance:

- <InForm\_acct>—InForm database account containing SDTM-formatted study data.
- <InForm\_pass>—Password for the above InForm database account.
- <InForm\_host>—InForm database server.
- <InForm\_port>—Port number where InForm database server listens for incoming connections.
- <InForm\_SID>—Oracle system identifier for the InForm database instance.
- <InForm\_service\_name>—Alias for the InForm database address containing connection information.

Finally, you need access to files extracted from database-3\_1\_2\_1\_xxx.zip, as described in section 1.2.3, or access to the WebSDM installation media.

### E.1 Add Net Service Name for InForm Database

On the WebSDM database server, add an entry for the InForm database service name to the tnsnames.ora file.

```
<InForm_service_name>=
(DESCRIPTION=
 (ADDRESS=
 (PROTOCOL=TCP)
 (HOST=<InForm_host>)
 (PORT=<InForm_port>)
) (CONNECT_DATA=(SID=<InForm_SID>))
)
```

---

**Note:** The WebSDM application does not require this entry. Use it to access the InForm database and execute the SQL commands listed below.

If modifying tnsnames.ora is not desired, you can substitute the value of <InForm\_service\_name> directly in the SQL commands in steps C.2 and C.3. Replace <InForm\_service\_name> with:

```
(DESCRIPTION=(ADDRESS=(PROTOCOL=TCP) (HOST=<InForm_host>)
(PORT=<InForm_port>)) (CONNECT_DATA=(SID=< InForm_SID>)))
```

---

## E.2 Create a Database Link

1. Connect to WebSDM DB as <ora\_dba\_acct>.
  - a. Type this command:

```
C:> sqlplus <ora_dba_acct>@<ora_net_service>
```
  - b. When prompted for the password, enter <ora\_dba\_pass>.
2. Grant Create DB Link privilege to the websdm master account by typing:

```
SQL>GRANT CREATE DATABASE LINK TO <websdm_master_acct>;
```
3. Exit SQL\*Plus.
4. Connect to WebSDM DB as <websdm\_master\_acct>.
  - a. Type this command:

```
C:> sqlplus <websdm_master_acct>@<ora_net_service>
```
  - b. When prompted for the password, enter <websdm\_master\_pass>.
5. Run the following command, with values substituted as appropriate. The <DB\_link\_name> is a new name that you provide.

```
SQL>CREATE DATABASE LINK <DB_link_name> CONNECT TO <InForm_acct>
IDENTIFIED BY <InForm_pass> USING '<InForm_service_name>';
```
6. Exit SQL\*Plus.
7. Repeat step 1 to connect to WebSDM DB again as <ora\_dba\_acct>.
8. Revoke Create DB Link privilege from the websdm master account by typing:

```
SQL>REVOKE CREATE DATABASE LINK FROM <websdm_master_acct>;
```

## E.3 Set Site Option to Allow InForm Import

1. Log into WebSDM using the default administrative account.
2. Click the **Settings** link at the top right corner of the page.
3. Click **Set Site Options**.
4. Select the **Allow data import from Oracle Health Sciences InForm** option, if it is not already selected.
5. Click **Save**.
6. Click **Continue**.
7. Log out.