Oracle® Argus Interchange

User's Guide

Release 8.0

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Oracle Argus Interchange User's Guide Release 8.0

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Contents

Preface

This Guide provides documentation on the tasks related to the handling of E2B reports in Argus Safety. These include configuration, validation, viewing, transmitting, monitoring and import of E2B reports.

Audience

This document is intended for the users and administrators of the Argus Interchange application.

Documentation Accessibility

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

Access to Oracle Support

Oracle customers 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.

Related Documents

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

Oracle Argus Documentation

The *documentation set* includes:

- *Oracle Argus Safety User's Guide*
- *Oracle Argus Safety Administrator's Guide*
- *Oracle Argus Safety Database Administrator's Guide*
- *Oracle Argus Dossier User's Guide*
- *Oracle Argus Affiliate User's Guide*
- *Oracle Argus Unblinding User's Guide*

- *Oracle Argus Interchange UICH DTD 2.1 Mapping Reference Guide*

Checking My Oracle Support

The Oracle Argus Safety product suite continues to grow and evolve. To help you use it and stay abreast of updates we provide between releases, it is a good practice to check My Oracle Support for information that enhances our released documentation.

To open the Oracle Argus Safety product page on My Oracle Support, complete the following steps:

1. Open a Web browser to `http:/support.oracle.com`.
2. Click **Sign In** and enter your user information.

   The My Oracle Support portal opens, displaying general news from several categories. If you do not yet have an account, click **Register here** and follow the instructions given on the registration page.
3. Click **Knowledge**.
4. In the **Browse any Product, by Name** field, enter **Oracle Argus Safety**.
5. Click **Go**. My Oracle Support loads the Oracle Argus Safety Knowledge Browser Product Page.

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.

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About Argus Interchange

Oracle Argus Interchange is an electronic submission and exchange module that enables the transmission of required ICH:E2B reporting functionality as well as the exchange of vital drug safety information with regulators and partners worldwide. Cases are reported instantly and accurately using standardized, worldwide reporting and transmission processes.

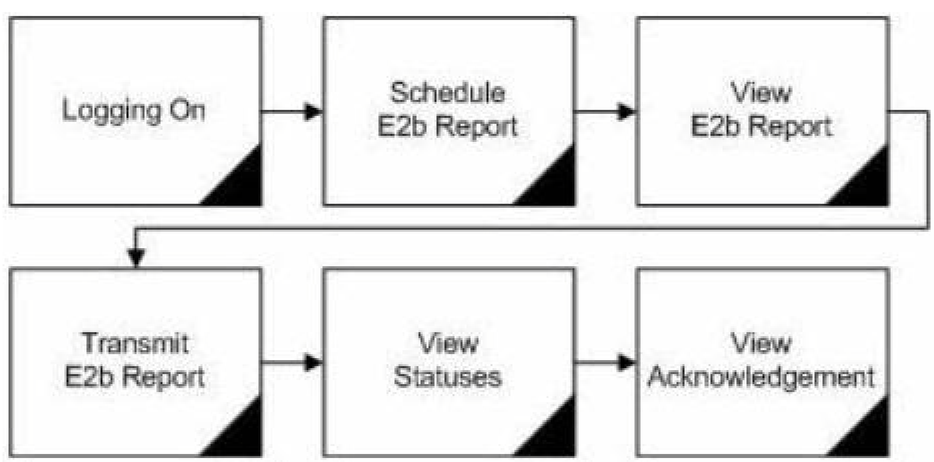
A color-coded graphical display provides peace of mind by delivering real-time insight into transmission status. Further, Argus Interchange is seamlessly integrated with Oracle Argus Safety, facilitating import, export, and transmission of cases. In addition, it supports immediate case triage upon electronic intake of data.

Argus Interchange provides the critical link to connect the pre-clinical and post-marketing safety information domains. This is the crucial component enabling pharma companies to communicate between their e-clinical and safety systems, delivering immediate return on investment gains. Argus Interchange will allow any standards-based systems (ICH:E2B to CDISC:ODM) to instantly exchange adverse events data. It thereby eliminates costly data entry redundancy and any possibility for introduction of errors.

Note: The term **E2B** that is used in this document refers to E2B (R2), E2B (R3), and eVAERS reports.

Argus Interchange Process Overview

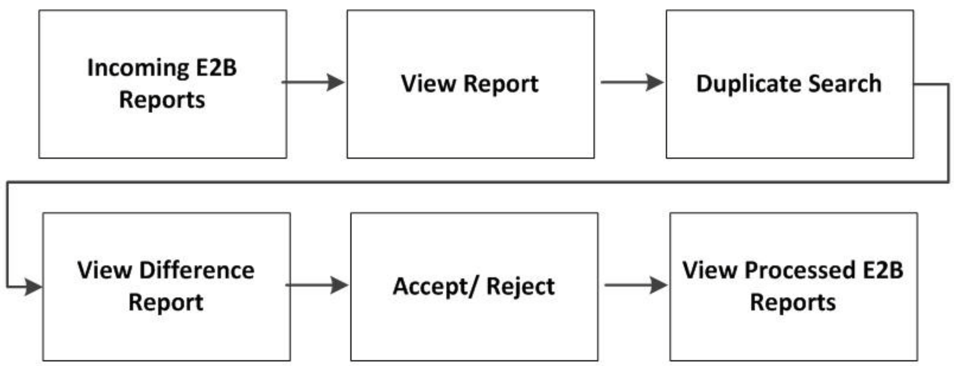
The following flowchart shows the steps to follow when using Argus Interchange.



The following table describes each of the steps in the preceding flowchart.

Task	Description
Logging on	Explains how to log on to Argus Safety.
Schedule E2B Report	Explains how to schedule an E2B Report for a case using the New Expedited Report dialog.
View E2B Report	Explains how to view a scheduled E2B Report in the ICSR Viewer and check for validation errors.
Transmit E2B Report	Explains how to transmit E2B reports by using the Bulk Reporting features in Argus Safety.
View Status	Explains how to view and understand the status of a transmitted E2B report.
View Acknowledgement	Explains how to view the detailed acknowledgement information from a trading partner or a regulatory authority.

The following flowchart displays the steps to import E2B Reports through Argus Interchange:



The following table describes each of the steps in the preceding flowchart.

Task	Description
Incoming E2B Reports	Explains how to view Incoming E2B Reports.
View E2B Reports	Explains how to view an Incoming E2B Report in the ICSR Viewer.
Duplicate Search	Explains how to search for possible duplicate cases in the Argus Safety system.
View Difference Report	Explains how to view differences between the current XML being imported (a message not yet imported into the database), the current case data in the database and the last imported case.
Accept/Reject	Explains how to accept or reject single/multiple E2B Follow-up/Initial reports.
View Process E2B Reports	Explains how to view the processed E2B Reports.

ICSR

ICSR is a a report that contains information describing a suspected adverse drug reaction related to the administration of one or more medicinal products to an individual patient.

E2B is the international standard for transmitting medicine adverse event reports specified by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

Minimum Requirement for Electronic Report Generation

The minimum requirements (mandatory) for generating an ICSR report are as follows:

1. One identifiable patient - any one of several data elements is considered sufficient to define an identifiable patient (such as initials, age, sex)
2. One identifiable reporter - any one of several data elements is considered sufficient to define an identifiable reporter (such as initials, address, qualifications)
3. One adverse event/reaction (or outcome), and
4. One suspect or interacting drug

Reporting Destination can be configured with a message profile for E2B(R2), E2B(R3) or eVAERS report form.

E2B (R2) report contains the following information:

A: Administrative and Identification Information

A.1 - Identification of the case safety report

A.2 - Primary source(s) of information

A.3 - Information on sender and receiver of case safety report

B: Information on the Case:

B.1 - Patient characteristics

B.2 - Reaction(s)/event(s)

B.3 - Results of tests and procedures relevant to the investigation of the patient

B.4 - Drug(s) information

B.5 - Narrative case summary and further information

E2B (R3) and eVAERS reports are built using HL7 version 3 (V3) messaging standards with the following sections:

Section A:

C.1 - Identification of the Case Safety Report

C.2 - Primary Source(s) of Information

C.3 - Information on Sender of Case Safety Report

C.4 - Literature Reference(s)

C.5 - Study Identification

Section B

D - Patient Characteristics

E - Reaction(s)/Event(s)

F - Results of Tests and Procedures Relevant to the Investigation of the Patient

G - Drug(s) Information, and

H - Narrative Case Summary and Further Information

The following are the key features of reports in HL7 format:

1. Structure and Cardinality - Messages are built using Health Level 7 Version 3 (HL7 V3) messaging standard.
2. International Standard Code Sets - International Standard Code Sets are used in HL7 messages: ISO 5218, ISO 639-2, NCI and UCUM.
3. Null flavors - ICH ICSR uses the codes from the HL7 Messaging Standard to categorize exceptions. Null flavor such as NI, NA, UNK enables transmission of an empty element and provides an explanation for the reason for the lack of data using codes. Confidential information such as Patient or Reporter's name and address can be masked by the sender due to security, privacy or other reasons by using MSK Null flavor.
4. Attachments can be presented in-line within the ICSR message itself. In-line data is transmitted as part of the encapsulated data value in the ICSR message.

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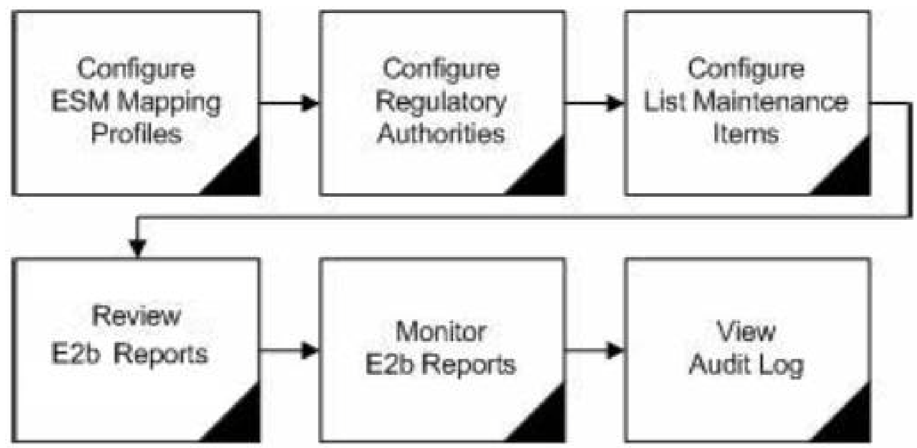
Configuring Argus Interchange

This section is intended for Argus Interchange Administrators. The flowchart shows the steps to follow when configuring, reviewing, and administering Argus Interchange.



Argus Interchange Mapping Utility

The Argus Interchange Mapping Utility enables you to store multiple profiles. This enables companies to transmit E2B reports to multiple agencies. The Argus Interchange Mapping Utility maintains an audit log that tracks every change made to the settings. You can also use this utility to view Trading Partner Configurations. This chapter includes discussions of the following:

- Logging On and Off Interchange
- Viewing Regulatory Authorities/Trading Partners
- Configuring Argus Interchange Service
- Adding a Database for Argus Interchange Service
- Viewing the Audit Log
- Comparing DTD Profiles
- E2B Codes Translation
- E2B Extensions

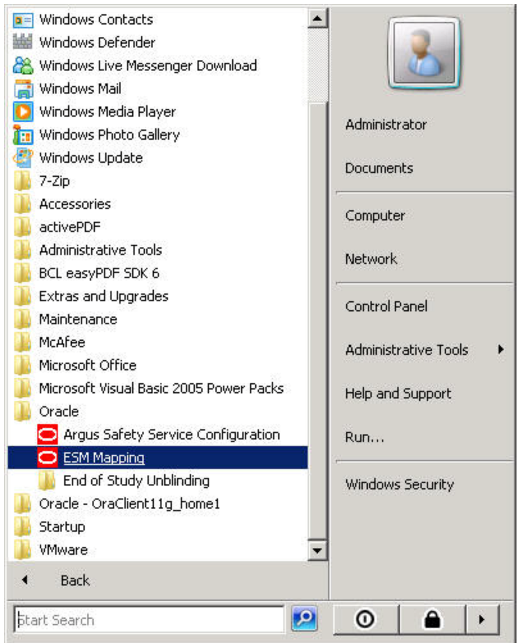
Logging On and Off Interchange

This section provides information about a logging in and out of Interchange.

Logging On to Interchange

To log on to Interchange:

1. Go to Start-->Programs-->Oracle-->ESM Mapping.



2. Enter the User Name, Password, and Database in the log on dialog.

Note: The User Name and Password for the Argus Interchange Mapping Utility are created through User Configuration in Argus Console. This is done by selecting the ESM Admin role from the list of available roles in the User Role listbox.

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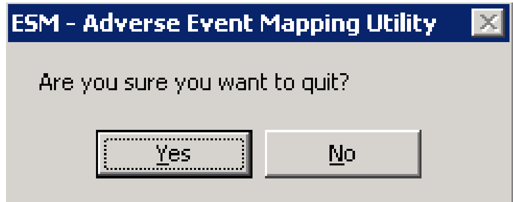
3. Click Login.

Exiting from Interchange

To exit from the Argus Interchange Mapping Utility:

1. Select Administrator -> Exit to open a confirmation dialog.



2. Click Yes to exit Argus Interchange Mapping Utility.

Working with Profiles

The Argus Interchange Mapping Utility provides the following standard Message and Acknowledgement profiles:

- ICH-ICSR V2.1 MESSAGE TEMPLATE
- ICH-ICSR V2.1 MESSAGE TEMPLATE - EMA
- ICH-ICSR V2.1 MESSAGE TEMPLATE - FDA
- ICH-ICSR V3.0 MESSAGE TEMPLATE
- ICH-ICSR V1.1 ACKNOWLEDGEMENT TEMPLATE
- ICH-ICSR V1.1 ACKNOWLEDGEMENT TEMPLATE - EMA
- ICH-ICSR V1.1 ACKNOWLEDGEMENT TEMPLATE - FDA
- CBER EVAERS V1.0 MESSAGE TEMPLATE

Beginning Argus 8.0, the following profile template has been added:

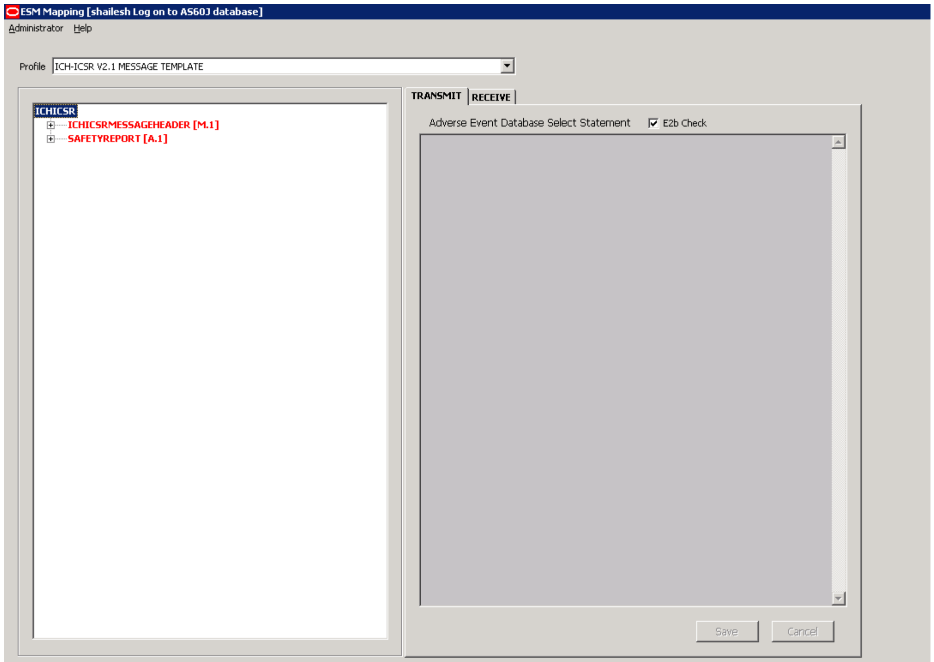
ICH-ICSR E2B R3 MESSAGE TEMPLATE

This section provides information about working with profiles and includes discussions of the following:

- Defining a Profile
- Printing a Profile
- Copying a Profile
- Deleting a Profile

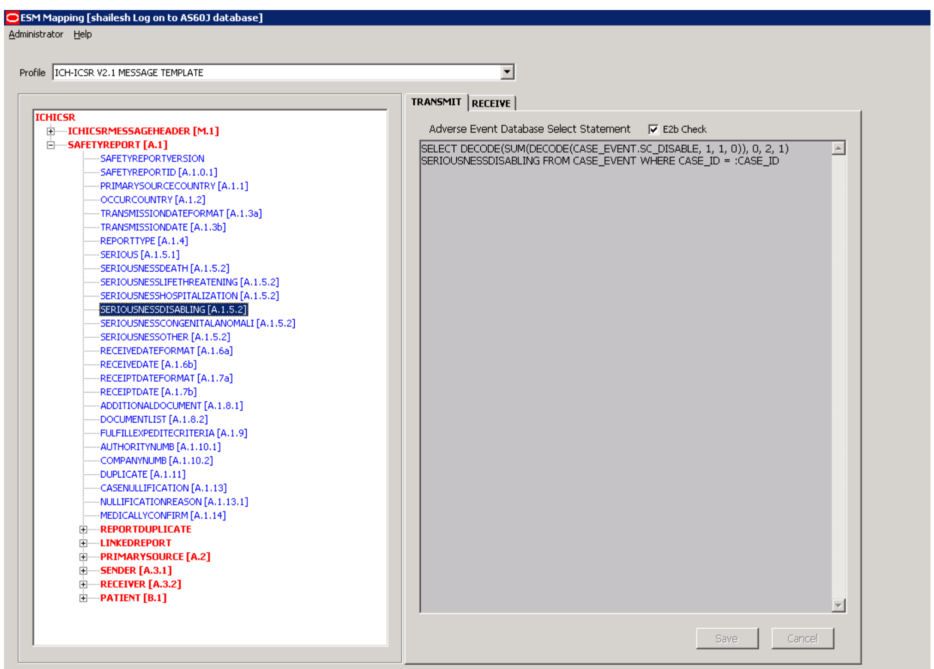
Defining a Profile

This section describes how to view or modify the rules of a DTD profile in Argus Interchange Mapping Utility. You can view profile details by selecting a Profile from the Argus Interchange Mapping Utility window.



The following table lists and describes items that are common to each tab of the Argus Interchange Mapping Utility.

Using the Transmit Tab The following is an illustration of the Transmit tab:



To view details in the Transmit Tab:

1. Select a profile from the Profile drop-down list.
2. Click Transmit.

The following tables lists and describes the items on the Transmit tab:

Item	Description
Adverse Event Database Select Statement	Enables you to enter and view the SQL logic used to extract the value of the selected element of the DTD profile from AE database.
E2B Check checkbox	Indicates whether the selected profile is used in the E2B check functionality in Argus. The E2B check function is used to validate E2B reports based on the validation rules defined for the DTD profiles. Only the profiles that have the E2B check selected are used for validation.

Printing a Profile

This section describes how to setup your printer and print the profile.

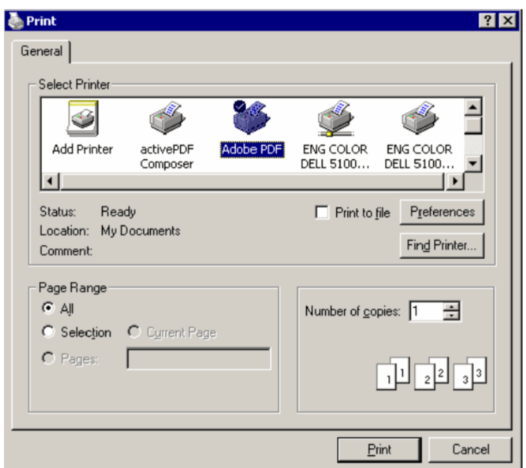
Setting Up the Printer

You should set up your printer before printing a profile.

To set up your printer

1. Select Administrator -> Printer Setup to open the Printer Setup dialog box.
2. Select the default printer from this dialog box.

The following is an illustration of the Print dialog box.

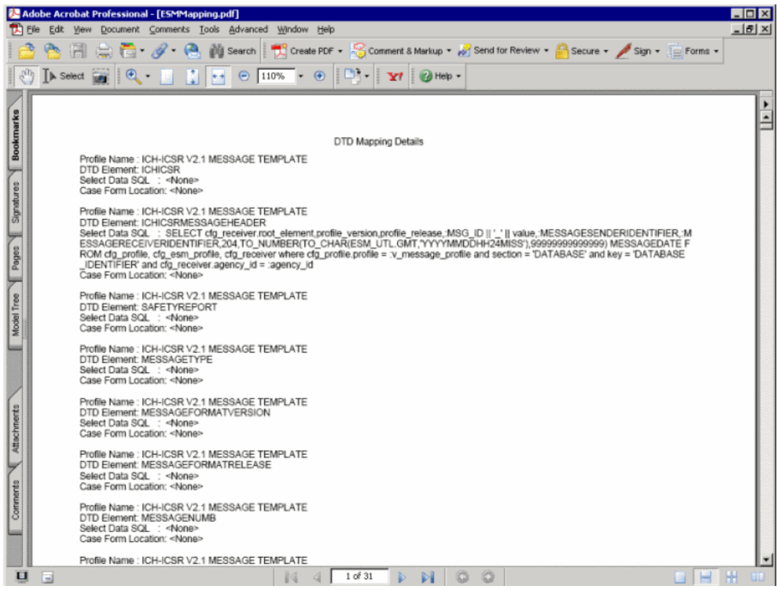


Printing a Profile

Use the following procedure to print a profile.

1. Select Administrator -> Print Profile.
2. This prints the selected profile to your default printer.

The following is an illustration of a printed profile.

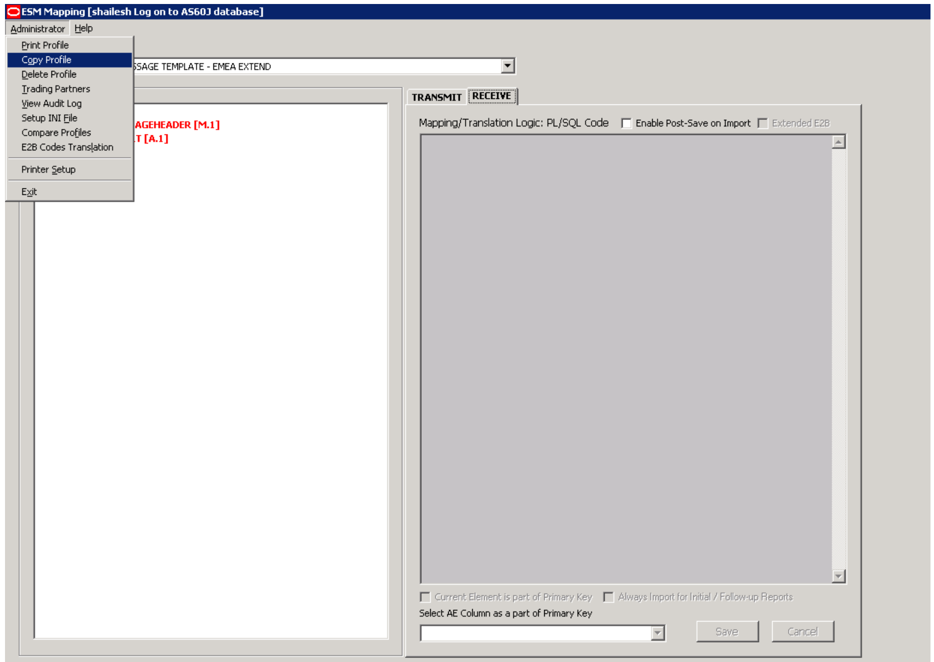


Copying a Profile

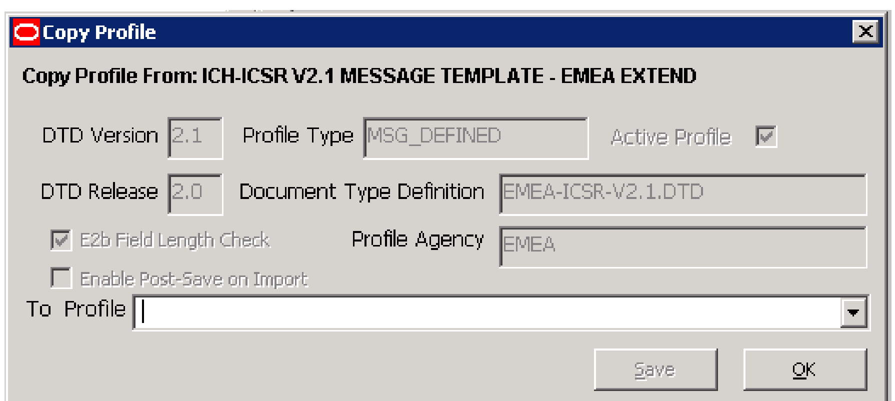
Note: The Copy Profile option can be used to create custom E2B profiles with customized Export / Import mapping logic for any E2B element. However, any new changes / fixes applied to factory E2B profiles are not automatically applied on the custom E2B profiles. Hence, the custom profile logic may get obsolete by any Argus Safety version upgrade which has changes / fixes applied to factory E2B profiles. In such a scenario, customers should re-create their custom E2B profile again, by copying the new factory E2B profile and applying their custom Export / Import mapping logic manually.

Use the following procedure to copy a profile.

1. In the Profile list, select the profile to copy.



2. Select Administrator -> Copy Profile, to open the Copy Profile dialog box.



3. Type the profile name in the To Profile field, click Save, and click OK.

Deleting a Profile

You can only delete profiles created or modified in the Interchange Mapping Utility interface. You cannot delete the pre-installed Argus Interchange profiles.

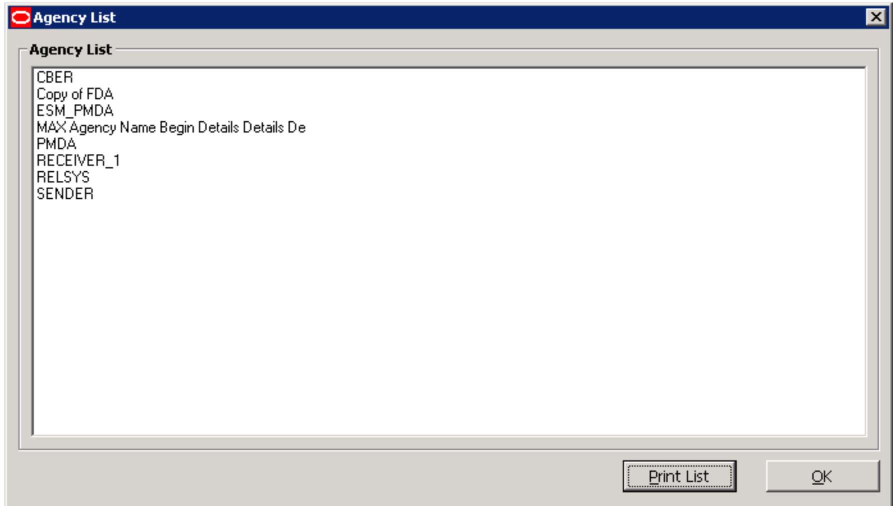
To delete a profile

1. Select the profile to delete from the Profile list.
2. Select Administrator -> Delete Profile.
3. Click Yes to confirm the deletion of the profile.

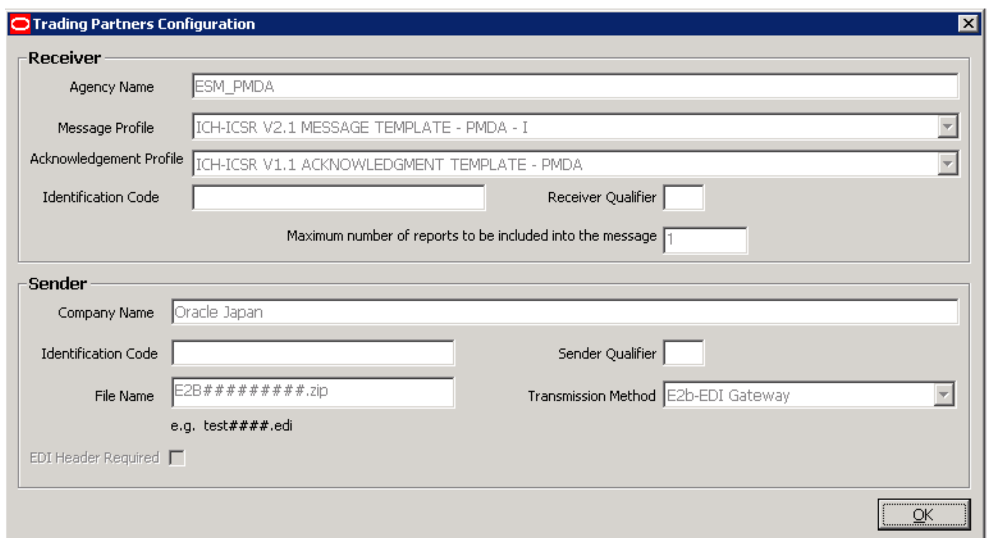
Viewing Regulatory Authorities/Trading Partners

Use the following procedure to view regulatory authorities/trading partners.

1. Select Administrator->Trading Partners to open the Agency List dialog box.



2. Double-click the required Regulatory Authority or Trading Partner to view its details.
3. The system opens the Trading Partner Configuration dialog box. You cannot modify the information in the dialog box.



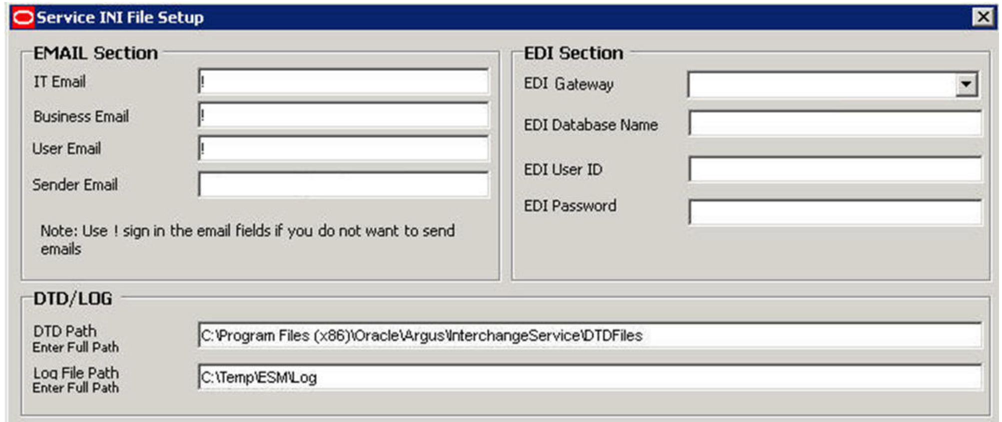
Note: To modify or create new Regulatory Authorities/Trading Partners, choose Reporting Destination in the Code List in Argus Console.

Configuring Argus Interchange Service

You can configure the Argus Interchange Service by updating the initialization (INI) file from the Argus Interchange Mapping interface.

To configure Argus Interchange Service:

1. Select Administrator -> Setup INI File menu in the Interchange Mapping Utility to open the Service INI File Setup dialog box.



2. Use the items in the Service INI File Setup dialog to configure the Argus Interchange Service INI file.
3. Enter the data for each field as required.

Service INI File Setup Dialog Box

The following tables lists and describes the fields in the Service INI File Setup dialog box.

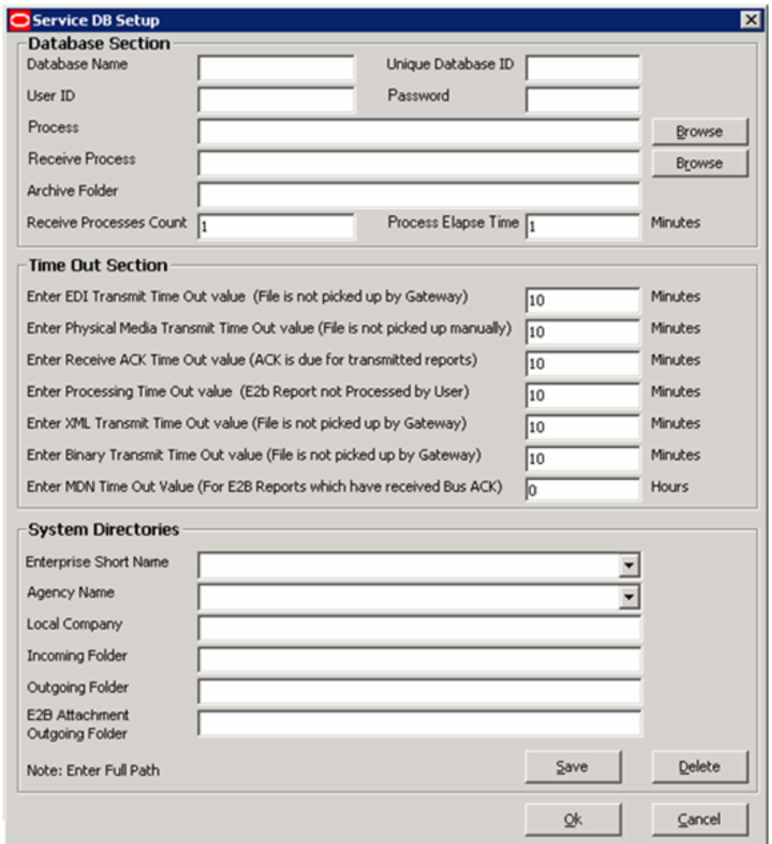
Item	Description
IT E-mail	Enter the e-mail address that Argus Interchange Service should use to send e-mails, if the transmit time out occurs for Physical Media or EDI Gateway.
Business E-mail	Enter the e-mail address that Argus Interchange Service should use to send e-mails, if the Receive ACK time-out value is reached.
User E-mail	Enter the e-mail address that Argus Interchange Service should use to send e-mails, when the user does not process the E2B Report within the time-out value. The Argus Interchange Service uses SMTP as its mail system.
Sender E-mail	Enter the e-mail address that Argus Interchange Service should display, as the 'From' address in the e-mails that it sends.
EDI Gateway	Select the name for the EDI Gateway - from either Axway Cyclone or Oracle B2B.
EDI Database Name	Enter the database name for the EDI software.
EDI User ID	Enter the user name for EDI database.
EDI Password	Enter the password for the user name associated with the EDI database.
DTD Path	Enter the path for the DTD file.
Log File Path	Enter the path where the Argus Interchange Service will write the log files.
Multiple Database Section	Displays all the configured databases for ESM Service.
Delete Button	Click Delete to remove the entire Database Configuration from ESM Service INI File.

Adding a Database for Argus Interchange Service

You can configure the Argus Interchange Service to support multiple database.

To configure a database:

1. In the Setup INI File dialog box, double click Add New Process to open the Service DB Setup dialog.



2. Use the items in the Service DB Setup dialog to configure the ESM Service INI file.
3. Enter the data in the fields as required.

Note: ESM Service.ini can be configured for MAX_FILES_IMPORT_PER_RUN at database level under the Database section. This should be set to a number. This determines how many files are read from incoming folder so as to allocate to Receive Process(es). This includes both ICSR reports and Acknowledgments. If it is not defined, an internal limit of 1000 is assumed.

Service DB Setup Fields

The following table lists and describes the fields in the Service DB Setup dialog box.

Item	Description
Database Name	Enter the name of the Adverse Event database.
Unique Database ID	Identifies each database uniquely. In the case of multiple databases, the value of this field should be unique.

Item	Description
User ID	Enter the user name for the Service.
Password	Enter the password associated with the User Name entered in the USER ID field.
Process	Enter the full path of the ESMProc.exe file. The system uses this path to locate the ESMProc.exe file.
Receive Process	Enter the full path of the E2BReceive.exe file. The system uses this to locate the E2BReceive.exe file.
Archive Folder	Enter the full path where the system places the file processed by Argus Interchange.
Receive Processes Count	Enables you to specify multiple E2B receive processes You can specify from 1 to 5 E2B receive processes The default is 1.
Process Elapse Time	Enter the time interval for the Argus Interchange Process to run.
Enter EDI Transmit Time out Value	The amount of time, in minutes, that must pass before the system sends an e-mail message when an E2B Report has not been transmitted within a specified time period. Note: The minimum value for the time-out is 10 minutes.
Enter Physical Media Transmit Time out Value	Enter amount of time, in minutes, that must pass before the system can send an e-mail message when an E2B Report has not been sent manually by a specified person within a specified time period. Note: The minimum value for the time-out is 10 minutes.
Enter Receive ACK Time Out Value	Enter the amount of time, in minutes, that must pass before the system can send an e-mail message when an ACK message has not been received within a specified time period. Note: The minimum value for the time-out is 10 minutes.
Enter Processing Time Out Value	Enter the amount of time, in minutes, that must pass before the system can send an e-mail message when an Incoming Report has not been processed within a specified time period. Note: The minimum value for the time-out is 10 minutes.
Enter XML Transmit Time Out Value	Enter the amount of time, in minutes, that must pass before the system can send an e-mail message when an XML file is not picked up by the Gateway. Note: The minimum value for the time-out is 10 minutes.
Enter Binary Transmit Time Out Value	Enter the amount of time, in minutes, that must pass before the system can send an e-mail message when a binary file is not picked up by the Gateway. Note: The minimum value for the time-out is 10 minutes.
Enter MDN Time Out Value	Enter the amount of time, in hours, that must pass before the system stops polling the MDN information from the EDI server after receiving the Business ACK for a transmitted report.
Enterprise Short Name	Select the relevant enterprise short name, from the alphabetically-sorted list, containing all the enterprise short names. When an enterprise is selected, it loads the list of agencies for that enterprise in the Agency Name drop-down list.

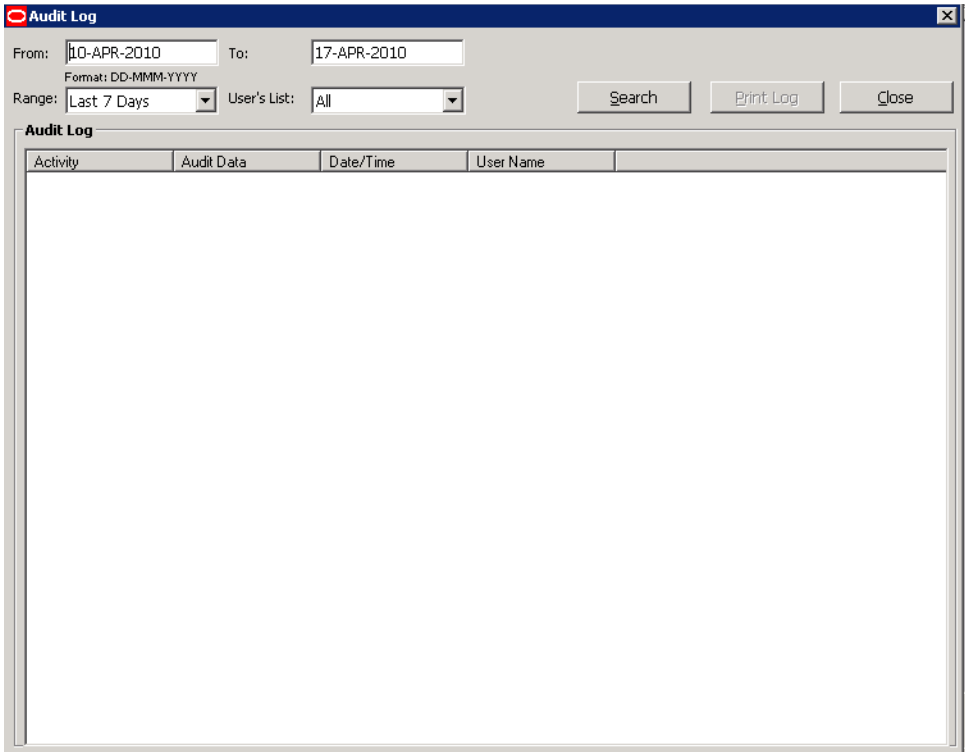
Item	Description
Agency Name	Select the Agency from the drop-down list. This list contains all the agencies of the enterprise which had been selected in the Enterprise Short Name drop-down list. Note: If you change an agency name and also change the Incoming/Outgoing folders for the agency, the application prompts you to save the changes made.
Local Company	The system automatically populates this field when Agency is selected.
Incoming Folder	Enter the path to the folder where incoming files are stored.
Outgoing Folder	Enter the path to the folder where outgoing files are stored.
E2B Attachment Outgoing Folder	Enter the path to the folder where outgoing E2B attachments are processed.
Save Button	Click Save to set the Folder Paths configured for the Agency as Default. When selecting another agency to configure from the Drop Down, all the Paths will remain.
Delete Button	Click Delete to delete the entire configuration for the Agency selected only.

Viewing the Audit Log

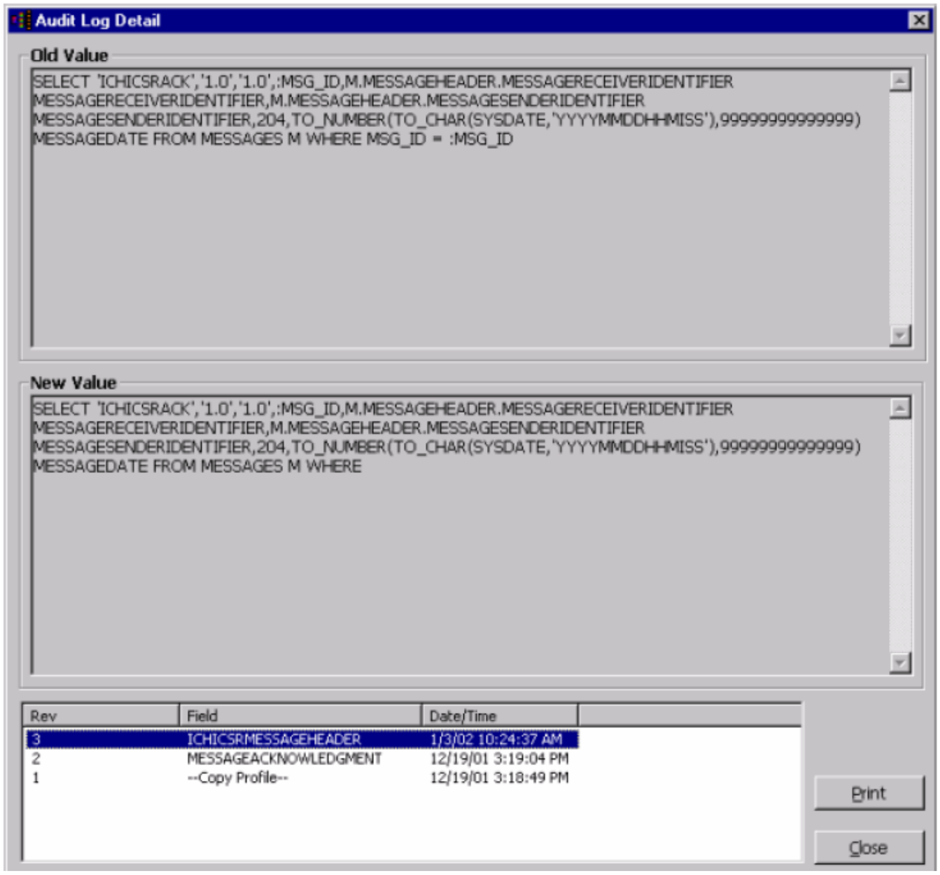
The audit log stores changes made to the system from the application in the audit log. You can also view and filter individual changes.

To view the audit log:

1. Select Administrator -> Audit Log.
2. When the system opens the Audit Log dialog box, enter the appropriate data in each field and click Search.



3. When the system displays the search results, double-click a row to view detailed information about the changes made in the Audit Log Detail dialog box.



4. Select an item in the list at the bottom of the Audit Log Details dialog to view details of the old value and the new value of the selected item.

Audit Log Dialog Box Fields

The following table lists and describes the fields in the Audit Log dialog box.

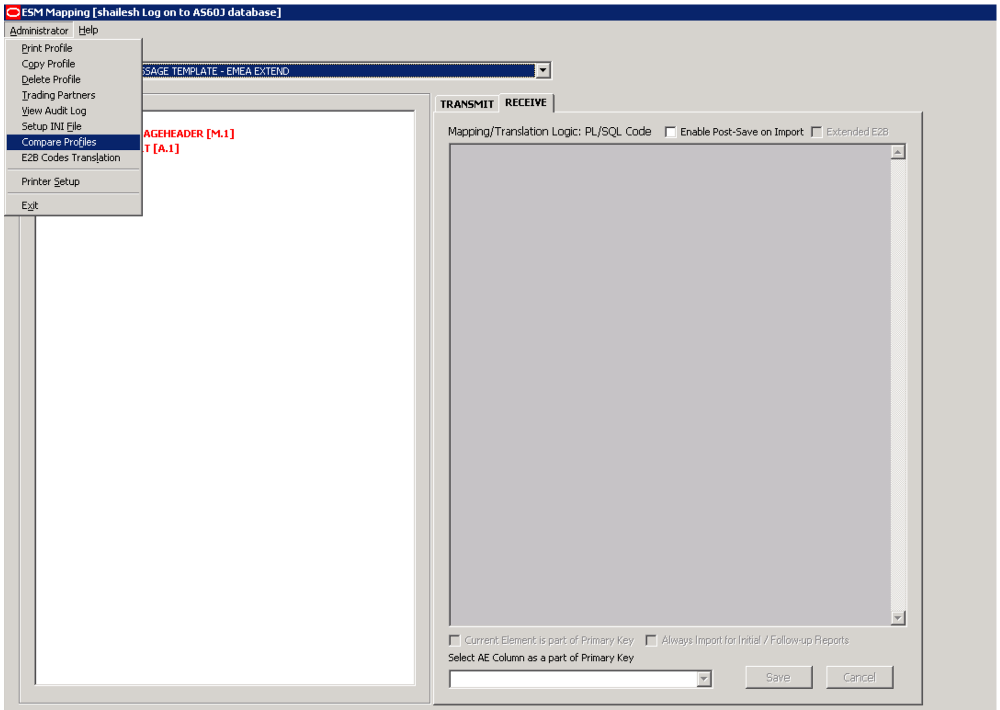
Item	Description
From	Enter the search start date.
To	Enter the search end date.
Range	Select a pre-configured date range on for the search. Note: When the Argus Interchange Audit log is invoked, it shows the default range of the last 7 days.
User's List	Select a user from the list of users.
Print Log	Prints the current view.
Search	Performs the search.
Close	Closes the dialog.

Comparing DTD Profiles

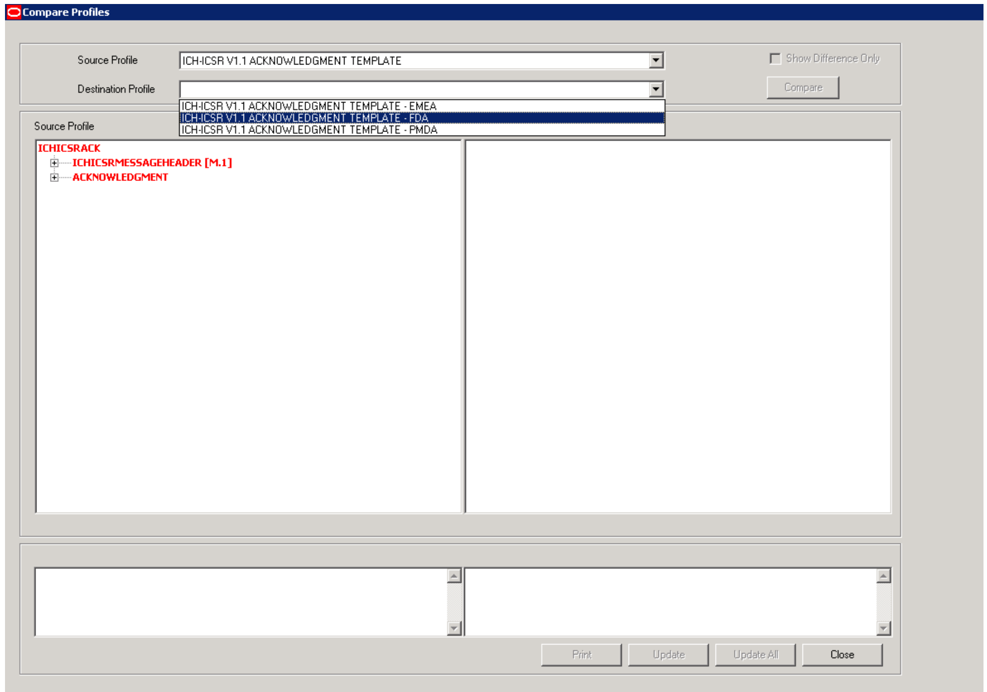
You can compare two DTD profiles to find element-level differences. Select a source profile in the left pane and a target profile in right pane and run the Compare Profiles utility to generate the differences. The Compare Profiles utility also enables you to update the SQL statements (at the element level) of the Destination Profile elements with those of the Source Profile.

To compare DTD profiles:

1. On the Argus Interchange Mapping Utility menu bar, click Administrator -> Compare Profiles.



2. When the system opens the Compare Profiles dialog box, use the items in the Compare Profiles dialog to compare profiles.



3. Enter the data in the files as required.

Compare Profile Dialog Box Fields

The following table lists and describes the fields in the Compare Profile dialog box.

Item	Description
Source Profile drop-down	Is used for selecting a source profile from the available profiles configured in the system.
Destination Profile drop-down	Displays the profiles with the same DTD version and type (message/acknowledgement) as the ones in the Source profile.
	Note: The source profile is to be selected before selecting the destination profile. The destination profile is disabled if you have not selected the source profile.
Show Difference Only	Displays those nodes that contain different SQL statements between the source and destination profiles when this checkbox is checked.
Compare	Compares the differences between the source and destination profiles when this button is clicked.
	Note: The elements that are different in the Source and Destination profiles are displayed in a light gray background color.
Source Profile pane	Displays the source profile and its elements in a tree structure. When you click on any of the elements, the corresponding SQL statements are displayed on the source profile textbox, which is on the left-corner below the Source Profile pane.

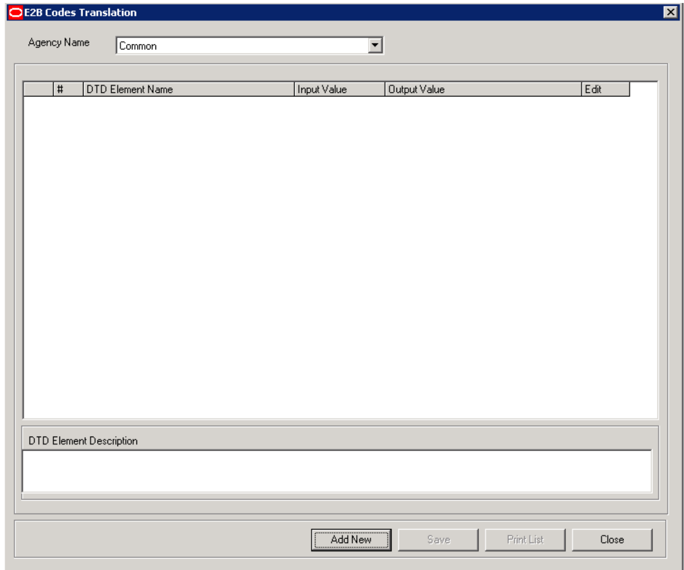
Item	Description
Destination Profile pane	Displays the destination profile and its elements in a tree structure. When you click on any of the elements, the corresponding SQL statements will be displayed on the Destination profile textbox, which is on the right-corner below the Destination Profile pane.
Print	Prints all the SQL statements of the source and the destination profile with differences highlighted. Note: If there are no differences between the source and destination profiles, the following pop-up message is displayed: "No differences found' and no report shall be printed."
Update	Updates the individual SQL statements related to each element. Clicking the Update button also updates SQL statements in the destination profile. Note: The Update button is enabled when the nodes with different SQL statements are clicked.
Update All	Updates all the differences in SQL statements across all the elements between the source and destination profiles. Note: When a user clicks the Update All button, the following pop-up message is displayed: "Are you sure you want to update all the SQL statements in Destination Profile with Source Profile?" Clicking Yes updates all the SQL statements whereas clicking No does not update.
Close	Closes the Compare Profiles window.

Note: The Update and Update All buttons are never enabled when the profile selected from the Destination Profile is of the type template.

E2B Codes Translation

E2B Codes Translation enables you to configure rules to translate the E2B codes and values in the incoming E2B reports, which come from different trading partners to preferred values in the AE system during case creation.

In the Interchange Mapping Utility, click Administrator -> E2B Translation Codes to open the E2B Code Translation screen.



E2B Codes Translation Fields

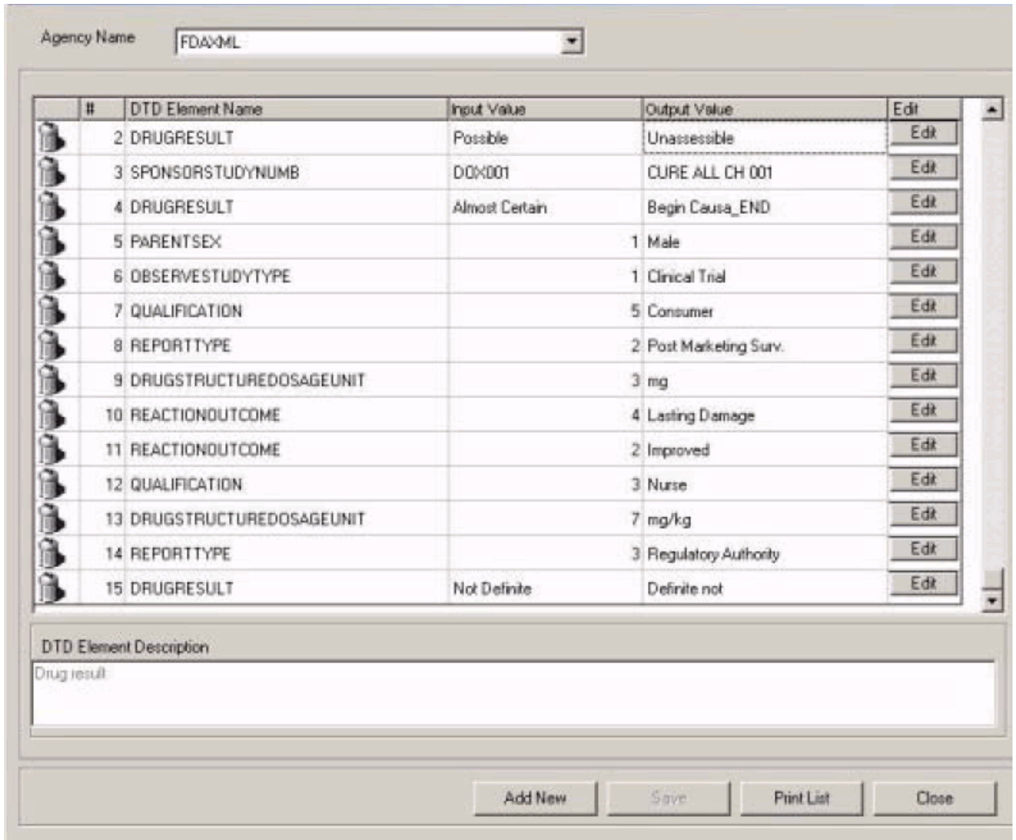
The following table lists and describes the fields on the E2B Codes Translation screen.

Item	Description
Agency Name	Enables the user to select an agency name from the drop-down list box.
#	Displays the serial number.
DTD Element Name	Displays the DTD element name.
Input Value	Displays the type of input value
Output Value	Displays the type of output value.
Edit	Enables you to edit the information

Configuring E2B Codes Translation

Use the following procedure to configure E2B Codes Translation.

1. Select the Agency Name from the drop-down list box to displays the DTD Elements and their descriptions.
2. Click Edit to edit the DTD Element Name, Input Value, Output Value, and DTD Element Description.



3. Click Save to save your changes.

E2B Extensions

You can use the existing reporting destination configuration to choose an extended E2B profile. The system uses the agency and company identifier to identify the profile to use and sends the information in the following XML elements:

```
<messagesenderidentifier>Company X</messagesenderidentifier>
```

```
<messagereceiveridentifier>Agency Y</messagereceiveridentifier>
```

The Interchange mapping utility also supports the defined extended E2B elements as follows:

- A switch in the Interchange mapping tool identifies a profile as either a standard profile or an extended E2B profile but only for the Receive tab. The additional fields are formatted as follows:

  <XXX>_EXTENSION []

  where:

  XXX is the tag name followed by _EXTENSION to indicate that this is an extended E2B tag element

  When using this switch:

  – Do not enter any blank spaces or underscore characters (_) in the XXX naming convention.

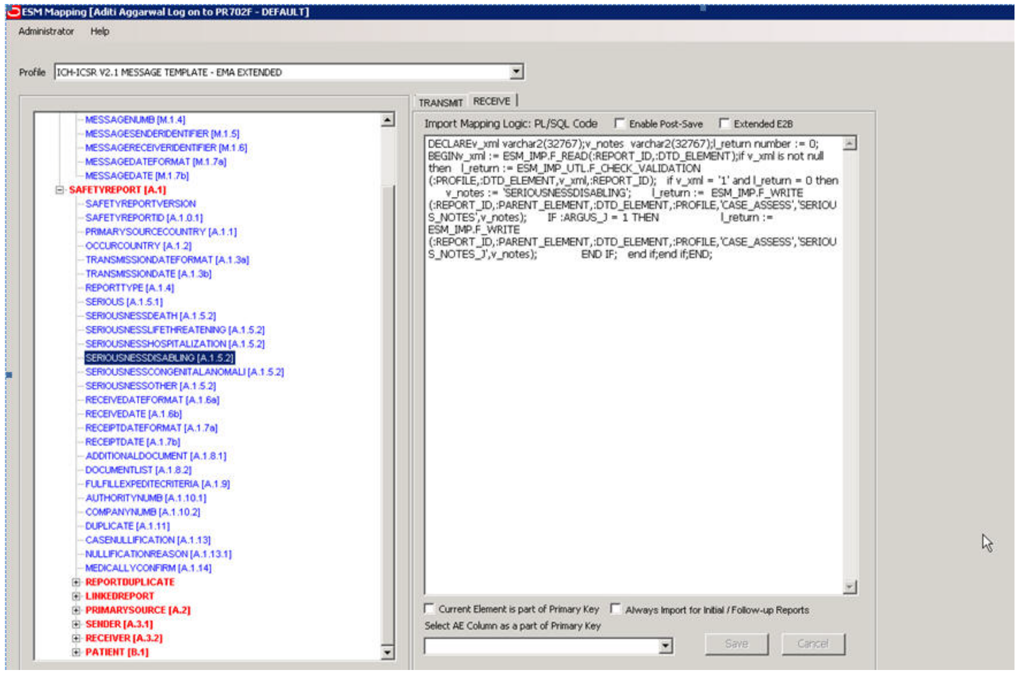
- In the extended E2B tags, the element number in the brackets ([ ]) is always empty. For example, Patient Ethnicity, Event Hospitalized Start Date / Stop Date.
- This switch is enabled only for profiles copied from the Factory profiles (default unchecked). This flag is disabled for all factory profiles.
- During configuration, GPS updates the DTD profile with this information before it adds any additional E2B elements.
- The extended E2B fields are mapped to existing Argus fields or to user-defined fields, as appropriate. For example, the system maps the following extended E2B fields to the following Argus tables.

E2B + Field	Argus Case Form UI Field Name	Argus Field Label Description
patientethnicity_extension	PATIENT | Patient Ethnicity	Patient Ethnicity
reactionintensity_extension	EVENTS | Event Intensity	Event Intensity
reactionhospstartdateformat_extension	Argus Date entry format YYYYMMDD or YYYYMM or YYYY	Hospitalized Start Date Format
reactionhospstartdate_extension	EVENTS | Hospitalized Start Date	Hospitalized Start Date
reactionhospstopdateformat_extension	Argus Date entry format YYYYMMDD or YYYYMM or YYYY	Hospitalized Stop Date Format
reactionhospstopdate_extension	EVENTS | Hospitalized Stop Date	Hospitalized Stop Date

- The system sends an acknowledgement when the report is accepted or rejected by the user.

You can view the extended elements for the following:

- ICSR Viewer
  - No updates to the CIOMS / MedWatch Reports
  - The Decoded View / SGML View displays the additional elements added as a part of the Extended E2B



- E2B Selective Intake for Initial and E2B Difference Report for Follow-up E2B Reports
  - You can selectively import the additional fields the system adds to the Extended E2B in the Argus case.
  - The PDF reports display the additional fields added to the Extended E2B.
- The E2B Warnings/Errors display the warnings/errors if warnings or errors defined for the fields added to the Extended E2B.

Argus Console

The Argus Console enables you to configure the Regulatory Authorities to which E2B Reports need to be submitted. In accordance with ICH Guidelines, you can configure additional Code List items with new E2B codes.

This section includes discussions of the following:

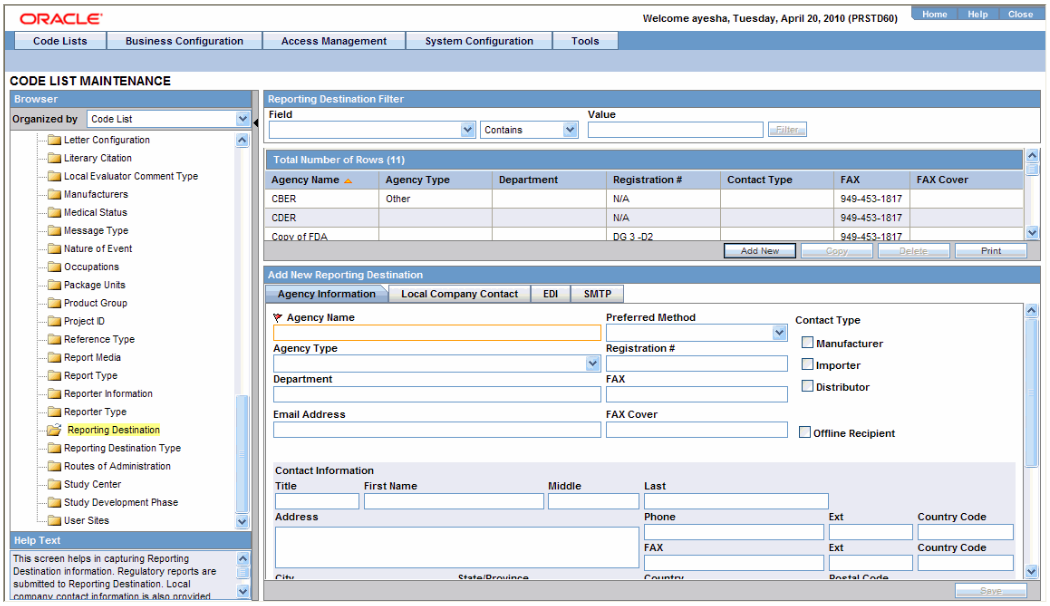
- Configuring Regulatory Authorities
- Configuring SMTP
- Configuring Code List Items

Configuring Regulatory Authorities

Transmitting E2B reports to an Agency/Trading Partner, requires you to create a regulatory authority entry in the Code List. After creating the regulatory authority, you can transmit regulatory reports to it.

To configure a regulatory authority:

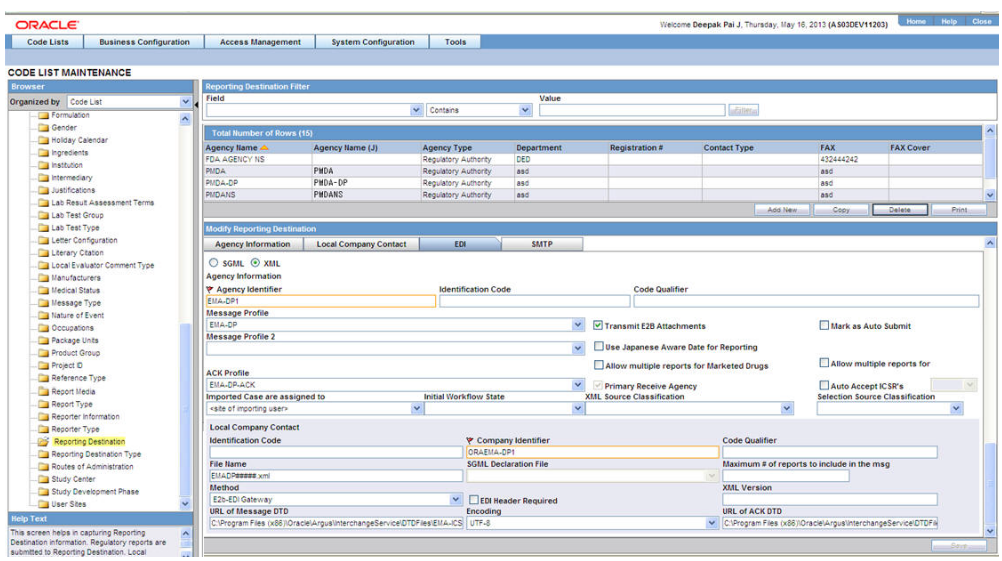
1. On the Argus Console, Click Code Lists -> Argus.
2. When the system opens the Code List Maintenance screen, select Reporting Destination from the list.



Note: If a report is already scheduled for a Reporting Destination, then clicking on the Delete button displays an error message that this item is already being used, and hence, cannot be deleted.

Refer to the Argus Safety Guide for information on using the first three tabs of the Reporting Destination.

3. Click the EDI tab, select the appropriate data for each item, and enter the data in the fields as required.



EDI Tab Fields

The following table lists and describes the fields on the EDI tab.

For Argus J users, an additional field called "Message Profile 2" shows up for the configuration of the PMDA - J profile. This field is required for PMDA agency to specify PMDA J profile.

Field/Control Name	Description
SGML/XML	Enables the user to select whether to send the report in SGML or XML format.
Agency Identifier	Enables the user to enter the routing ID configured in Cyclone for the sender community.
Identification Code	Enables the user to enter the agency Duns code, a unique identification code that identifies the trading partner. This field is disabled for the E2B (R3) profile.
Code Qualifier	Enables the user to enter the code qualifier here. The code qualifier is used to interpret the identification code. This field is disabled for the E2B (R3) profile.
Message Profile	Enables the user to select a message profile.
Mark as Auto Submit	Enables the user to mark the report for auto submission.
Auto Accept ICSR's	Click this checkbox to auto accept ICSR's. This checkbox is visible only when case numbering is set to **Automatic**.
ACK Profile	Enables the user to select the acknowledgement profile.
Primary Receive Agency	Enables the user to select the primary receiving agency.
Imported Cases are assigned to	Enables the user to select the country, where the imported cases need to be assigned. **Note:** This list comprises the configured Argus sites. The default value is the site of the importing user.
Initial Workflow State	Enables the user to configure the initial workflow state of the case. **Note:** This list comprises Argus workflow states, with the default value being blank. If you select blank as the workflow state, it is treated as a new case being booked-in.
XML Source Classification	The system enables the user to configure the XML Source Classification and the PDF Source Classifications used for classifications defined while the Source E2B File / PDF for Initial Intake or E2B Differences report is classified. When a case is accepted as an initial or follow-up case, the system attaches the source XML and the Initial Selection PDF to the case on the Additional Info tab.
Selection Source Classification	Enables the user to select the source classification from the drop-down.
Transmit E2B Attachments	Click this checkbox to transmit E2B attachments. If this checkbox is checked in the Reporting Destination Code List, case form attachments are sent to the specified reporting destination.
Attachment Classification	Enables the user to select the attachment classification.
Identification Code	Enables the user to enter the company Duns code, a unique identification code that identifies the trading partner.
Company Identifier	Enables the user to enter the company identifier
Code Qualifier	Enables the user to enter the code qualifier here. The code qualifier is used to interpret the identification code.

Field/Control Name	Description
File Name	Enables the user to enter the file name
SGML Declaration File	Enables the user to enter the SGML Declaration File.
Maximum # of reports to include in the msg	Enables the user to enter the maximum number of reports that will be transmitted in one message.
Method	Enables the user to select a method here. This field contains **E2B ESTRI Gateway** and **E2b Media** values.
EDI Header Required	Enables the user to generate the EDI Header
XML Version	Enables the user to enter the XML Version.
URL of Message DTD	Enables the user to enter the path where the message DTD resides on the internet or enter full path if it is located on the disk.
Encoding	Enables the user to select the character set encoding used in XML
URL of ACK DTD	Enables the user to enter the path where the ACK DTD resides on the internet or enter the full path if it is located on the disk.

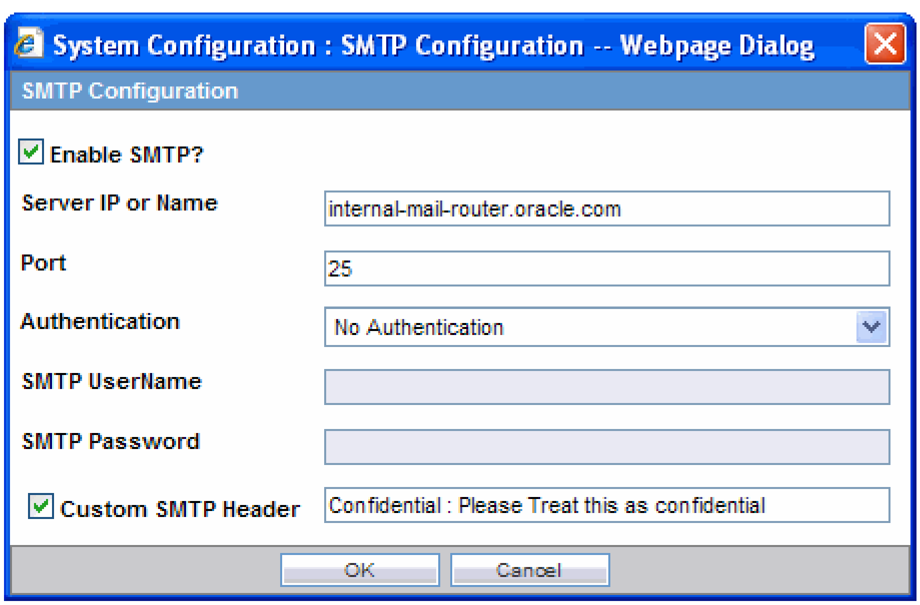
Configuring SMTP

Argus Interchange Mapping Utility can be configured to send emails to notify the appropriate people on the occurrence of some incidents or errors while processing E2B reports. These emails are sent using Argus Safety Service. You can use Argus Console if you need to configure these emails to be sent using SMTP.

To enable Argus Safety Service to use the SMTP protocol to send e-mail to the e-mail server, use the SMTP Configuration Utility in the following way.

To configure SMTP:

1. Open Argus Console.
2. When the system opens the Code List Maintenance screen, click System Configuration -> SMTP Configuration.



3. When the system opens the SMTP Configuration dialog box, enter the appropriate data in each field.

SMTP Configuration Dialog Box Fields

The following tables lists and describes the fields in the SMTP Configuration dialog box.

Item	Description
Server IP or Name	The SMTP server IP address or name.
Port	The port number. The default port number is 25.
Authentication	The authentication type to use. Basic Authentication -- The user must enter a user name and password in the Username and Password fields. No Authentication -- The Username and Password fields are disabled. NTLM Authentication, the authentication of the OS user logged into the system is automatically passed. Additionally, the Username and Password fields are disabled in this authentication.
SMTP Username	The SMTP username.
SMTP Password	The SMTP password.
Enable SMTP?	Select this check box to ensure that AG Service uses SMTP to send e-mail.

Configuring Code List Items

Argus Safety Codelist values are associated to E2B Codes for the applicable factory data items. If you enter new codelist values, appropriate E2B codes must be entered for sending the newly added data in E2B reports.

3

Validating E2B Reports

In order to successfully transmit any E2B Report, it must validated for its mandatory components before transmitting the report.

Why perform an E2B Check?

During case data entry and prior to E2B file generation, the user may want to verify that sufficient data and the quality of data collected will generate a valid E2B file.

To do so, a Data Validation check is required for E2B profiles and to provide a listing of data elements that do not satisfy the criteria required to generate an E2B report.

On performing an E2B check, the system performs a validation and lists the following types of validation errors for the data elements that are failing the validations in 'E2B Report data check errors and warnings':

1. Mandatory
2. Mandatory Optional
3. Together DTD Element Validation
4. Other Validation
5. Date Validation
6. E2B Generation Validation (Fatal Validations)

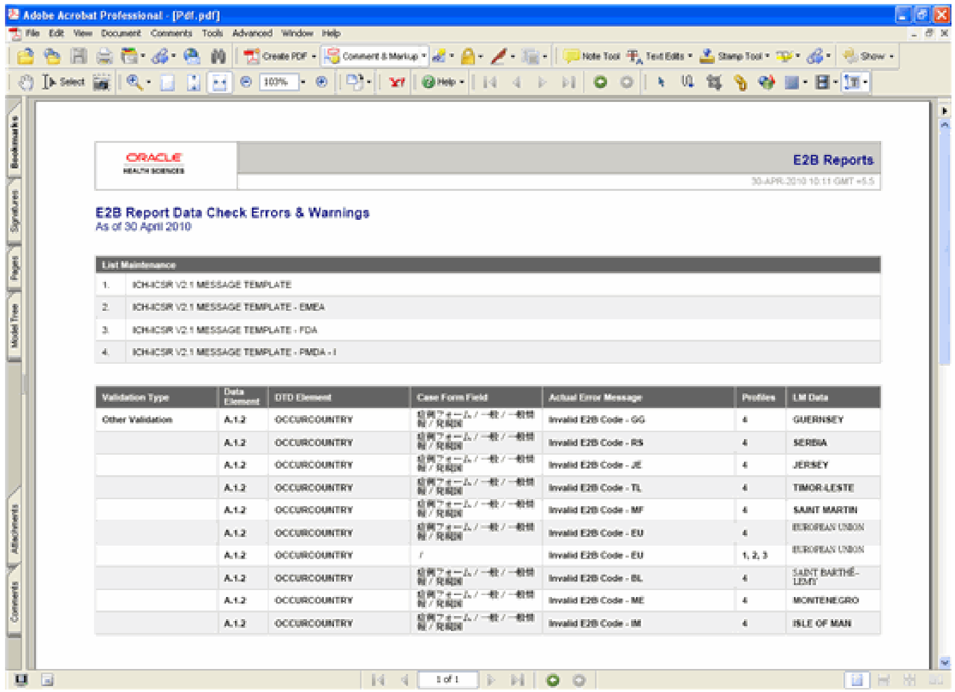
You can run an E2B check by clicking the E2B icon from the Quick Launch menu shown below.

Note: The E2B check icon is visible on the Quick Launch Toolbar ONLY if a case is open and active on the user session.

Running an E2B check validates if the E2B report has all these mandatory elements present that is required for its successful processing.

This check performs the function that prints the “E2B Report – DTD Length Check Warnings” and “E2B report – DTD Validation”.

The following illustration shows a sample E2B check report that is generated in PDF format:



E2B Reports

30-APR-2010 10:11 GMT +5.5

E2B Report Data Check Errors & Warnings
As of 30 April 2010

List Maintenance	
1.	ICH-ICSR V2.1 MESSAGE TEMPLATE
2.	ICH-ICSR V2.1 MESSAGE TEMPLATE - EMEA
3.	ICH-ICSR V2.1 MESSAGE TEMPLATE - FDA
4.	ICH-ICSR V2.1 MESSAGE TEMPLATE - PMDA - I

Validation Type	Data Element	DTD Element	Case Form Field	Actual Error Message	Profiles	LM Data
Other Validation	A.1.2	OCCURCOUNTRY	症例フォーム / 一般 / 一般情報 / 発現国	Invalid E2B Code - GG	4	GUERNSEY
	A.1.2	OCCURCOUNTRY	症例フォーム / 一般 / 一般情報 / 発現国	Invalid E2B Code - RS	4	SERBIA
	A.1.2	OCCURCOUNTRY	症例フォーム / 一般 / 一般情報 / 発現国	Invalid E2B Code - JE	4	JERSEY
	A.1.2	OCCURCOUNTRY	症例フォーム / 一般 / 一般情報 / 発現国	Invalid E2B Code - TL	4	TIMOR-LESTE
	A.1.2	OCCURCOUNTRY	症例フォーム / 一般 / 一般情報 / 発現国	Invalid E2B Code - MF	4	SAINT MARTIN
	A.1.2	OCCURCOUNTRY	症例フォーム / 一般 / 一般情報 / 発現国	Invalid E2B Code - EU	4	EUROPEAN UNION
	A.1.2	OCCURCOUNTRY	/	Invalid E2B Code - EU	1, 2, 3	EUROPEAN UNION
	A.1.2	OCCURCOUNTRY	症例フォーム / 一般 / 一般情報 / 発現国	Invalid E2B Code - BL	4	SAINT BARTHÉ-LEMY
	A.1.2	OCCURCOUNTRY	症例フォーム / 一般 / 一般情報 / 発現国	Invalid E2B Code - ME	4	MONTENEGRO
	A.1.2	OCCURCOUNTRY	症例フォーム / 一般 / 一般情報 / 発現国	Invalid E2B Code - IM	4	ISLE OF MAN

As can be seen in the PDF, the sample report displays the case form fields where the validation error has occurred.

Apart from the case form location where the error occurred, the report lists the type of error, data elements, DTD elements, the actual message/cause of the error, and the profiles which were tested for each validation type.

The validation checks are profile-dependent but every E2B check report tests for Mandatory Elements check and Mandatory Optional Elements check.

Report Generation Validations

The system performs the following validations at the time of report generations and displays validation error if there are failures:

1. Missing Mandatory Elements
2. Missing Mandatory Optional Elements
3. Length Validation for character data
4. M2 Code validation
5. NCI Code data validation (for eVAERS only)
6. Report File Size validation (for eVAERS only)

The system displays an error message in the following scenarios:

1. While generating draft E2B or eVAERS report using Draft tool button, if the default Reporting Destination is not specified for E2B or eVAERS in Common Profile Switches.
2. While generating draft/final E2B or eVAERS report for the Reporting Destination which is not configured with valid Message Profile as E2B or eVAERS respectively.

3. While generating eVAERS report with inline attachments and size of xml file exceeds the maximum file size limit specified in Common Profile Switch.

4

Transmitting and Monitoring Reports

Argus Safety provides utilities that enable you to schedule and transmit E2B reports. Using these utilities, you can also track the status of the transmitted E2B reports. This chapter includes discussions of the following:

- Logging In and Out of Argus Safety
- Scheduling an E2B Report
- Generating a Scheduled E2B Report
- Transmitting E2B Reports

Logging In and Out of Argus Safety

Before starting Argus Safety, ensure that your company's Argus Safety Administrator of your company has created an account for you and that you have the correct Username and Password for the system. Be aware of the following:

- If you enter an incorrect username or password three (3) consecutive times, the system disables the Login button and displays the following message:

  The login button has been disabled due to 3 consecutive incorrect entries of Username or Password. Please refresh the page to enable the Login button.

- The Date/Time format is DD-MMM-YYYY HH:MM:SS to reflect the 24-hour format used by the Web server.

To log in to the Argus Safety application:

1. Open Microsoft Internet Explorer and enter the Uniform Resource Locator (URL) of Argus Safety Web in the Address bar.
2. When the Argus login screen opens, enter your username and password in the appropriate fields.

   > **Note:** The Sign-on screen displays all the products currently in the Oracle Health Sciences Safety Suite. Each product in the list has a hyperlink to open the Oracle Health Sciences Resources website page that provides the product data sheets.

3. Select the appropriate database from the Database drop-down list and click **Login**.

4. Once the system authenticates your log in, you can access the modules that are enabled in the Console.

To Log Out of the Argus Application

Click Logout on the top-right frame of the window to log out of the application.

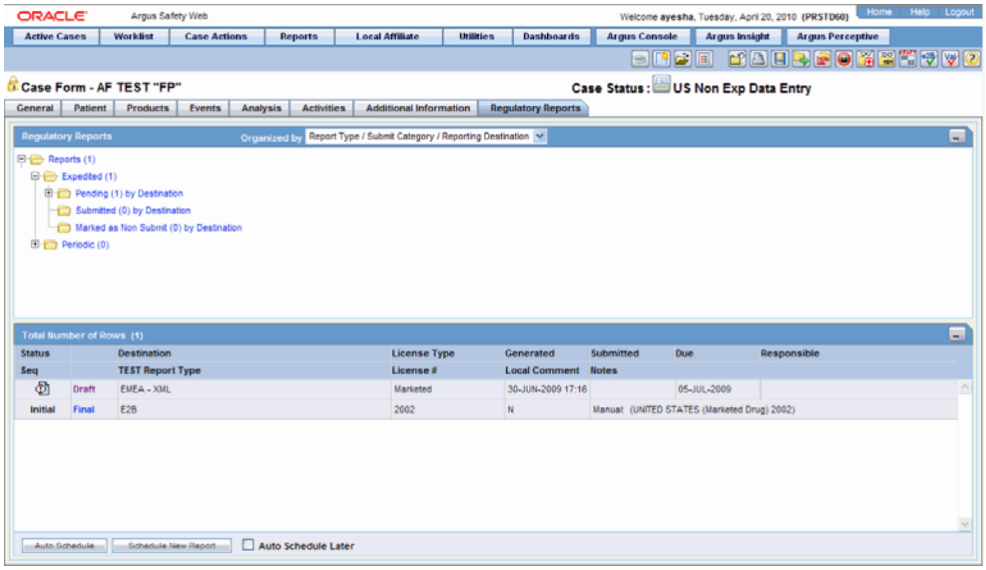
Scheduling an E2B Report

Argus Safety enables you to schedule your E2B reports. In addition, it allows you to generate E2B reports that comply with the adverse event reporting requirements of different regulatory agencies.

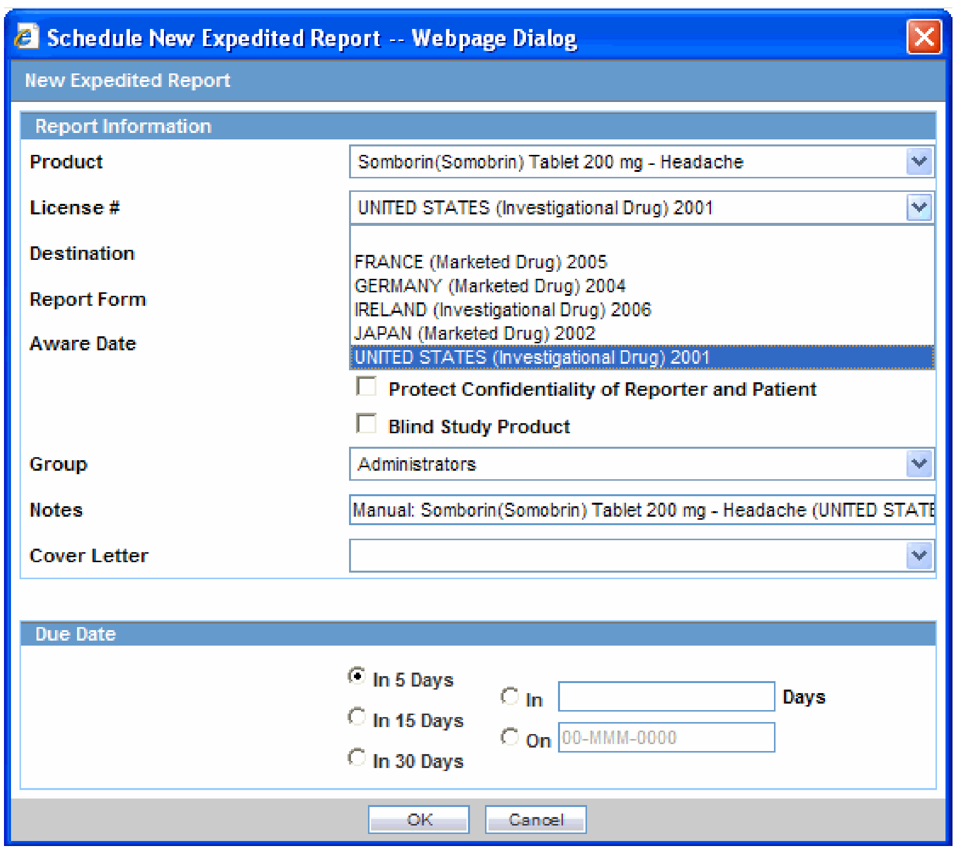
Note: When you generate an E2B report, some characters entered by the user in the case form may not be display in the same way in the E2B report. Some characters are represented differently in the E2B report such as & for (&), < for (<), > for (>), ' for (') and " for (") as per XML specifications.

To schedule an E2B report:

1. Open a case in Argus Safety and click the Regulatory Reports tab.
2. When the system opens the Regulatory Reports tab, click Schedule New Report.

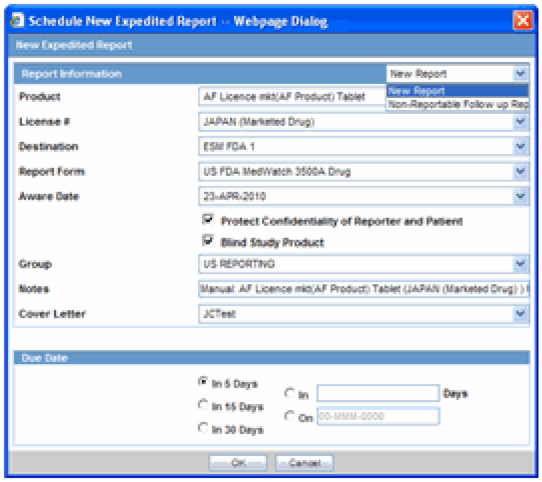


3. When the system opens the New Expedited Report dialog box, enter the relevant information and click OK.



New Expedited Report Dialog Fields

The Schedule New Expedited Report window has a drop-down list on the top section.



The following table lists and describes the fields in the New Expedited Report dialog box.

Item	Function
Product	Select the Company Suspect Product from this drop-down list.
License Number	Select the particular license for which the report is to be scheduled.
Destination	Select the Regulatory Agency to which the report is to be sent.
Report Form	Select the Report Form from this drop down list.
Message Type	Select the message type from the drop-down list. **Note:** This field is displayed when an E2B or eVAERS report is selected as the Report Form. If the Report Form is selected as eVAERS then the Message type is set to ichicsr and is disabled.
Aware Date	List the date when you became aware of the case. Select the Protect Confidentiality of Reporter and Patient checkbox if you do not wish to disclose the identity of the reporter and the patient of the case.
Group	If you want to assign the report to a specific group, the group can be selected from this drop down list.
Notes	This field is directly mapped to the License but you can modify this field to put in extra notes, as desired.
Cover Letter	You can attach a cover letter with the report, if desired.
Due Date	You can decide to schedule a report to be due in either 5, 15, or 30 days or any number of days or even on any specific date.

Note: Product, License Number, Destination, Report Form (E2B), and Due Date must be entered in the New Expedited Report dialog to schedule an E2B report.

Note: The system allows you to generate E2B reports through AG Service irrespective of the your access rights for blinded information. However, the Blind protected users are not allowed to view E2B reports despite having an Argus Interchange license. If such a user tries to view the E2B report, the system generates the message: "Report is generated but system is unable to show the report as user is protected from study information."

Generating a Scheduled E2B Report

Use the following procedure to generate a scheduled E2B report.

1. E2B report can be manually generated by clicking the draft/final links in the row that corresponds to the scheduled E2B Report in In the Regulatory Reports tab. The report is generated and can be viewed in the ICSR Viewer. If a validation error occurs during E2B report generation, the validation details are stored in the Report Details dialog.
2. E2B report is generated by AG Services for a locked case which has scheduled E2B report.

Attachments in Reports

Case Form Attachments are sent to Reporting Destination with E2B(R2) report as described below:

1. If attachment classification in the case is specified in the Reporting Destination, system reads such Attachments and converts .XLS, .TXT, .TIF, .DOC, .RTF, .PNG, .JPG or .BMP them into PDF and combine with the PDF attachments if any in the case.
2. The single merged PDF has each attachment which is merged available as a link (bookmark) by the classification name provided for the attached file.
3. Attachments are sent only if there is a E2B report sent out for that Agency. Attachments are not sent for nullification reports.

Case Form Attachments are embedded within the ICSR that are sent in report format such as E2B(R3) and eVAERS. Only those attachments are sent in the report for which attachment classification is specified in the Reporting Destination. Attachment data is encoded using B64 format. Attachments for E2b(R3) are compressed before embedding to ICSR using compression algorithm configured. Default algorithm used in DF(Deflate).

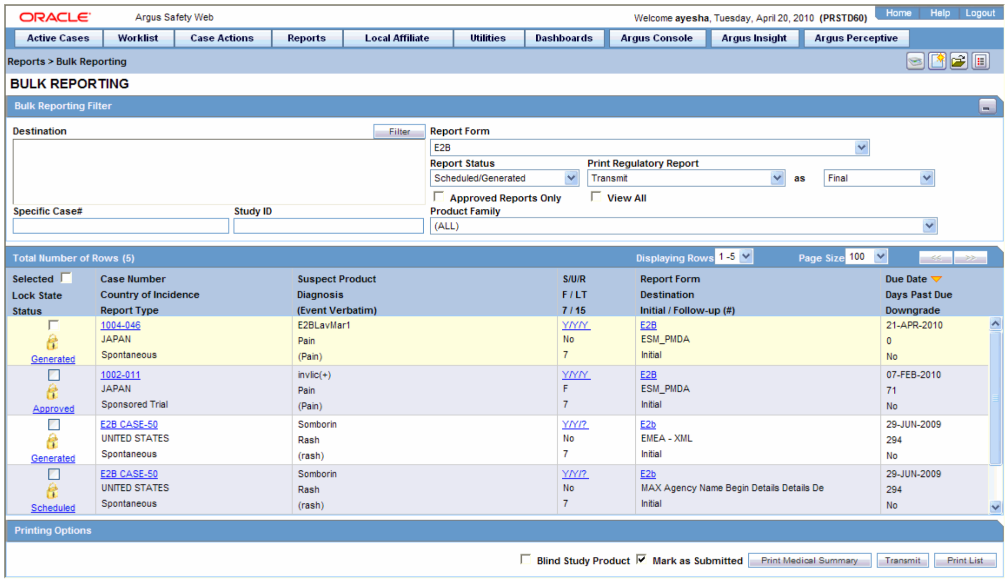
Transmitting E2B Reports

Argus Safety enables you to simultaneously submit multiple adverse event reports to ease the submission process. This section describes how you can use the Bulk Reports by Case and the Bulk Reports by Form features to transmit E2B reports.

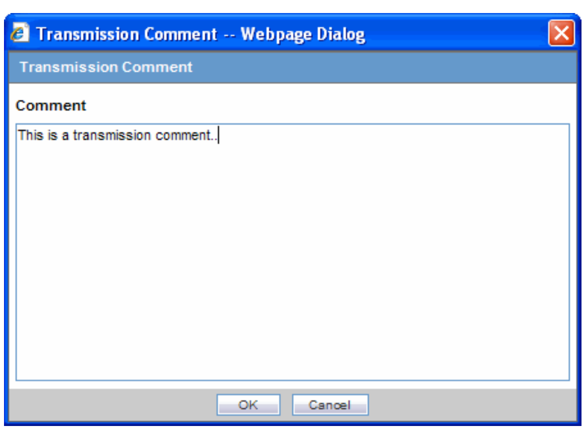
Transmitting Bulk Reports by Form

Use the following procedure to transmit Bulk Reports by Form:

1. Click Reports ->Bulk Reporting.



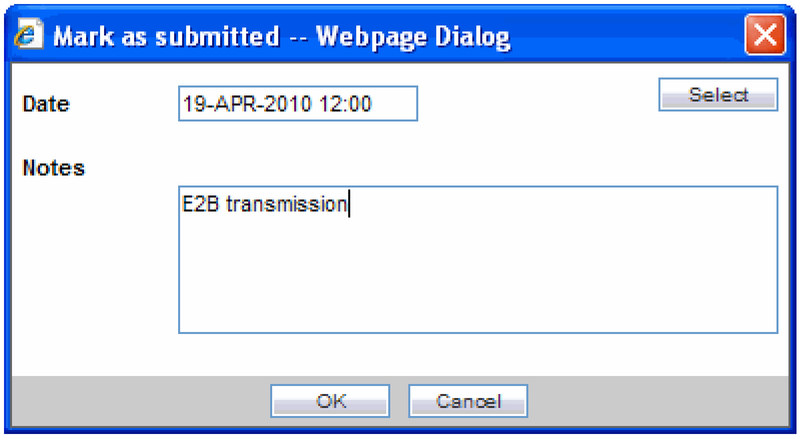
2. When the system opens the Bulk Reporting dialog box, enter the appropriate data in the fields.
3. In the Report Form list, select E2B.
4. Under Printing Options, select Transmit.
5. Select the Mark as Submitted check box if it is required to mark the report as "submitted" after the transmission is successful.
6. Click OK after all the required items in the dialog have been entered. Use the table at the end of this topic to understand the function of each item in the dialog.
7. When the system opens the Transmission Comments dialog box, enter the notes for transmission.



8. Click OK to transmit the report(s)

   OR

Click Cancel to close the dialog box without transmitting the report.



9. If the Marked as Submitted check box was selected in step 5, the system opens the Report Submission Information dialog box.

   Enter the submission notes in the Notes field and click OK.

   Note:

   If the Marked as Submitted check box was not selected, the Report Submission Information dialog does not appear automatically. In this case, once the report has been successfully transmitted, it can be marked as "submitted" from the Worklist as follows:

   Go to Worklist ->Bulk E2B Transmit and verify that the View All radio button is selected.

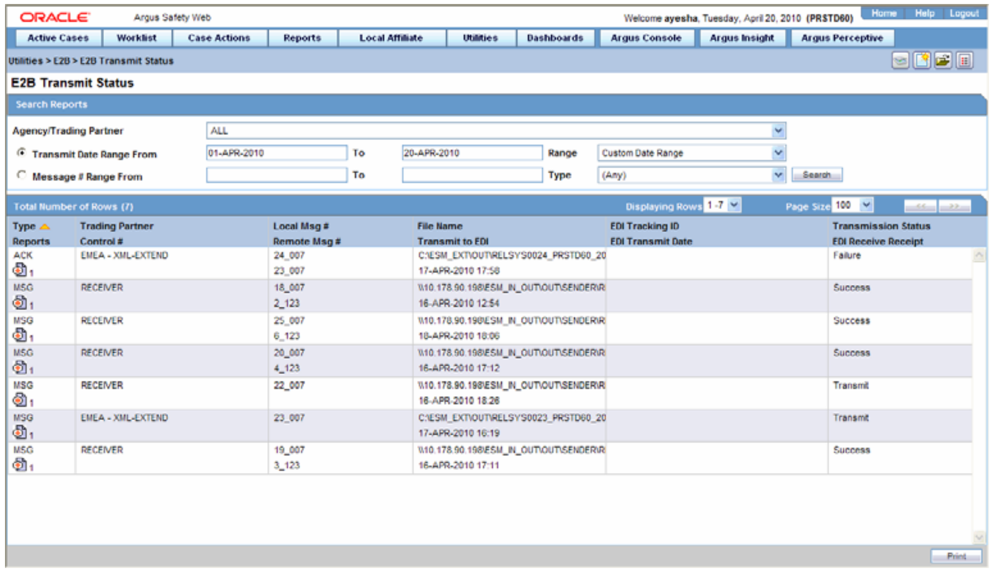
   Scroll in the list to locate the required report. If the report status is "Success", click the report icon and select Mark Report as Submitted.

   In the Report Submission Information dialog box, enter the submission notes and click OK.

Monitoring E2B Transmit Status

Use the following procedure to monitor E2B Transmit Status:

1. Click Utilities -> E2B -> E2B Transmit Status
2. When the system opens the E2B Transmit Status dialog, enter the appropriate data.



E2B Transmit Status Fields

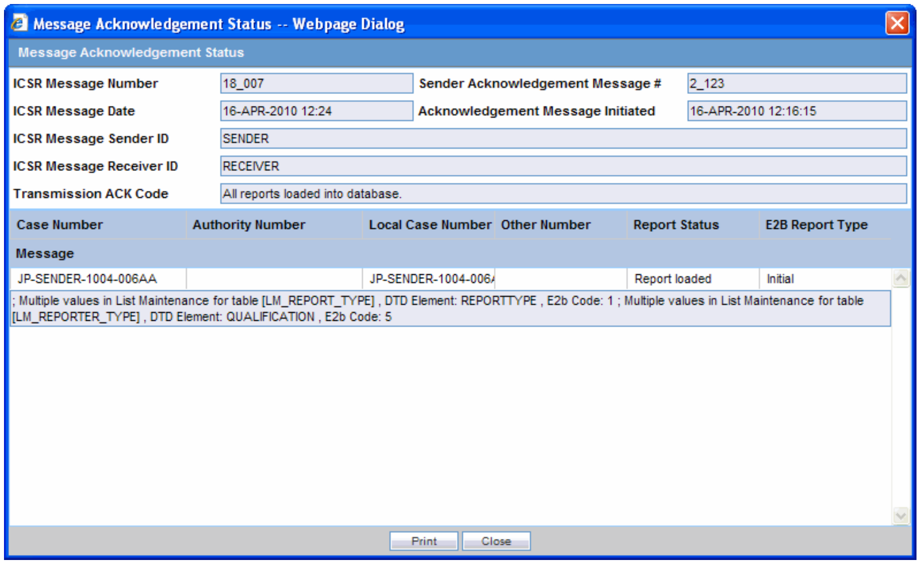
The following table lists and describes the fields in the E2B Transmit Status dialog box.

Item	Description
Column Headers	Clicking the column header sort the data by that column alternately in a ascending and descending order.
Agency / Trading Partner	Enables you to filter data by selecting the Agency / Trading Partner from the list.
Transmit Date Range From	The search start date.
Transmit Date Range To	The search end date
Range	A pre-defined date that you select from the list.
Message # Range From	The beginning message number for the search.
Message # Range To	The ending message number for the search.
Type	Enables you to filter data by selecting the pre-defined Type of Message (MSG, ACK) from the list.
Print	Enables you to print the current view.
Search	Enables you to perform the search.

Note: The EDI Header control number is shown only for EDI files.

1. Select the appropriate agency or trading partner from the Agency/Trading Partner list.
2. Select the appropriate option, Transmit Date or Message # to search by transmit date or by message number.
3. Enter the appropriate search criteria beside the selected option and click Search.

4. In the search results, click the appropriate report.
5. The Message Acknowledgement Status dialog appears.



6. This dialog provides detailed information about the transmission status of the report. Enter the data for each field as required.

Message Acknowledgement Status Dialog Fields

The following table lists and describes the fields in the Message Acknowledgement Status dialog box.

Item	Description
ICSR Message #	This is the message number of the transmission from the sender.
ICSR Message Sender ID	This is the sender name or identification.
ICSR Message Date	This is the date and time the sender transmitted the message.
Acknowledgement Message #	This is the acknowledgement message number sent by the receiver.
ICSR Message Receiver Identifier	This is the receiver name or identifier.
Acknowledgement Message Initiated on	This is the date and time the receiver got the message.
Transmission Acknowledgement Code	This code indicates whether the receiver loaded all reports or only a portion of the reports into the database.
Case Number	This is the original case number for adverse event.
Authority Number	If the E2B report originates from a regulatory authority, this is the report identification number assigned by the regulatory authority.
Local Case Number	The system uses this number when it retransmits a message. This is the case number at the local organization that is re-transmitting a report it received.
Other Number	The system uses this number when a report originates from an entity other than a trading partner or a regulatory authority.

Item	Description
Report Status	Report status can be either "Report Loaded" or "Report not loaded".
E2B Report Type	This is one of the following report types: Initial Follow up Nullification Duplicate.
Message	This indicates whether an error message is associated with the transmission or receipt of the report.

Monitoring E2B Receive Status

Use the following procedure to monitor E2B Receive Status:

1. Select Utilities -> E2B -> E2B Receive Status.
2. When the system opens the E2B Receive Status dialog box, enter the appropriate data in each field.

E2B Receive Status Dialog Fields

The following table lists and describes the fields in the E2B Receive Status dialog box.

Item	Description
Agency / Trading Partner	Enables you to filter data by selecting the Agency / Trading Partner from the list.
Receive Date Range From	The search start date.
Receive Date Range To	The search end date.
Range	Enables you to select a pre-defined date range
Message # Range From	The beginning message number for the search.
Message # Range To	The ending message number for the search.
Type	Enables you to filter data by selecting the pre-defined Type of Message (MSG, ACK) from the list.
Control #	The control number.
Local Msg #	The local message number.
Remote Msg #	The remote message number.
Total Reports	The total number of reports.
Rejected Reports	The number of rejected reports.
File Name	The name of the received file.
Received from EDI	The date and time the file was received.
Transmission Status	The transmission status for the file.
Print	Enables you to print the current view.
Search	Enables you to initiate the search.

> **Note:** The EDI Header control number is shown only for EDI files.

1. Select the appropriate agency or trading partner from the Agency/Trading Partner list
2. You can search for the receive status by either receive date or message number. Select the appropriate option among Transmit Date and Message #.
3. Enter the appropriate search criteria beside the selected option and click Search.
4. In the search results, double-click the appropriate report.
5. When the system opens the Message Acknowledgement Status dialog, enter the appropriate data in each field.

Message Acknowledgement Status Dialog Fields

The following table lists and describes the fields in the Message Acknowledgement Status dialog box.

Item	Description
ICSR Message Number	This is the sender's transmission message number.
ICSR Message Sender ID	This is the sender name or identifier.
ICSR Message Date	This is the date and time the sender transmitted the message.
Acknowledgement Message #	This is the receiver's acknowledgement message number.
ICSR Message Receiver Identifier	This is the receiver name or identification.
Acknowledgement Message Initiated on	This is the date and time the message was received.
Transmission Acknowledgement Code	This indicates whether the receiver loaded all transmitted reports or part of the transmitted reports into the database.
Case Number	This is the original case number for adverse event.
Authority Number	If the E2B report originates from a regulatory authority, this is regulatory authority's report identification number.
Local Case Number	The system uses this number when it retransmits a message. This is the case number at the local organization that is re-transmitting a report.
Other Number	The system uses this number if the report originates from an entity other than a trading partner or a regulatory authority.
Report Status	Report status can be either "Report Loaded" or "Report not loaded."
E2B Report Type	This is the report type. It can be one of the following Initial Follow up Nullification Duplicate
Message	This indicates whether an error message is associated with the transmission or receipt of the report.

Validation Check of Incoming Message

Prior to updating the transmission status of the reports, the application identifies the type of incoming message and validates the incoming message. The E2B service processes all the incoming messages located in a folder either in incoming EDI directory or physical media directory. Incoming E2B Messages are retrieved as SGML from a shared directory. The incoming folder is configurable in Argus Interchange Mapping Utility. E2B message is parsed to check the validity of the SGML file using the correct version of DTD. The incoming message is saved after checking that message is in compliance with DTD.

The recipient of the E2B message acknowledges receipt of message and notifies the sender about the validity and usability of the data in the reports. The acknowledgment message is called as ICSR Acknowledgment Message. When a message is acknowledged, workflow status of the E2B report is updated with one of the following three status:

- All reports loaded into recipient database
- ICSR Error, not all reports loaded into database
- SGML parsing error no data extracted

The acknowledgement contains two sections, one concerning the validity of the message as a whole and the second containing comments on the validity of the individual reports within the message. Create a folder and configure it through the Argus Interchange Mapping Utility, where all the incoming messages can be stored. The Interchange service processes the received message and moves it in the Archive folder.

The message is validated based on the ICH ICSR acknowledgement specifications and the format of the message identified by DTD version. Correctness of receiver and sender identifier present in the message header is also validated to verify that the message is not sent to the wrong recipient.

The content of the message is validated based on the following:

- Required Data
- Data Type
- Data Length
- Field Value

The system identifies message type (acknowledgement) and the DTD version of the message. If the application is unable to identify the message type or DTD version, then the error is logged in the log table and further processing is stopped. The application sends an email to configured email address indicating the failure to read the message.

Application checks for the presence of the duplicate in the system based on the 'Sender identifier' and 'Acknowledgement Message Tracking #'. Processing of the acknowledgement is stopped, if duplicate message is found in the database and an error is logged into the log table.

The following table describes the error messages and reasons for the occurrence of corresponding errors.

Process	Error message	Possible Reason of error
Read the Incoming message from the folder	XML File not in path.	File is removed.

Process	Error message	Possible Reason of error
Identification of the incoming message type	<<File Name>> not a valid XML File	File format is not as per ICH guidelines.
Identification of the incoming message type	Not valid ICH ICSR message Tag '<ichicsrmessageheader>' not found	File does not contain the valid ICH Message Header.
Identification of the incoming message type	Failure to identify the type of incoming message. Either Tag <messagetype> is missing/misspelled or tag does not contain valid value. The valid values are ICHICSR, ICHICSRACK	The incoming file is identified as a message or acknowledgment. The identification value is wrong.
Identification of the incoming message type	Record not found in CFG_PROFILE table for DTD version '2.0', DTD release '1.0', Active profile = 'Y' and profile type starts 'ACK%'	Profile does not exist in cfg_profile table.
Validation of the incoming message type	M2 Validation failed for incoming message. The following are the elements and values:<<Element, value>>	M2 validation failed on the message header.
Identification of the incoming acknowledgement type	Invalid ICH ICSR message Tag '<messageacknowledgment>' not found.	File does not contain the valid ICH Acknowledgment Header.
Processing acknowledgment	Record not found in MESSAGES table for the ICSRMESSAGE number <<MessageNum>> ICSRMESSAGE receiver identifier <<receiver info>> for the received acknowledgment	Record is deleted from the database.
Processing acknowledgment	Duplicate acknowledgment received for ICSRMESSAGE number <<message number>> and ICSRMESSAGE RECEIVER IDENTIFIER <<receiver info>>	Acknowledgment already exists for this message number.
Processing acknowledgment	<reportacknowledgment> section is missing from the received acknowledgment, MESSAGE number <<message number>>	Acknowledgment does not contain the report acknowledgment body.
Processing acknowledgment	Record not found in SAFETYREPORT table for company number <<Company Number>> and msg_id <<message id>>	Record is deleted from SAFETYREPORT table from database.

Refer to the sample email messages that are sent to the configured email address in case of message validation failure:

- In case of invalid XML format:

  From: E2B service user

  Subject: <<file name>> not valid XML formats file

  Content: This mail has been sent by the system to notify that the system has failed to identify the file <<file name>> as a valid XML file.

  Error has occurred on Line: <<line no>>, Source Text <<Error Text>>, Error Code <<Parsing Error Code>>, Error Reason <<Error Reason>>

Thanks,

<< E2B service user >>

- In case the application fails to identify the incoming message:

  From: E2B service user

  Subject: Failure to Identify the Type of Incoming Message.

  Content: This mail has been sent by the system to notify that the system has failed to identify the type of the incoming message (Acknowledgement or a Message) present in the file <<Incoming Message File Name>>.

  Thanks,

  << E2B service user >>

- In case of validation failure of the incoming acknowledgement:

  From: E2B service user

  Subject: Validation Failure of the Incoming Acknowledgement.

  Content: This mail has been sent by the system to notify that the system has failed to further process the incoming acknowledgement present in the file <<Incoming Message File Name>>.

  The following are the reasons for this failure:

  #<n>. <<Insert the corresponding relevant error message.>>

  Thanks,

  << E2B service user >>

You can view the acknowledgement information of a report such as acknowledgement message tracking #, acknowledgement report tracking #, date acknowledge initiated, company ICSR message, and error reported by receiver, in the Report Details dialog.

The status of the each E2B report is updated based on the information extracted from the ICSR acknowledgment, irrespective of the transmission status (Success or Failure). Refer to the section "Viewing Acknowledgement Information" on page 4-16 for viewing the acknowledgement information.

Nullification Reports

The system can automatically schedule, generate, and transmit a Nullification Report under the following circumstances:

- When a case is deleted and an E2B Report is submitted to a reporting destination based on the Profile switch for sending E2B nullifications.
- When an E2B report is submitted and marked as unsubmitted from Reports | Compliance | Submitted Reports:
  - The Reason for Unsubmitting the report is sent as the nullification reason for the report.
  - If the user selects the Send Nullification on Unsubmission of E2B Reports check box, the system also sends a nullification to the reporting destination where the E2B Report was previously submitted.
  - If the user does not select the Send Nullification on Unsubmission of E2B Reports check box, the system does not send a nullification to the reporting

destination where the E2B Report was previously submitted unless the user deletes the case.

– If a previous nullification for the E2B Report or an unsubmitted report is sent for a case and the case is deleted at a later date, the system does not send a duplicate nullification for the previous report.

– When the system generates the Nullification report, the system updates the following E2B items with updated values from the previous report.

Updated E2B Items	Update Content
M.1.4	System uses a different unique number from that used in the last report.
M.1.7a	System enters the message date format.
M.1.7b	System enters the message date.
M.2	System increments this value every time it transmits the report.
A.1.3a	System enters the message date format.
A.1.3b	System enters the message date.
A.1.13	System enters 1=Yes on the Nullification report.
A.1.13.1	System enters the reason for the Nullification report.
J.2	System increments this value every time it transmits the report.
J.4b	System enters the PMDA Acknowledgement Number.
J.5	System increments this value every time it submits the report.
J.6	System will enter 1. 1 means that it is a completion report.
J.7	System will remove the value of this tag, if it was present in the previous report.

- When you accept a Nullification report, the system creates an Action Item in the case. The action item tells you that the system will delete the case if you click OK on the acceptance dialog for all unarchived cases.
  – Action Item is a type-ahead field and its default is blank.
  – The field is populated with values from the action item configured in the code List.
  – You can assign the number of days until the action item is due in the Due In field. The system enables this field after you select an Action Item type.
  – The system calculates the due date as follows: System Date (local client date) + Due In number of days.
  – The system puts the System Date (local client date) in the Date field.
- When creating the action item, you can select a value from the Code List and the Action Item Description. The system uses the following format: Nullification: xxx

  where:

  xxx is the value entered in the Notes field.
- By default, the system assigns the action item to the user group in the User Group field.
  – There can be a maximum of 25 user groups in the drop-down list.

- The system performs a like search when you select a value in the User Group field.
- If the User Group field is blank, the system does not assign the action item.
- This is enabled after you select an action item.

- If you do not select an action item, the system does not create an action item for the case.
- If you accept multiple cases, the system creates action items for all accepted cases.
- The system skips open, locked, or archived cases or cases you don't have permission to access.
- If the system archives a case while you are accepting the nullification report, the system displays the Archived Case dialog to enable you to open the archived case.
- After you reopen the case, the system displays the Accept Nullification E2B dialog.
- If you do not have permission to reopen an archived case, the system displays the following message:

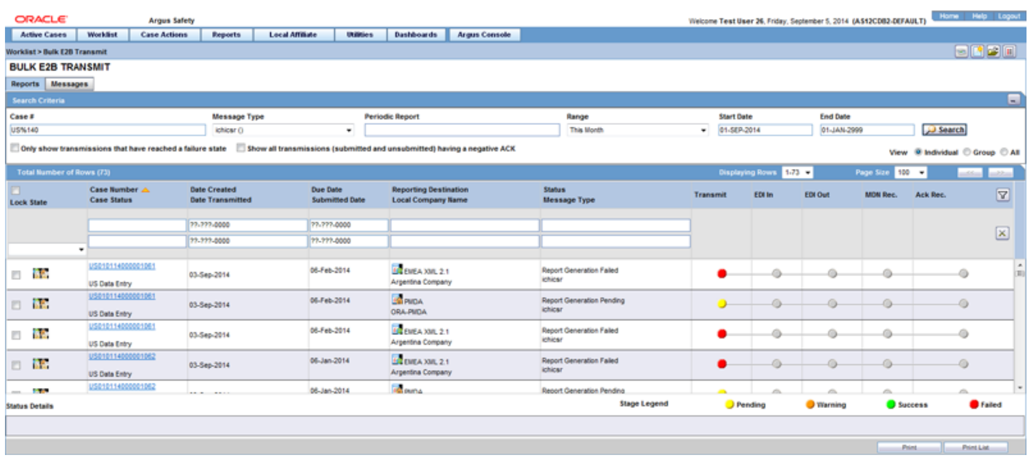
  You do not have permission to Re-Open an archived/closed case.

Viewing Status

Argus Safety provides the feature to monitor the transmission status of E2B reports.

Use the following procedure to check the status of transmitted E2B reports.

1. Select Worklist -> Bulk E2B Transmit.



2. Click the **Reports** tab to view the transmission status of E2B reports.
3. Click the **Message** tab to view the transmission status of individual E2B messages.

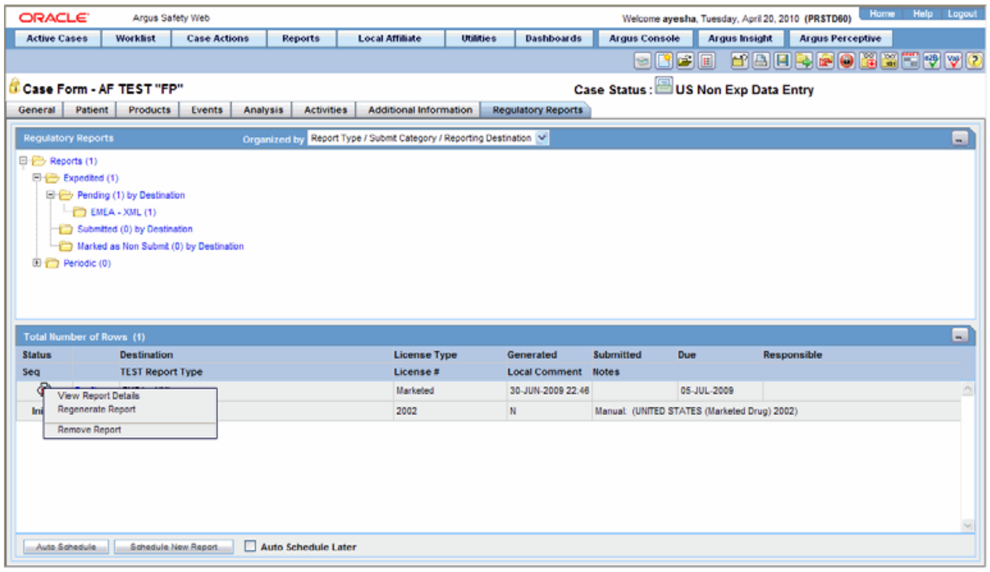
Viewing Acknowledgement Information

In Argus Safety, you can view detailed acknowledgement information for a report sent to a trading partner or a regulatory authority. Use the following procedure to view acknowledgement information.

The status of each report is updated, based on the information extracted from the ICSR acknowledgment, irrespective of the transmission status (Success or Failure).

The acknowledgement information such as acknowledgement message tracking #, acknowledgement report tracking #, date acknowledge initiated, company ICSR message and error reported by receiver is displayed in the Report Details dialog.

1. On the Regulatory Reports tab of the Case Form, click the E2B report and select View Report Details.



2. When the system opens the Report Details dialog, click View ACK Information to view the acknowledgement details for that report. If the report is rejected, an error message or a comment appears in the Notes area of the dialog

   When the Acknowledgement Information dialog opens:

   Click Print to print the acknowledgement details

   OR

   Click OK to close the dialog box.

5
Using the ICSR Viewer

The ICSR Viewer enables you to open E2B files and view them in different formats.

> **Note:** The term **E2B** that is used in this document refers to E2B (R2), E2B (R3), and eVAERS reports.

You can print these files from the ICSR viewer. This chapter includes discussions on the following:

- Opening the ICSR Viewer
- Exporting an XML File

Opening the ICSR Viewer

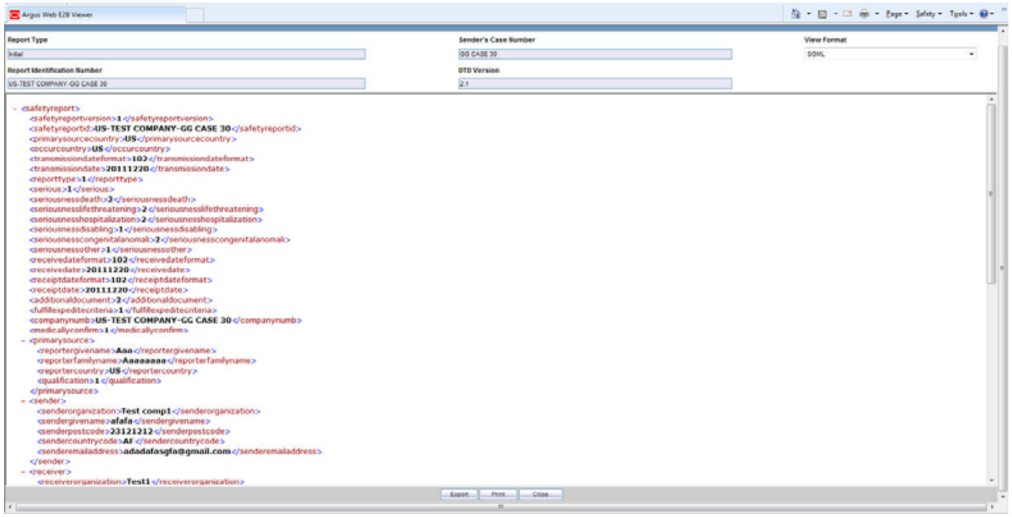
The ICSR Viewer enables you to view your E2B reports in the following views:

View	Description
XML	Displays the report in the XML format. This view is applicable for non-Japanese E2B reports.
Decoded View	Displays all the data elements in groups and subgroups. Elements are eligible for decoding with their decoded values in parentheses. A link is provided in the Decoded View to view the attachments that are sent along with the report.
HL7 View	This view is applicable for only E2B (R3) and eVAERS reports. This view displays the report in HL7 format.
CIOMS	For details on the CIOMS view, refer to the "E2BCIOMSMapping" document. This view is applicable for only E2B (R2) reports.
MedWatch	For details on the MedWatch view, refer to the "E2BMedWMapping" document. This view is applicable for only E2B (R2) reports.

Exporting an XML File

The system enables you to use the following procedure to export an XML file.

1. Click the Final E2B report type on the Regulatory Reports tab.
2. When the system opens the ICSR Viewer window, select XML from the View Format drop-down list.



3. When the system displays the contents of the XML file, click Export.
4. When the system displays the XML report, click File -> Save As.
5. When the system opens the Save As dialog box:
   a. Enter a name for the file.
   b. Browse to the folder where the file is to be saved
   c. Click Save to save and export the XML file.

Note: Exporting an E2B report can only be done from the XML view on final reports. If you select draft, the Export button becomes unavailable.

6

Importing E2B Reports

Incoming E2B Reports

Incoming E2B Reports can be viewed from the Incoming E2B Report screen.

This release does not support import of eVAERS.

This section includes discussions on the following:

- Conversion of E2B (R3) reports to E2B (R2) format (applicable only for E2B (R3) reports)
- Searching for Duplicate Cases
- Using the View Differences Report
- Viewing the E2B Report
- Accepting Single/Multiple E2B Reports

Conversion of E2B (R3) reports to E2B (R2) format (applicable only for E2B (R3) reports)

On receiving E2B (R3) report from a Reporting Destination, it is converted to E2B (R2) format before displaying the report in E2B Pending screen. System performs file format checks to be in HL7 format while receiving E2B report from an Agency configured with E2B (R3) profile. If the inbound E2B (R3) file format does not match the expected file format by sender, the inbound transmission is not processed. System converts the incoming E2B (R3) report to E2B (R2) format using BFC XSLs provided by ICH.

While converting E2B (R3) to E2B (R2) format, system extends the size of narrativeincludeclinical B.5.1 to 100.000 characters from the current size of 20,000 characters. If the text for B.5.1 goes beyond 100,000 characters due to BFC logic then characters beyond 100,000 characters is truncated.

The system performs other data checks such as format validation, M2 validation checks on the converted E2B (R2) report as per E2B (R2) profile that is configured in the internal common profile switch and displays the report in the E2B Pending screen.

Searching for Duplicate Cases

The Duplicate Search dialog for E2B report allows you to search for possible duplicate cases in the Argus Safety system. You can select different combinations of search criteria. When more than one criterion is selected, only cases that satisfy all criteria are listed. By default, only the fields that are present in the E2B Report are checked for the Duplicate Search.

Use the following procedure to perform a duplicate search.

1. Select Reports -> E2B Pending Report.
2. When the system opens the Incoming E2B Reports dialog, right-click a case to perform a duplicate search.
3. The system displays the search results at the bottom of the dialog box.

Duplicate Search Dialog Box Fields

The following table describes the fields present in the Duplicate Search dialog.

Field	Description
Agency	The name of the primary agency.
Original Case Number	The submitter's original case number.
Message Number	The case message number.
Product Name	The name of any product on XML.
Generic Name	The active substance on XML.
Report Type	The type of report.
Study ID	The unique value that identifies the study.
Receipt Date	The date Argus received the report and saved it in the system.
Center ID	The ID of the center.
Sal.	The salutation, such as Mr. or Mrs.
Suffix	The suffix, if applicable, that follows the name (e.g., Jr., Sr.,III, etc.)
First Name	The first name of the patient.
Last Name	The last name of the patient.
Country of Incidence	The country where the incident occurred.
State	The state where the incident occurred.
Postal Code	The postal code of the area where the incident occurred.
Patient Name	The name of the patient.
Event Desc.	A description of the adverse event.
Initials	The initials of the patient.
Onset Date	The date from the first reaction or adverse event occurred.
Pat. ID	The unique value that identifies the patient.
Age/Units	The age of the patient.
Pat. DOB	The patient's date of birth.
Gender	The gender of the patient.
Reference #	National Regulatory Authority's Report Number, used as a Reference Number.
Journal	The journal name of the literature reference.

Field	Description
Keyword	Select the check box and enter a keyword to be searched, if required.
Title	Select the check box and enter a title to be searched, if required.
Nullification Reason	The reason the case was nullified.
Accept Initial E2B as Follow-Up	Enables you to accept initial E2B as a follow-up to an existing case.
Search	Finds results matching the specified search criteria.
View E2B	Enables you to view the E2B report.
Accept E2B Case	Enables you to accept an E2B case.
Reject E2B Case	Enables you to reject an E2B case.
View Warning	Enables you to view warnings associated with the case.
View Differences	Enables you to view the differences between the XML to be imported (a message that is not yet imported into the database), the current case data in the database, and the last imported case. Note: This button is available only for follow-up and nullification reports.
Case Number	The case number of the case matching the search criteria.
Pat. Initials	Displays the initials of the patient in the case matching the search criteria.
Action	Enables you to view the Case Summary dialog.
Project ID	Displays the Project ID of the case matching the search criteria.
Study ID	Displays the Study ID of the case matching the search criteria.
Date	Displays the date of the case matching the search criteria.
Country	Displays the country name of the case matching the search criteria.
Product	Displays the product name involved with the case matching the search criteria.
Event	Displays the event involved with the case matching the search criteria.
Report Type	Displays the report type of the case matching the search criteria.
Reporter	Displays the reporter involved with the case matching the search criteria.

Note: The search output is displayed in the Total Number of Rows section. You can click the Action icon to view the Case Summary dialog.

Using the View Differences Report

The View Differences Report enables you to view differences between the following:

- The current XML being imported (a message not yet imported into the database)
- The current case data in the database

- The last imported case.

Click View Differences from the Duplicate Search screen to view the View Differences report. View Differences is available only for follow-up and nullification reports only.

The following table lists and describes the fields in the View Differences report:

Field	Description
Trading Partner	Enables you to view the name of the Trading Partner sending the E2B report. Note: The Lock/Archive icon displayed with this field indicates the status of the case.
DTD Version	Enables you to view the DTD version of the follow-up E2B report.
Case Number	Displays the sender's original case number for the E2B report.
Follow Up #	Displays the sequence number of the follow-up for the E2B report.
Total Number of Rows	Allows you to select the type of E2B Difference to view from: Current E2B vs. Current Case in Database Current E2B vs. Last Imported E2B Current Case in Database vs. Last Imported E2B
Import	This check box highlights import differences.
E2B Element	Refers to the data elements in the incoming E2B report or in the existing report.
Current E2B	Refers to the data in the incoming XML that has not yet been accepted in the current E2B.
Current Case in Database	Refers to the data in the current case in the database.
Last Imported E2B	Refers to the data showing the last imported E2B.
Accept Follow-up	Allows you to accept follow-up reports with the corresponding fields selected for import.
Reject Follow-up	Enables you to reject follow-up reports for import.
Print List	Provides the difference report in a PDF format.
Close	Enables you to close the window.

Displaying Differences

The differences in the E2B reports are displayed in the following manner:

- Addition - New elements on incoming XML are highlighted in grey.
- Deletion - Deleted elements are highlighted in red.
- Modification - Modified elements are highlighted in yellow.

Viewing the E2B Report

Use the following procedure to view the E2B Report:

1. Select Reports -> Duplicate Search and right-click to the Duplicate Search dialog box.

2. Click View E2B to view the E2B report in the ICSR Viewer. You can also view an E2B report from the E2B Pending screen by right-clicking on a row and selecting ICSR Viewer.

Accepting Single/Multiple E2B Reports

Use the following procedure to accept single and multiple E2B reports:

1. Select Reports -> E2B Pending to open the Incoming E2B Report dialog box.
2. When the system opens the E2B Pending screen:

   To accept a single report, right-click on it and select Accept E2B

   OR

   To accept multiple reports, select the check boxes for each report and click Accept E2B.
3. When the system opens the Acceptance of Initial Report Confirmation dialog box, enter the password and any relevant notes.
4. Click OK to accept the case.

> **Note:** The acceptance of multiple E2Bs can be performed only when the system numbering is set to Automatic.

5. If the system is configured to automatically number cases, the system opens the case accepted dialog appears with the generated case number.
6. Click OK to close this dialog.

> **Note:** If the system is configured to manually number cases, you will be prompted to enter a case number for the case that is being accepted.

E2B Initial/Follow-up Intake

During case acceptance, you can access selective acceptance fields in the report.

- The Selective Acceptance feature is enabled only for single initial ICSRs and is a right-click option.
- If you select multiple ICSRs, the system disables this button.
- If you select a single follow-up or nullification ICSR, the system disables this button.
- When the system displays the E2B Difference Report dialog, you can select the elements required to create or update a case without the system displaying the Case Number and Follow-up Number in the difference report dialog for initial reports.
- The following changes have been made to the Initial Intake and the Follow-up Difference Report dialogs:
  - The system displays the decoded view to enable you to select the elements (e.g., US [United States]).
  - The system prints the check box options for the Initial Intake and Follow-up Difference Report dialogs.

  - The label is updated to Select when selecting elements for the Initial Intake and the Follow-up Difference report dialog.
- You must select the following fields before the system will permit you to accept the Initial case. By default, all the fields are selected.
  - Country of Incidence (default and grayed out)
  - Report Type (default and grayed out)
  - Initial Receipt Date (default and grayed out)
  - Any one Product
  - Any one Event Term
- If you fail to select these fields, the system displays the following message:

  E2B cannot be imported as it does not meet minimum Argus requirements.
- The system permits you to print the Initial ICSR report.
- When you click Accept Initial, the system displays the Accept E2B Case dialog. When you complete the data elements and click OK, the system displays the Error/Warning message dialog for any elements you have selected.
- Once you accept the case as an initial or follow-up case, the system attaches the Source XML (ICSR) and the Initial Selection PDF to the case in the Additional Info tab.
- For Auto Accepted ICSRs, the system does not attach the source PDF in the case because the source XML is attached.
- Initial/Follow-up Source XML
  - Attachment Classification. As specified in the Reporting Destination for the XML source classification.
  - Date. The system date when the case you accepted XML for the case.
  - Description. The acceptance notes you entered for XML.
  - When you click the Source ICSR, you can see the ICSR when opening the ICSR View (ICSR Viewer).
- Initial Selection PDF
  - Attachment Classification: As specified in the Reporting Destination for the Selection Source Classification.
  - Date: The system date when you accepted XML for the case.
  - Description: The date you entered acceptance notes for XML.
- Follow-up Source XML
  - When you click the Source ICSR PDF or the E2B Difference Report, you can view the Initial Selection PDF or the E2B Difference Report in a different IE window.
- Once you accept a case as an initial or a follow-up ICSR, the system prefixes the Business Level Acknowledgement Notes with the case number in the following format:

  Imported Case #: XXXXX

  where:

  XXXXX is the case number

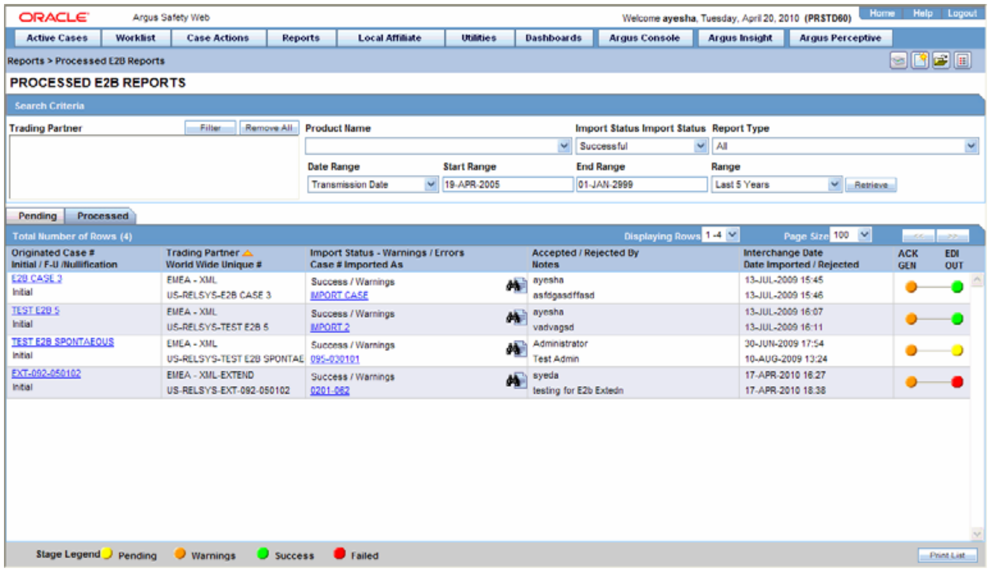
- The system attaches the current notes sent in the Business Level Acknowledgement.
- If the system receives the ICSR via the physical gateway (configured at the reporting destination level), the system sends a low level ACK to indicate the file was received by the Argus Interchange Service.
- The system places this file in the Physical Out folders as configured for the reporting destination in the E2B Mapping Configuration.
- For EDI received files, the system continues to let the EDI Gateway send the low level ACK as it does currently.
- The Interchange Services does not process the low level ACK received in the Physical In destination folder, but enters any errors in the log file since the file will always be rejected by the Interchange Service.

E2B Follow-up Acceptance for Closed/Locked Cases

- If you try to accept follow-up information for a closed or locked case, the system prompts you to unarchive or unlock the case for processing after entering the password and acceptance notes.
- If the case is in archived state while you are accepting the report, the system displays the Case Re-open dialog to enable you to open the case.
- If the case is in locked state while you are accepting a report, the system displays the Case Unlock dialog to enable you to unlock the case.
- After you reopen the case, the system accepts all updates as defined in the follow-up information you selected.
- If you do not have permission to reopen an archived or locked case, the system displays the following message:
- You do not have permission to Re-open an Archived/Closed case or Locked Case.
- If you select multiple open, locked, or archived cases or if you do not have permission to open the case, the system skips the cases.
- The system does not create follow-up actions for cases that it accepts automatically.

Processed E2B Reports

The Processed E2B Reports screen contains a list all processed E2B Reports. Click the Processed E2B Reports tab on the Incoming Reports screen to view the Processed E2B Reports screen.



The Processed E2B screen contains the following:

- Search Criteria
- Total Number of Rows

The following table lists and describes the fields in the Total Number of Rows section on the Processed E2B screen.

Field	Description
Originated Case#	Displays the Originated Case Number of the case.
Initial/F-U/Nullification	Displays the Initial/F-U/Nullification status.
Trading Partner	The name of the trading partner.
World Wide Unique#	The World Wide Unique # for the case.
Import Status - Warnings/Errors	The import status of the case and any associated warnings/errors.
Case # Imported As	The Case Number used when importing the case.
Accepted / Rejected By	Identifies who accepted or rejected the case.
Notes	The case notes.
Interchange Date	The Interchange Date.
Date Imported/Rejected	The date the case was imported/rejected.
ACK Gen	Yellow indicates the case is still pending Orange indicates the case is accepted with warnings / errors Red indicates the user or system rejected the case. Green indicates the case has been successfully imported.

Field	Description
EDI Out	Yellow indicates the system is waiting to send the report out of the EDI / XML or PHY out folders Green indicates the report is already sent out of the EDI / XML or PHY out folders Red indicates that the EDI gateway failed to send the report out of the EDI / XML or PHY out folders.