Oracle Argus Safety

Unblinding User's Guide

Release 7.0.3

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Oracle Argus Safety Unblinding User's Guide Release 7.0.3

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Preface

This document describes the steps for installing and configuring the components of the Argus Safety Unblinding application.

Audience

This document is technical in nature and presents technical details about the processes it discusses. It assumes that you are a qualified ORACLE Database Administrator. We recommend reading the entire document before execution the Interface programs.

About This Book

This manual contains:

Chapter 1, "Using the EOSU Generic Software"

Provides information for configuring and using the EOSU software including:

- Logging in to EOSU and Starting a Profile Configuration
- Configuring a New EOSU Profile
- Copying, Modifying, and Deleting Profiles
- Executing an EOSU Profile
- Using the EOSU Report Viewer
- Exiting from EOSU

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Related Documents

This section lists the manuals for all Oracle Argus products. You can order printed manuals from the Oracle iStore.

Oracle Argus Documentation
The *documentation set* includes:

- *Oracle Argus Installation Guide*
- *Oracle Argus Interchange User's Guide*
- *Oracle Argus Affiliate User's Guide*
- *Oracle Argus Safety Console User's Guide*
- *Oracle Argus Safety User's Guide*
- *Oracle Argus Safety End of Study Unblinding User's Guide*
- *Oracle Argus Dossier User's Guide*

Conventions

The following text conventions are used in this document:

Convention	Meaning
boldface	Boldface type indicates graphical user interface elements associated with an action, or terms defined in text or the glossary.
italic	Italic type indicates book titles, emphasis, or placeholder variables for which you supply particular values.
`monospace`	Monospace type indicates commands within a paragraph, URLs, code in examples, text that appears on the screen, or text that you enter.

1

Using the EOSU Generic Software

This chapter provides information about using the EOSU generic software and includes discussions of the following:

- Logging into EOSU and Starting a Profile Configuration
- Configuring a New EOSU Profile
- Copying Profiles
- Modifying Profiles
- Deleting Profiles
- Executing the EOSU Profile
- Using the EOSU Report Viewer
- Exiting from EOSU

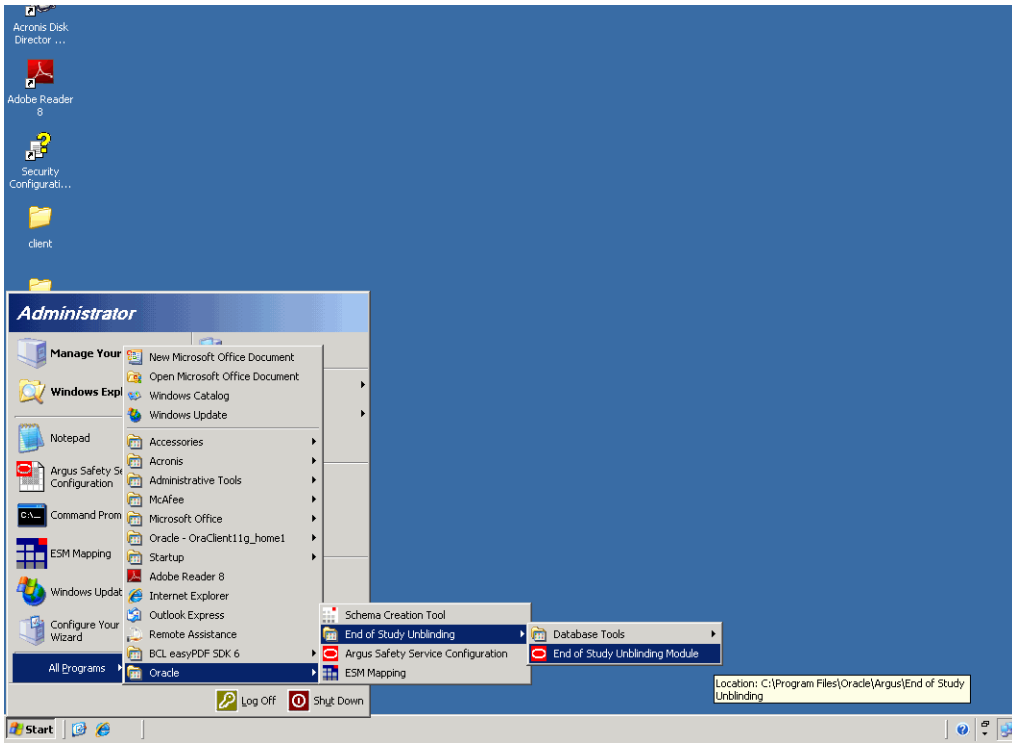
Logging into EOSU and Starting a Profile Configuration

You must have specific access rights before you can log in to the EOSU Application. If you have difficulty logging in to the application, consult your System Administrator to verify that you have the following:

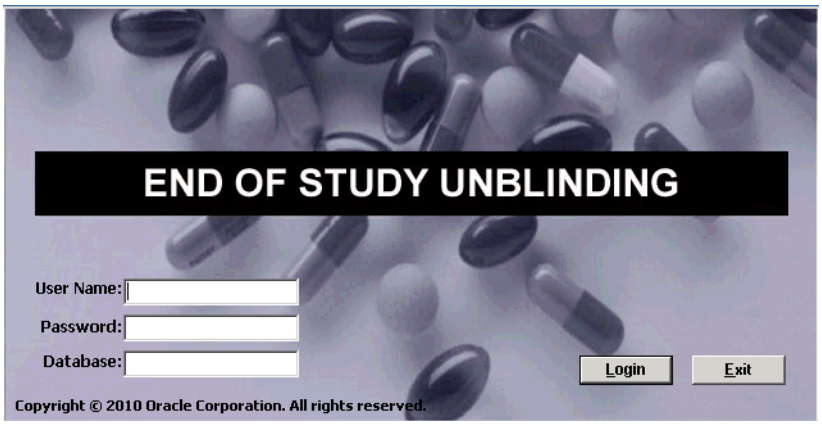
- Allow Closures of Cases access
- Allow Locking of Cases access
- Allow Unblinding of Cases access
- Membership in the End of Study Unblinding group

Use the following procedure to log in to EOSU:

1. Select **Start** => **Programs** => **Oracle** => **End of Study Unblinding**.



2. When the **log in** window opens:



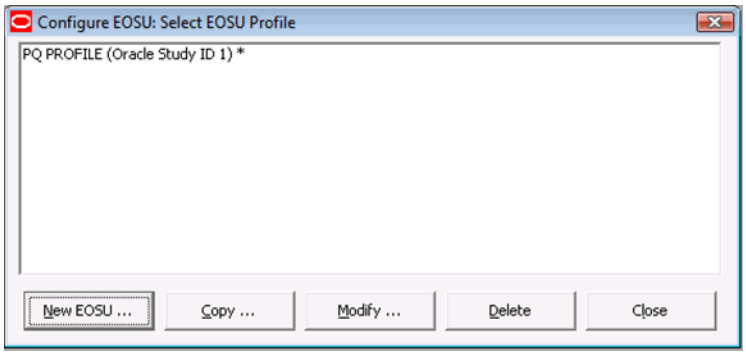
- Enter the user name in the User Name field.
- Enter the user password in the Password field.
- Enter the name of the database where Argus Generic is installed in the Database field.
- Click Login.

3. When the EOSU application opens, choose **EOSU=> Configure EOSU**.

Note: In a Multi-tenancy install, select Enterprise after the EOSU login screen. This does not appear in a single-tenancy install.

---

4. EOSU opens the **Configure EOSU: Select EOSU Profile** window.



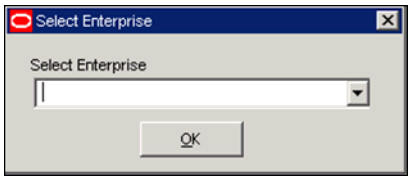
Note: An asterisk (*) next to a profile name indicates that the profile configuration is incomplete and cannot be executed.

- Click New EOSU to create a new EOSU profile.
- Click Copy to copy an existing EOSU profile.
- Click Modify to modify an existing EOSU profile.
- Click Delete to delete an existing profile.
- Click Close to close the current window.

Logging into a Multi-tenant Installation

When you log into the EOSU tool in a multi-tenant installation, a pop-up prompts you to choose the Enterprise for which the data is displayed in the EOSU tool.

- The drop-down menu in the following pop-up displays an alphabetically-sorted list of Enterprise Short Names for all the active Enterprises that the user has access to as “Enterprise User” in Console => User Management.



  - The default value is blank when the pop-up initially displays.
  - The OK button is only enabled when a non-blank value is selected.
- If you only have access to one Enterprise, the pop-up does not display and EOSU tool loads the data for that Enterprise automatically.
- If you are configured as an "Enterprise User", there are no active Enterprises, the system displays a message box with the OK button enabled, and the following message: “There are no active Enterprises for the User for the EOSU tool”.

Note: Enterprise switching without re-login is not provided in the EOSU Tool. If you need to switch to a different Enterprise partition, you must logout and then login again for the other Enterprise.

Enterprise Short Name

The EOSU window header displasy the Enterprise Short Name based on the **Display Enterprise Short Name in Application Header** option in common profile switches.If this option is not selected, the EOSU window header will not display the Enterprise Short Name and uses the existing following format:

EOSU [<User Full Name> Log on to <Database Name>]

If this option is selected, the EOSU window header appends the Enterprise Short Name along with the database name using a hyphen, as shown:

EOSU [<User Full Name> Log on to <Database Name> - <Enterprise Short Name>]

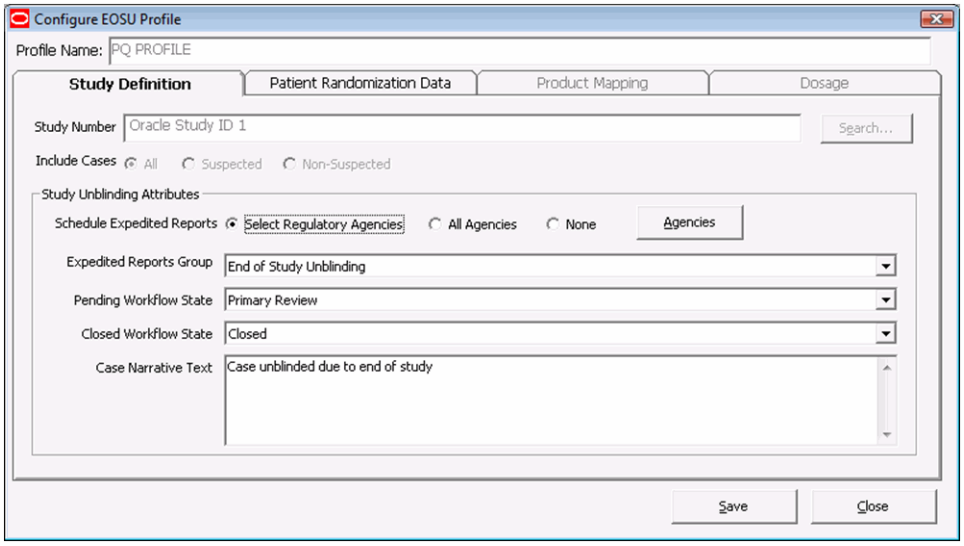
Configuring a New EOSU Profile

Configuring a new EOSU profile requires several procedures as follows:

- Configuring a Study Definition
- Loading Randomization Data
- Mapping Treatment Codes to Products
- Configuring Dosage Details for treatments and study projects

Configuring a Study Definition

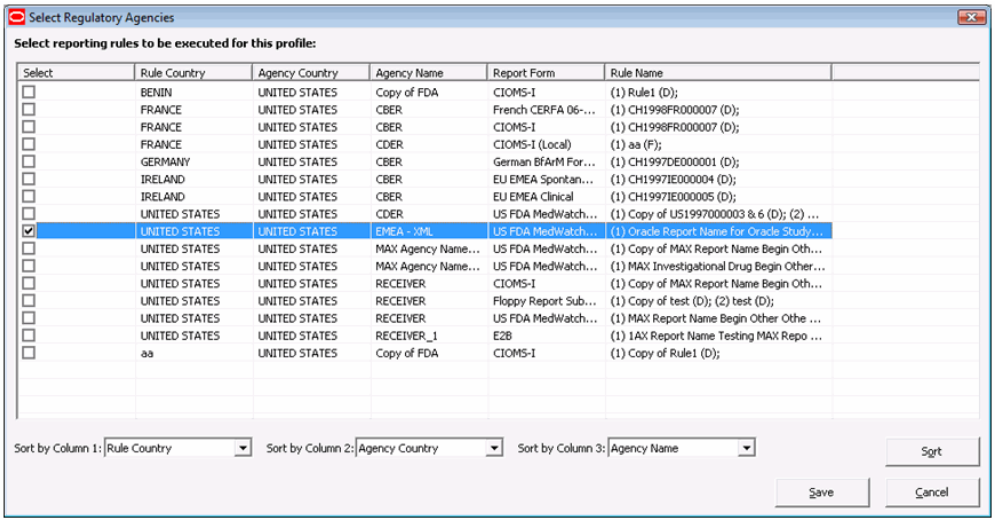
You configure a study definition on the **Study Definition** tab of the **Configure EOSU Profile** dialog box. Table 4-1lists the fields/controls on the tab and describes the function of each one.



The following table describes Study Definition Tab Fields and Controls:

Field/Control	Description
Study Number	Enables you to select a specific study. You can select a study **only** if the **Study is eligible for Unblinding** option is selected in Argus.
Include Cases	Restricts the selection of cases to All, Suspected, or Non-Suspected according to Case Assessment values for Causality.
Schedule Expedited Reports	Enables you to all/partial/no reporting rules for the case being unblinded.
Expedited Reports Group	Enables you to replace the group for all reports scheduled for this profile.
Pending Workflow State	Replaces the case state for all cases processed by this profile that have an unsubmitted report as part of the case.
Closed Workflow State	Defines the workflow state to be used for closed cases.
Case Narrative Text	Enables you to enter relevant information about the case.
Search…	Enables you to search for a particular study.
Agencies	This button is enabled only if the Select Regulatory Agencies option button has been selected.
Save	Enables you to save the profile.
Close	Enables you to close the profile.

If you select **Select Regulatory Agencies** in the **Schedule Expedited Reports** field when you are configuring a study definition, EOSU also displays the **Select Regulatory Agencies** dialog box. This dialog displays all the Reporting Rules in the Argus Application, grouped by Rule Country, Agency Country, Agency and the Report Form Name. The column headers can be stretched to make the column wider to display more data. Table 4-2 lists and describes the fields and controls in this dialog box.

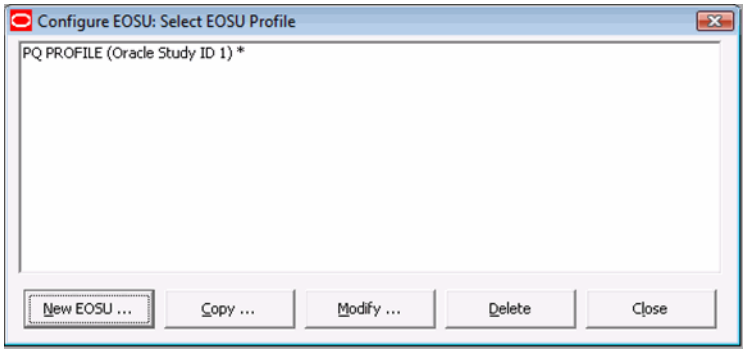


The following table describes Select Regulatory Agency Dialog Box Fields and Controls:

Field/Control	Description
Select	Enables you to select the reporting rules this profile is to execute.
Save	Saves the reporting rules and closes the dialog box.
Cancel	Closes the dialog box without saving data.
Sort	Sorts the data according to the options selected in the Sort by Column 1, Sort by Column 2, and Sort by Column 3.

To configure a Study Definition:

1. In the EOSU Unblinding software, choose **EOSU** > **Configure EOSU**.
2. When the **Configure EOSU: Select EOSU Profile** window opens:



   - Click New EOSU to create a new EOSU profile.
3. When the Study Definition tab opens. Enter data as required. Click Save to go to the next tab within the configuration.
   - Type the study ID in the Study Number field.
   - Select the cases to include by clicking the appropriate option button in the Include Cases field.
   - Select the appropriate option button in the Schedule Expedited Reports field.
   - Select the appropriate group from the Expedited Reports Group drop-down list.
   - Select the workflow state from the Pending Workflow State drop-down list.
   - Select the workflow state for all closed cases from the Closed Workflow State drop-down list.
   - Type any relevant data in the Case Narrative Text field.
   - Click Save to safe the Study Definition.
4. If you chose Select Regulatory Agencies in the Schedule Expedited Reports field in the preceding step, the system displays the Select Regulatory Agencies dialog box.
   - Click in the appropriate checkboxes to select one or more Agency/Rule.
   - Click Save.

Loading Randomization Data

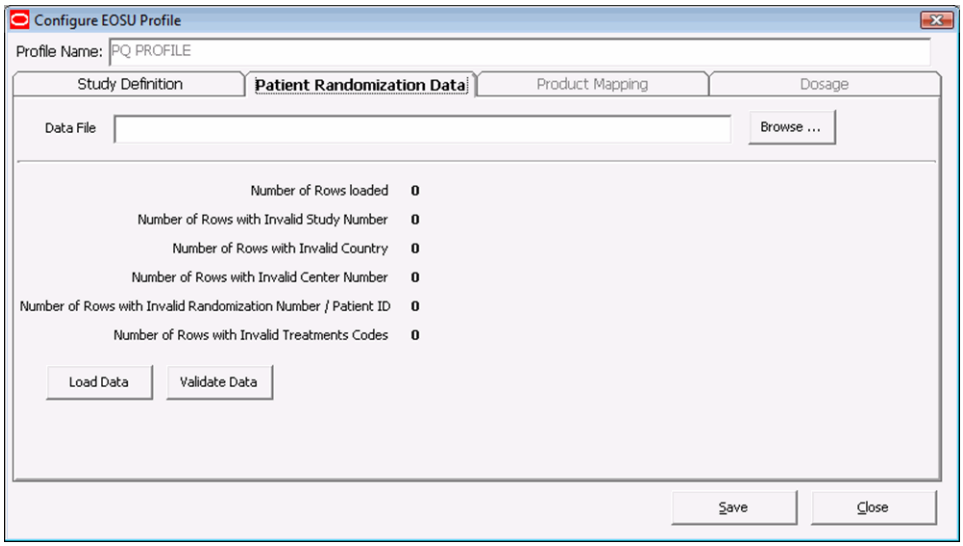
You can load randomization data for the EOSU profile from the **Patient Randomization Data** tab. Table 4-3lists and describes the fields and controls on the tab.

The following table describes Patient Randomization Data Tab Fields and Controls:

Field/Control	Description
Data File	Enables you to select the data file to load.
Load Data	Clicking this button loads data into the Randomization Data Tables.
Validate Data	Clicking this button validates the data and generates a report that you can access through the Report Viewer.
Save	Enables you to save the data on the tab.
Close	Enables you to close the tab without saving the data.

To load randomization data for the profile

1. In the **Configure EOSU Profile** dialog box, click the **Patient Randomization Data** tab.



2. When the **Patient Randomization Data** tab opens:
   - Click Browse and select the appropriate Excel data file to load.
   - Click Save.

Mapping Treatment Codes to Study Products

On the **Product Mapping** tab, you can map treatment codes from the Randomization Data to Study Products.

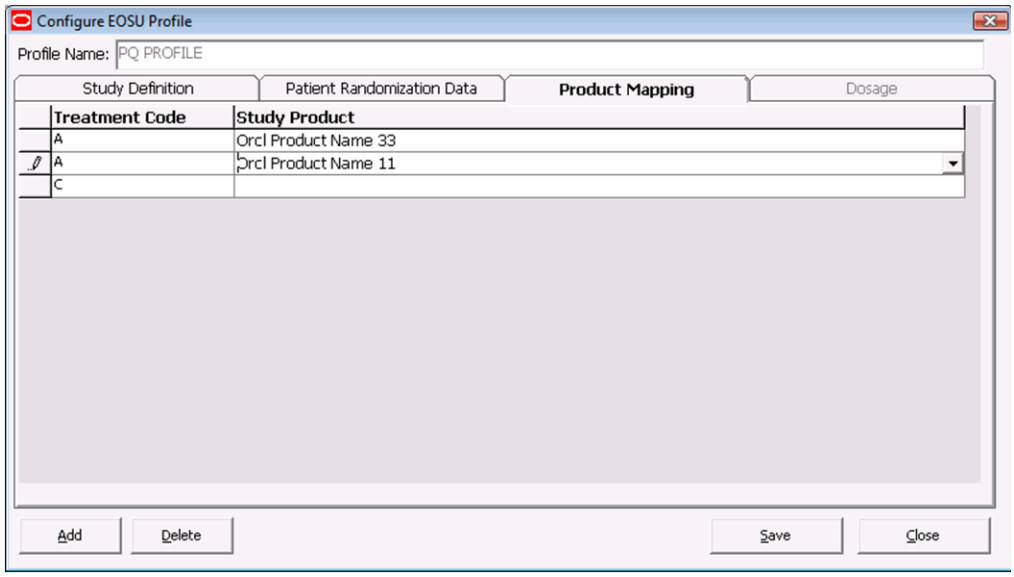
Note: This release is intended to un-blind only Drug based Studies. Vaccine and Device based studies **are not** supported. EOSU **will not** show Products with Device and Vaccine licenses on the Profile configuration (Treatment Code to Study Product Mapping).

The following table lists and describes the fields and controls on the **Product Mapping** tab.

Field/Control	Description
Add	Enables you to: Add a new treatment code to study product mapping Unblind a treatment code for multiple study products.
Delete	Deletes the current row in the table.
Saves	Saves the current profile with the new data.
Close	Closes the Configure EOSU Profile dialog box.

To configure product mapping

1. Click the **Product Mapping** tab.



2. When the **Product Mapping** tab opens:
   - Select the appropriate treatment code for each study product from the Treatment Code drop-down.
   - Click Save to proceed to the Dosage tab.

Configuring Dosage

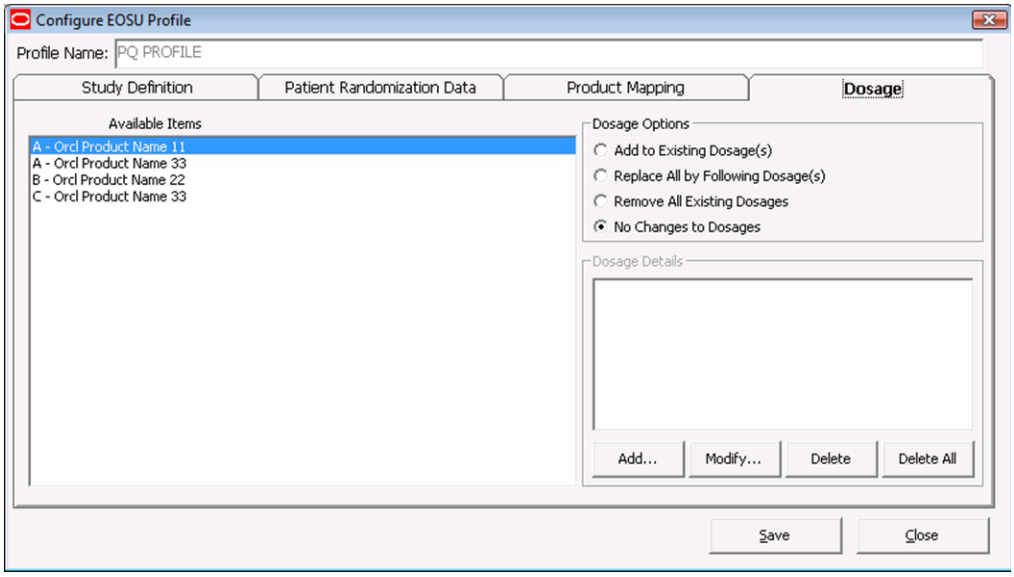
You can enter dosage details for each treatment and study product on the **Dosage** tab.

The following table describes the Dosage Tab Fields and Controls:

Field/Control	Description
Available Items	Contains a list of available dosage records for the profile.
Dosage Options	Enables you to select how you want to handle the dosage Add to Existing Dosages - Add a specified dosage amount to the current dosage. Replace All by Following Dosages - Replace the current dosage with a new dosage. Remove All Existing Dosages - Remove all dosages from the selected dosage record. No Changes to Dosages - Do not make any changes.
Dosage Details	Enter the details regarding the dosages for the selected dosage record.
Add	Enables you to add a dosage record.
Modify	Enables you to modify an existing dosage record.
Delete	Enables you to delete an existing dosage record.
Delete All	Enables you to delete all dosage information
Save	Saves the dosage information.
Close	Closes the Dosage tab without saving the data.

To configure dosage:

1. Click the **Dosage** tab.



2. When the **Dosage** tab opens:
   - Select the appropriate dosage record from the Available Items list.
   - Select the appropriate option from the Dosage Options list.
   - Add. Modify, Delete, or Delete All the dosage as required.
   - Click Save.

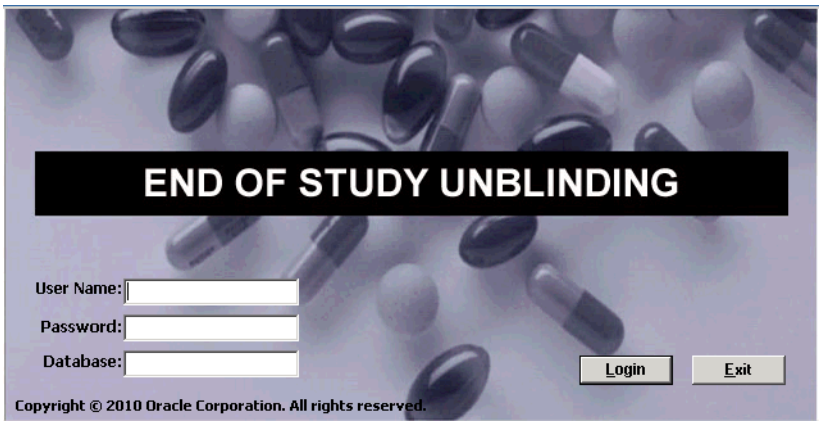
Copying Profiles

A profile can be copied to another profile from the Profile Configuration Screen. The following restrictions apply when copying the profile:

- Only one profile with a specific **Study** and **Include Cases** option (Suspected, Non-Suspected or All) can exist in the database.
- A profile with **ALL** as the **Include Cases** option cannot be copied to any other profile. **ALL** includes Suspected and Non-Suspected case.
- When copying a profile where the Include Cases option is **Suspected**, the system automatically creates another profile with the **Non-Suspected** flag is checked (assuming the same study with Non-Suspected option did not exist before).
- When the system copies a profiles where the Include Cases option is **Non-Suspected**, the system automatically creates another profile with the **Suspected** flag checked (assuming the same study with Suspected option did not exist before)

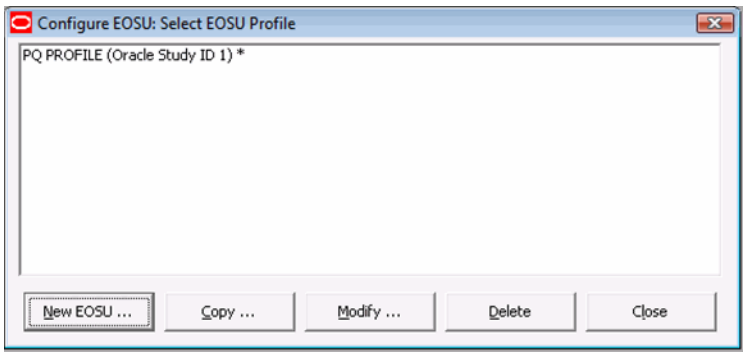
Use the following procedure to copy an existing profile:

1. Select **Start** => **Programs** => **Oracle** => **End of Study Unblinding** => **End of Study Unblinding**.
2. When the **log in** window opens:



   - Enter the user name in the User Name field.
   - Enter the user password in the Password field.
   - Enter the name of the database where Argus Generic is installed in the Database field.
   - Click **Login**.
3. When the EOSU application opens, choose **EOSU=> Configure EOSU.**
4. EOSU opens the **Configure EOSU: Select EOSU Profile** window.

Note: An asterisk (*) next to a profile name indicates that the profile configuration is incomplete and cannot be executed.



- Click Copy to copy an existing EOSU profile.

5. The system copies the profile.

Modifying Profiles

A profile can be modified from the Profile Configuration Screen. You can modify parameters on all tabs except on the **Study Definition** tab. On that tab, you can modify all parameters except the following:

- Study Number
- Include Cases

To modify a profile:

1. Select **Start** => **Programs** => **Oracle** => **End of Study Unblinding** => **End of Study Unblinding**.
2. When the **log in** window opens:
   - Enter the user name in the User Name field.
   - Enter the user password in the Password field.
   - Enter the name of the database where Argus Generic is installed in the Database field.
   - Click Login.
3. When the EOSU application opens, choose **EOSU=>=> Configure EOSU.**
4. EOSU opens the **Configure EOSU: Select EOSU Profile** window.

> **Note:** An asterisk (*) next to a profile name indicates that the profile configuration is incomplete and cannot be executed.

   - Click Modify to make changes to an existing EOSU profile.
5. When the system opens the Configure EOSU Profile dialog box:
   - Modify the data on the various tabs as necessary.

Deleting Profiles

You can delete a profile. When deleting a profile, be aware of the following restrictions:

- If there is a past attempt to unblind cases with the same profile, the system will not allow you to delete the profile.
- Profiles are only deleted logically. An EP_DELETED column in the EOSU_ PROFILE table which, when not null, indicates that this profile has been deleted

Use the following procedure to delete a profile:

1. Select **Start** => **Programs** => **Oracle** => **End of Study Unblinding** => **End of Study Unblinding**.
2. When the **log in** window opens:
   - Enter the user name in the User Name field.
   - Enter the user password in the Password field.
   - Enter the name of the database where Argus Generic is installed in the Database field.
   - Click Login.
3. When the EOSU application opens, choose EOSU=> Configure EOSU.EOSU opens the Configure EOSU: Select EOSU Profile window.
4. EOSU opens the Configure EOSU: Select EOSU Profile window.

   Note: An asterisk (*) next to a profile name indicates that the profile configuration is incomplete and cannot be executed.

   - Click Delete to delete an existing EOSU profile.
5. The system deletes the profile.

Executing the EOSU Profile

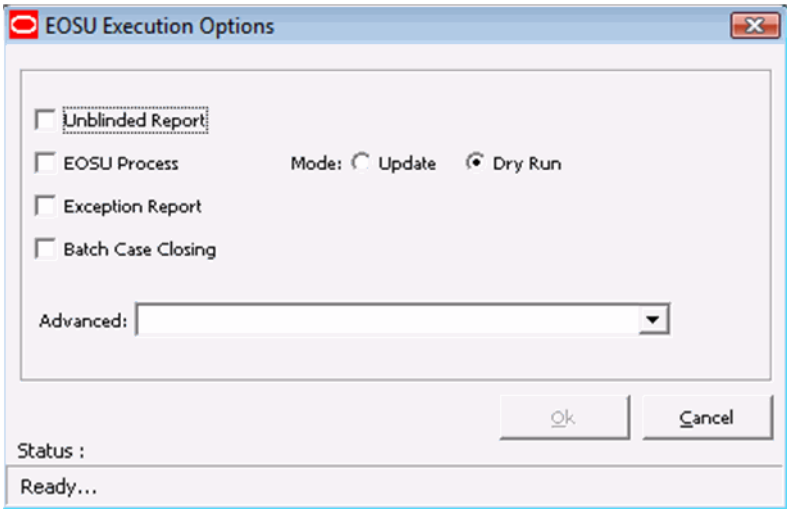
When you run an EOSU profile, you select **Execution Options** from the **EOSU Execution Options** dialog box. Table 4-6 lists and describes the function of each execution option.

The following table describes EOSU Execution Options:

Option	Function
Unblinded Report	Generates an Unblinded report.
EOSU Process	Executes the profile against the Argus database.
Exception Report	Generates an exception for the last execution.
Batch Case Closing	Performs batch case closing for cases selected under this profile.
Update	Updates the Argus data when you run the profile.
Dry Run	Generates and reviews log files before updating the Argus data.
Advanced	Enables you to specify an Advanced Condition to restrict the cases processed by each execution.

1. To execute a profile

1. Select **Start** => **Programs** => **Oracle** => **End of Study Unblinding** => **End of Study Unblinding**.
2. When the **log in** window opens:



   - Enter the user name in the User Name field.
   - Enter the user password in the Password field.
   - Enter the name of the database where Argus Generic is installed in the Database field.
   - Click Login.
3. When the EOSU application opens, choose **EOSU=> Execute EOSU.**
4. When the **Execute EOSU** dialog box opens:
   - Select a profile to execute.
   - Click **Run**.
5. Select the appropriate execution options. Click OK.
   - Select the appropriate Execution Options.
   - Click **Run**.

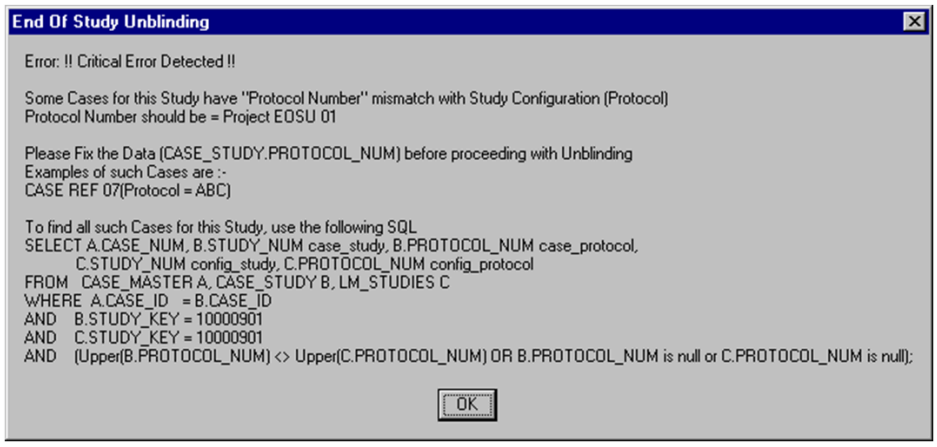
Error Messages

When executing an EOSU profile you may receive error messages under certain conditions.

Error Message: Protocol Number Mismatch

Error Message: !! Critical Error Detected !!

Error Display:



Reason for Error: The Study information (Protocol Number) does not match Study definition under List Maintenance.

As shown in the image above, a Case **CASE REF 07** shows protocol number **ABC** where the protocol number **Project EOSU 01** is used in study information. The EOSU software shows a maximum of four (4) cases followed by an SQL statement to help the user to capture all Cases with mismatched data. The User can then update the data in the database and re-execute the profile.

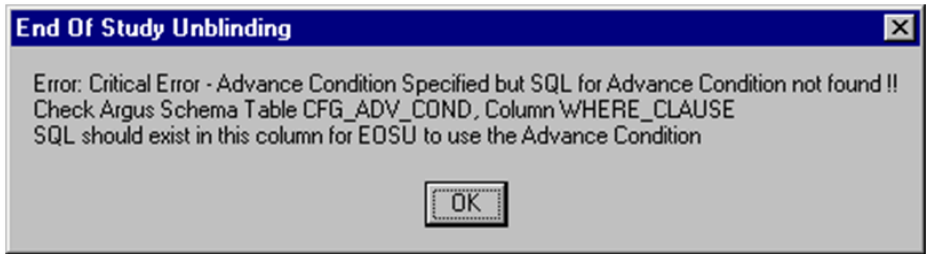
Resolution: Update the protocol number in list maintenance or update the Case Data (CASE_STUDY.PROTOCOL_NUM) with the matching PROTOCOL ID from the Clinical Study information and re-execute the profile

Comment: This message was introduced to prevent the system from hanging indefinitely when there is a data mismatch.

Error Message: No SQL for Advanced Condition

Error Message: Critical Error - Advance Condition…

Error Display:



Reason for Error: The where clause (CFG_ADV_COND.WHERE_CLAUSE) required to execute the EOSU software with an advanced condition (defined on the **EOSU Execution Options** dialog box to filter the number of cases being processed) is missing.

Exception Report Messages

The software generates an exception report for cases that cannot be Unblinded. The following is a list of possible errors that can be associated with failed cases:

- Case is in use by User <XYZ>. To release lock, request the user to login and logout.

- Case is unlocked or open.
- The Randomization data is missing for the Country, Study, Center, and Randomization Number.
- The Patient Exposure drug could not be located in LM_STUDIES.
- Case Narrative is larger than 32KB.
- There was an Oracle Error during breaking of the Blind. <Oracle Error Message>
- Failed in PROCESS_CASE. Oracle Text is <Oracle Error Message>
- Duplicate entries in Randomization Data (Country+Study+Center+Rand#) are matching the Case Data.

Using the EOSU Report Viewer

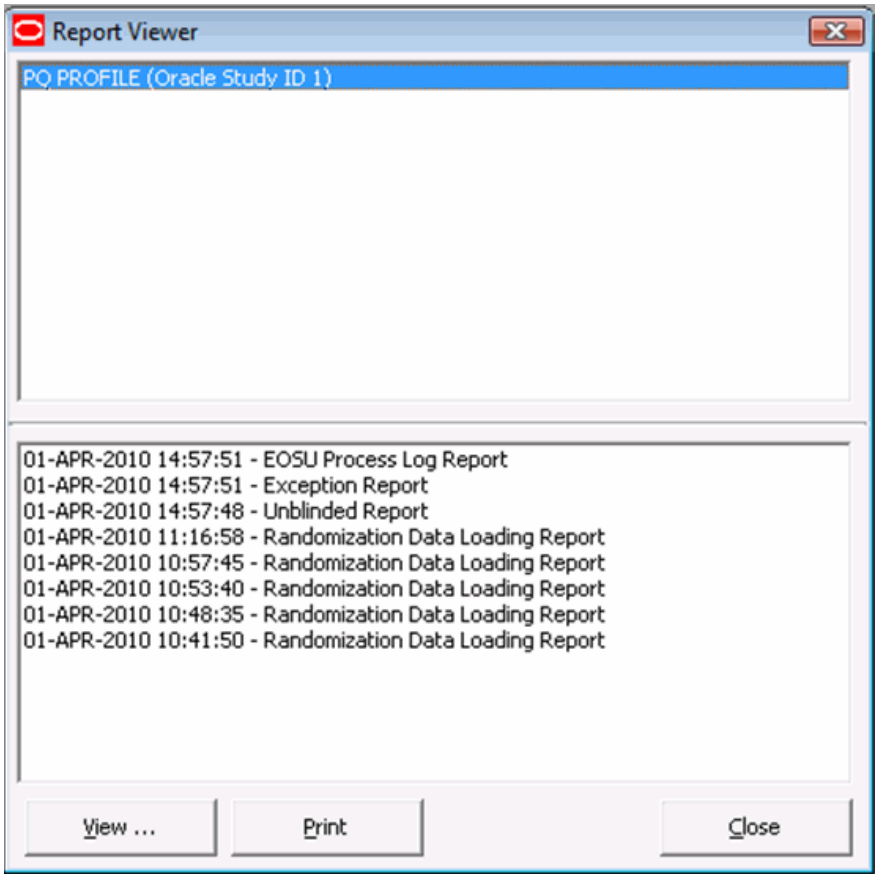
Use the EOSU Report Viewer to select and view unblinded reports. Table 4-7 lists and describes the fields and controls on the **Report Viewer** dialog box.

The following table describes EOSU Report Viewer Fields and Controls:

Field/Control	Description
View	Opens the report in Microsoft Word.
Print	Prints the report to the printer.
Close	Closes the current window.

Use the following procedure to use the EOSU Report Viewer:

1. Select **Start** => **Programs** => **Oracle** => **End of Study Unblinding** => **End of Study Unblinding**.
2. When the **log in** window opens:



- Enter the user name in the User Name field.
- Enter the user password in the Password field.
- Enter the name of the database where Argus Generic is installed in the Database field.
- Click Login.

3. When the EOSU application opens, choose **EOSU=> Report Viewer.**
4. When the **Report Viewer** dialog box opens:
   - Select a report to view from the list at the bottom of the dialog box.
   - Click View… to view the report in Microsoft Word.

Exiting from EOSU

You can exit from the EOSU application by doing either of the following:

- Select **File** => **Exit**.
- Press **ALT+F4**.

Uninstalling Client Software

Use Windows **Add or Remove Programs** under Control Panel to remove the EOSU client from machine.