

Oracle Argus Unblinding User's Guide



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Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Diversity and Inclusion](#)
- [Related resources](#)
- [Access to Oracle Support](#)

Documentation accessibility

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

Diversity and Inclusion

Oracle is fully committed to diversity and inclusion. Oracle respects and values having a diverse workforce that increases thought leadership and innovation. As part of our initiative to build a more inclusive culture that positively impacts our employees, customers, and partners, we are working to remove insensitive terms from our products and documentation. We are also mindful of the necessity to maintain compatibility with our customers' existing technologies and the need to ensure continuity of service as Oracle's offerings and industry standards evolve. Because of these technical constraints, our effort to remove insensitive terms is ongoing and will take time and external cooperation.

Related resources

For information about Oracle Argus patches, see [My Oracle Support](#).

All documentation and other supporting materials are available on the [Oracle Help Center](#).

Access to Oracle Support

To receive support assistance, determine whether your organization is a cloud or on-premises customer. If you're not sure, use Support Cloud.

Cloud customers receive support assistance through Support Cloud

Oracle customers that have purchased support have access to electronic support through Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface of Oracle Life Sciences Support Cloud (<https://hsgbu.custhelp.com/>)
- Japanese interface of Oracle Life Sciences Support Cloud へようこそ (<https://hsgbu-jp.custhelp.com/>)

You can also call our 24x7 help desk. For information, visit [Life Sciences Support | Oracle](#) or visit [Oracle Accessibility Learning and Support](#) if you are hearing impaired.

On-premises customers receive support assistance through My Oracle Support

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

1

Log into Oracle Argus Unblinding and Start a Profile Configuration

You must have specific access rights before you can log in to the Oracle Argus Unblinding 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 Oracle Argus Unblinding:

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

Note:

In a multi-tenancy install, select **Enterprise** after the Oracle Argus Unblinding login screen. This does not appear in a single-tenancy install.

4. Oracle Argus Unblinding opens the **Configure Argus Unblinding: Select Argus Unblinding Profile** window.

Note:

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

- Click **New Argus Unblinding** to create a new Oracle Argus Unblinding profile.
- Click **Copy** to copy an existing Oracle Argus Unblinding profile.
- Click **Modify** to modify an existing Oracle Argus Unblinding profile.

- Click **Delete** to delete an existing profile.
- Click **Close** to close the current window.

2

Log into a Multi-tenant Installation

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

- In the **Select Enterprise** drop-down menu, an alphabetically-sorted list of Enterprise Short Names appears 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 Oracle Argus Unblinding 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 Argus Unblinding tool.**



Note:

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

For more information, see:

- [Enterprise Short Name](#)

Enterprise Short Name

The Oracle Argus Unblinding window header displays 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 Oracle Argus Unblinding window header will not display the Enterprise Short Name and uses the existing following format:

Argus Unblinding [<User Full Name> Log on to <Database Name>]

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

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

3

Configure a New Oracle Argus Unblinding Profile

Configuring a new Oracle Argus Unblinding profile requires several procedures as follows:

- [Configure a Study Definition](#)
- [Load Randomization Data](#)
- [Map Treatment Codes to Study Products](#)
- [Configure Dosage](#)

Configure a Study Definition

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

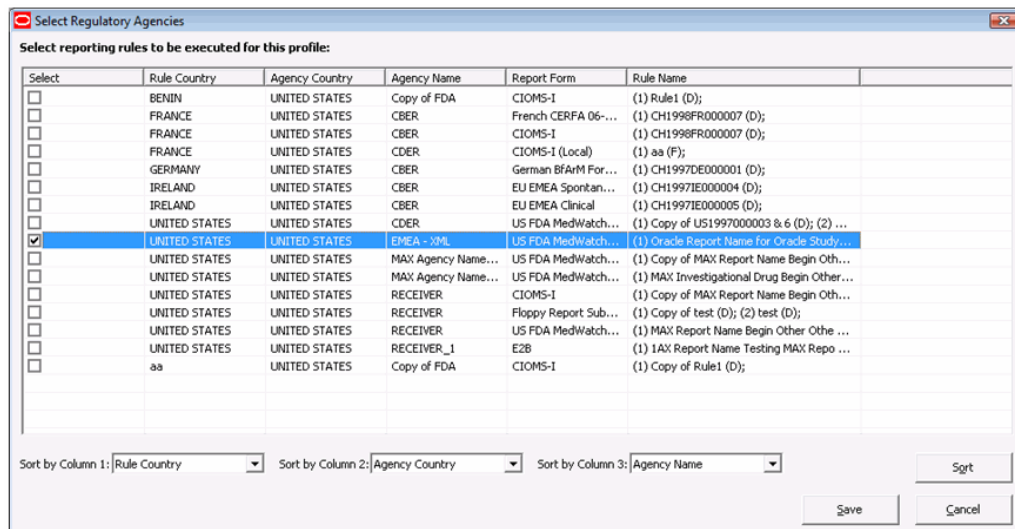
The screenshot shows the 'Configure EOSU Profile' dialog box with the 'Study Definition' tab selected. The 'Profile Name' is 'PQ PROFILE'. The 'Study Number' is 'Oracle Study ID 1'. The 'Include Cases' section has radio buttons for 'All', 'Suspected', and 'Non-Suspected'. The 'Study Unblinding Attributes' section includes a 'Schedule Expedited Reports' section with radio buttons for 'Select Regulatory Agencies', 'All Agencies', and 'None', and a button labeled 'Agencies'. Below this are dropdown menus for 'Expedited Reports Group' (End of Study Unblinding), 'Pending Workflow State' (Primary Review), and 'Closed Workflow State' (Closed). A text area for 'Case Narrative Text' contains the text 'Case unblinded due to end of study'. At the bottom are 'Save' and 'Close' buttons.

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 Oracle Argus Safety.
Include Cases	Restricts the selection of cases to All , Suspected , or Non-Suspected according to Case Assessment values for Causality.

Field/Control	Description
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, Oracle Argus Unblinding also displays the **Select Regulatory Agencies** dialog box. This dialog displays all the Reporting Rules in the Oracle Argus Safety 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. The following 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.

Field/Control	Description
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 Oracle Argus Unblinding software, choose **Argus Unblinding > Configure Argus Unblinding**.
2. When the **Configure Argus Unblinding: Select Argus Unblinding Profile** window opens:
 - Click **New Argus Unblinding** to create a new Oracle Argus Unblinding profile.
3. When the Study Definition tab opens, enter data as required. Click **Save** to go to the next tab within the configuration.
 - a. Type the study ID in the **Study Number** field.
 - b. Select the cases to include by clicking the appropriate option button in the **Include Cases** field.
 - c. Select the appropriate option button in the **Schedule Expedited Reports** field.
 - d. Select the appropriate group from the **Expedited Reports Group** drop-down list.
 - e. Select the workflow state from the **Pending Workflow State** drop-down list.
 - f. Select the workflow state for all closed cases from the **Closed Workflow State** drop-down list.
 - g. Type any relevant data in the **Case Narrative Text** field.
 - h. Click **Save** to save 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.
 - a. Click in the appropriate checkboxes to select one or more **Agency/Rule**.
 - b. Click **Save**.

Load Randomization Data

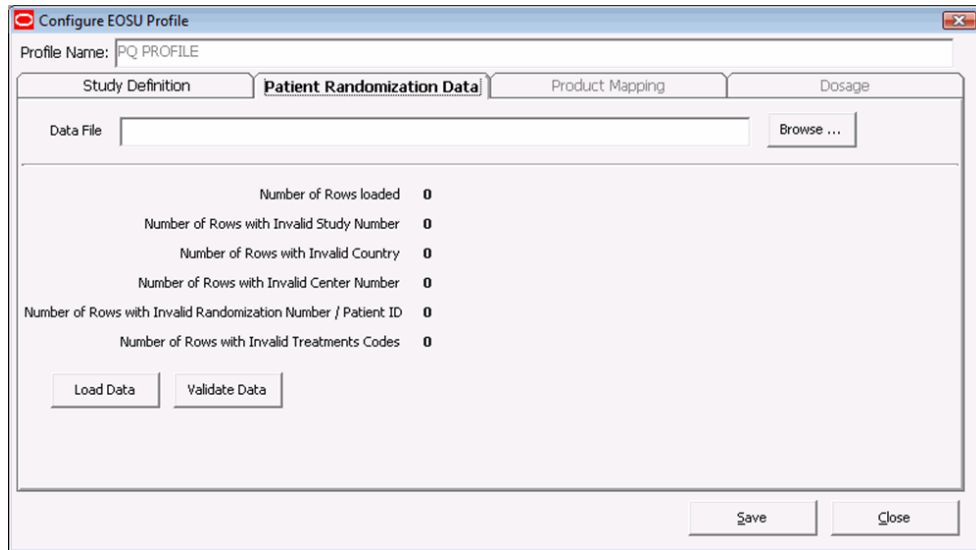
You can load randomization data for the Oracle Argus Unblinding profile from the **Patient Randomization Data** tab.

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 Argus Unblinding Profile** dialog box, click the **Patient Randomization Data** tab.



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

Patient Randomization Data file is an MS Excel file (version 5.0 onwards) that contains multiple attributes.

Data present in each record is validated against the data present in Case Form / Codelist tables, as per the rules below.

The records can be presented in any order.

Attribute	Data Type and length	Validation rules
Study number	VARCHAR2 (20)	Validated against LM_STUDIES. STUDY_NUM
Country of patient enrollment	VARCHAR2 (50)	Validated against LM_COUNTRIES. COUNTRY
Centre number	VARCHAR2 (20)	Validated against LM_CENTERS. CENTER_NO
Patient randomization number	VARCHAR2 (15)	Validated against CASE_PAT_INFO. RAND_NUM
Treatment code	VARCHAR2 (10)	Validates that data is not null
Patient ID	VARCHAR2 (10)	Validates that data is not null

 **Note:**

Leading zeros and spaces within the Patient Randomization Data don't need to be removed prior to loading. EOSU will treat each of the above fields and their associated fields within Argus as equal, if the values being compared are equal, once any leading zeros and spaces are removed.

Map Treatment Codes to Study Products

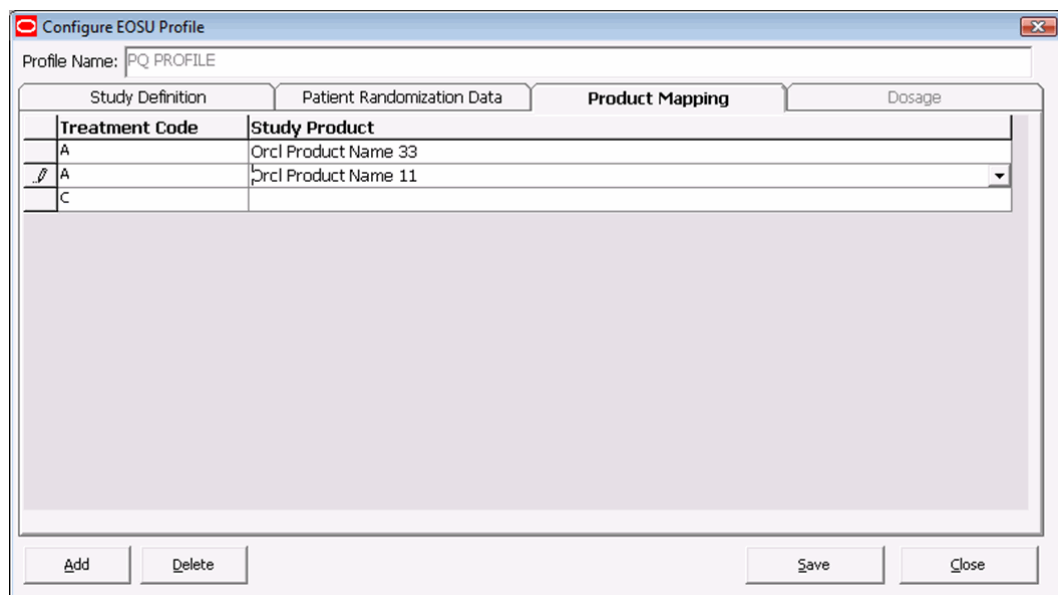
On the **Product Mapping** tab, you can map treatment codes from the Randomization Data to Study Products.

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 Argus Unblinding Profile dialog box.

To configure product mapping:

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



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

Configure Dosage

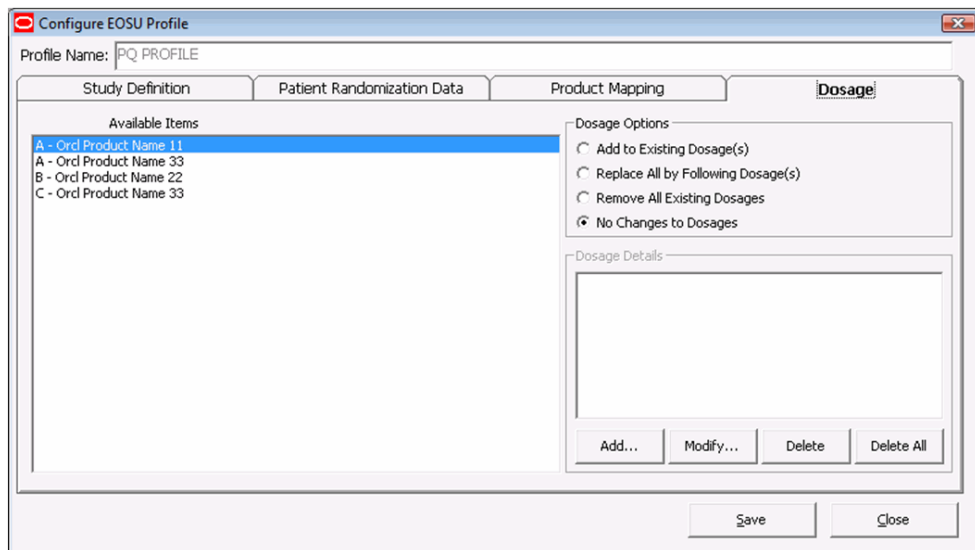
You can enter dosage details for each treatment and study product on the **Dosage** tab.

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:
 - a. Select the appropriate dosage record from the **Available Items** list.
 - b. Select the appropriate option from the **Dosage Options** list.
 - c. **Add, Modify, Delete, or Delete All** the dosage as required.
 - d. Click **Save**.

4

Manage profiles

In this section:

- [Copy Profiles](#)
- [Modify Profiles](#)
- [Delete Profiles](#)

Copy 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:
 - a. Enter the user name in the **User Name** field.
 - b. Enter the user password in the **Password** field.
 - c. Enter the name of the database where Oracle Argus Safety is installed in the **Database** field.
 - d. Click **Login**.
3. When the Oracle Argus Unblinding application opens, choose **Argus Unblinding> Configure Argus Unblinding**.
4. Oracle Argus Unblinding opens the **Configure Argus Unblinding: Select Argus Unblinding Profile** window.

Note:

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

5. Click **Copy** to copy an existing Oracle Argus Unblinding profile.

The system copies the profile.

Modify 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:
 - a. Enter the user name in the **User Name** field.
 - b. Enter the user password in the **Password** field.
 - c. Enter the name of the database where Oracle Argus Safety is installed in the **Database** field.
 - d. Click **Login**.
3. When the Oracle Argus Unblinding application opens, choose **Argus Unblinding > Configure Argus Unblinding**.
4. Oracle Argus Unblinding opens the **Configure Argus Unblinding: Select Argus Unblinding 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 Oracle Argus Unblinding profile.
5. When the system opens the **Configure Argus Unblinding Profile** dialog box:
 - Modify the data on the various tabs as necessary.

Delete 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 `Argus Unblinding_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:
 - a. Enter the user name in the **User Name** field.
 - b. Enter the user password in the **Password** field.
 - c. Enter the name of the database where Oracle Argus Safety is installed in the **Database** field.
 - d. Click **Login**.
3. When the Oracle Argus Unblinding application opens, choose **Argus Unblinding > Configure Argus Unblinding**.
4. Oracle Argus Unblinding opens the **Configure Argus Unblinding: Select Argus Unblinding 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 Oracle Argus Unblinding profile.

The system deletes the profile.

5

Execute the Oracle Argus Unblinding Profile

When you run an Oracle Argus Unblinding profile, you select **Execution Options** from the **Argus Unblinding Execution Options** dialog box.

The following table describes **Argus Unblinding Execution Options**:

Option	Function
Unblinded Report	Generates an Unblinded report.
Argus Unblinding Process	Executes the profile against the Oracle Argus Safety 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 Oracle Argus Safety data when you run the profile.
Dry Run	Generates and reviews log files before updating the Oracle Argus Safety data.
Advanced	Enables you to specify an Advanced Condition to restrict the cases processed by each execution.

To execute a profile:

1. Select **Start > Programs > Oracle > End of Study Unblinding > End of Study Unblinding**.
2. When the **log in** window opens:
 - a. Enter the user name in the **User Name** field.
 - b. Enter the user password in the **Password** field.
 - c. Enter the name of the database where Oracle Argus Safety is installed in the **Database** field.
 - d. Click **Login**.
3. When the Oracle Argus Unblinding application opens, choose **Argus Unblinding > Execute Argus Unblinding**.
4. When the **Argus Unblinding Execution Options** window opens:
 - a. Check **EOSU Process** and select the **Dry Run** radio button.
 - b. Click **OK**.

For more information, see:

- [Error Messages](#)
- [Exception Report Messages](#)

Error Messages

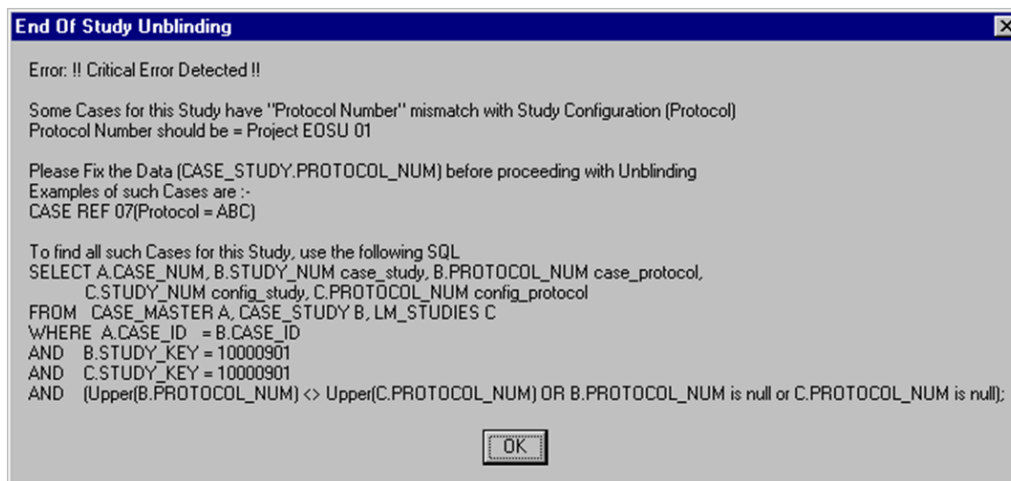
When executing an Oracle Argus Unblinding profile you may receive error messages under certain conditions.

- [Error Message: Protocol Number Mismatch](#)
- [Error Message: No SQL for Advanced Condition](#)

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 REF 07` shows protocol number `ABC` where the protocol number **Project Argus Unblinding 01** is used in study information. The Oracle Argus Unblinding 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.

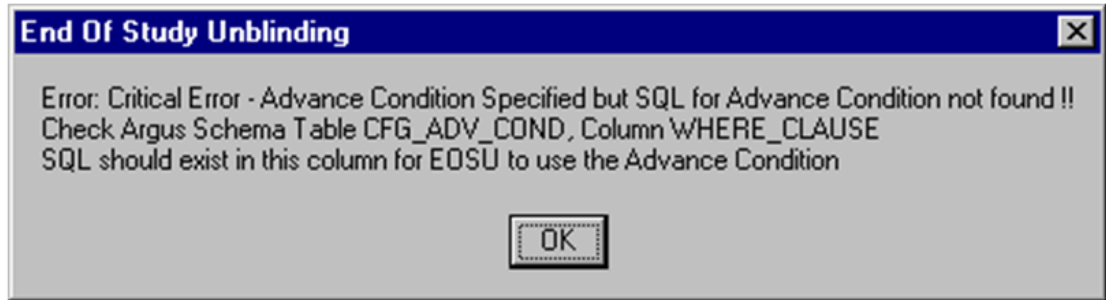
Resolution: Update the protocol number in list maintenance or update the Case Data (`CASE_STUDY.PROTOCOL_NUM`) with the matching `PROTOCOL` ID from the Clinical Study information and re-execute the profile

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 Oracle Argus Unblinding software with an advanced condition (defined on the **Argus Unblinding 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.

6

Use the Oracle Argus Unblinding Report Viewer

Use the Oracle Argus Unblinding Report Viewer to select and view unblinded reports.

The following table describes Oracle Argus Unblinding **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 Oracle Argus Unblinding **Report Viewer**:

1. Select **Start > Programs > Oracle > End of Study Unblinding > End of Study Unblinding**.
2. When the **log in** window opens:
 - a. Enter the user name in the **User Name** field.
 - b. Enter the user password in the **Password** field.
 - c. Enter the name of the database where Oracle Argus Safety is installed in the **Database** field.
 - d. Click **Login**.
3. When the Oracle Argus Unblinding application opens, choose **Argus Unblinding > Report Viewer**.
4. When the **Report Viewer** dialog box opens:
 - a. Select a report to view from the list at the bottom of the dialog box.
 - b. Click **View...** to view the report in Microsoft Word.

Oracle Argus Unblinding Updates

Oracle Argus Unblinding does not pick up a case that is globally or locally unlocked. These cases are logged in the exception report as today but with the failure reason modified to say

Case is unlocked (globally and/or locally) or open

The unblinded report includes these cases under one of the following three corresponding sections retaining the existing functionality:

- Not Locked and Not Closed Blinded Suspected cases
- Not Locked and Not Closed Blinded Not-Suspected cases
- Not Locked and Not Closed Cases Un-blinded (during study) cases

Oracle Argus Unblinding does not pick up a case that is pending local or global report submission. Oracle Argus Unblinding used to abort when a report was pending submission.

This has been fixed to skip the case when pending submission and log in the exception report with the failure reason

Case is pending report submission

The **unblinded report** includes these cases under one of the following three new sections:

- Pending Report Submission Blinded Suspected cases
- Pending Report Submission Blinded Not-Suspected cases
- Pending Report Submission Cases Un-blinded (during study) cases

Once unblinding is complete for a Local PRPT Case, the system shall continue to perform global lock as with existing functionality but shall not perform any local lock and hence shall not generate any local reports. It is expected that the customer shall manually local lock the case after local data entry, license selections and assessments.



Note:

The system shall determine the local reports based on the Local Reports Configuration and the reporting rules that were selected in the Oracle Argus Unblinding configuration. These cases shall also be not be picked by Batch Case Closing Module.

The unblinded report shall include these Local PRPT Case that had been unblinded but not been locally locked by the system after unblinding, under the following new section. Note that a case may appear in only one of the sections in the unblinded report. So a case listed under this new section shall not appear under the existing "Suspected Cases which were Un-blinded following the study end" section (or any other section).

Batch Case Closing Module shall retain the existing functionality and shall check both local and global reports if they are pending generation to determine if a case can be closed.

7

Exit from Oracle Argus Unblinding

You can exit from the Oracle Argus Unblinding application by doing either of the following:

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

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Uninstall Client Software

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