Oracle Life Sciences Argus Interchange

User's Guide

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Oracle Life Sciences Argus Interchange User's Guide, Release 2026.1.01

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Contents

8 Import ICSR Reports

Preface

This preface contains the following sections:

About this content

Except where noted, information in this guide applies to both Oracle Argus Safety and Oracle Safety One Argus environments.

Related resources

For information about Oracle Argus patches, see My Oracle Support.

All documentation and other supporting materials are available on the Oracle Help Center.

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About Oracle 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, Oracle Argus Interchange is seamlessly integrated with Oracle Argus, facilitating import, export, and transmission of cases. In addition, it supports immediate case triage upon electronic intake of data.

Oracle 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. Oracle 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.

For more information, see:

- ICSR Process Overview
- MIR Process Overview

ICSR Process Overview

Individual Case Safety Reports (ICSRs) contain information about a suspected adverse reaction by an individual patient to one or more medicinal products.

E2B is the international standard for transmitting adverse event data, which was developed by the International Council for Harmonisation (ICH).

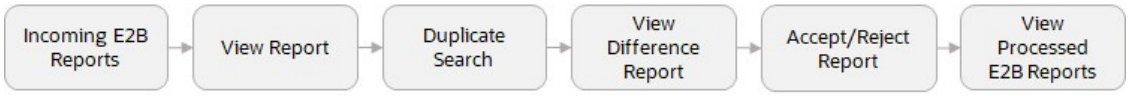
This flowchart shows the steps to follow when working with ICSR reports.

> **Note**
>
> This section applies only to Argus Safety environments. For Safety One Argus environments, refer to the *Oracle Life Sciences Consolidated Intake User Guide*.

The following table describes each step of the process.

Task	Description
Log in	Log in to Oracle Argus Safety.
Case Data Entry	Enter case information.
Schedule E2B Report	Schedule an E2B Report for a case manually or using auto-schedule.
View E2B Report	View a scheduled E2B report in the ICSR Viewer and check for validation errors.
Transmit E2B Report	Transmit the E2B reports by using the Bulk Reporting screen in Oracle Argus Safety.
View Status	View the status of a transmitted E2B report.
View Acknowledgement	View the detailed acknowledgement information from a trading partner or a regulatory authority.

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



The following table describes each step of the import process.

Task	Description
Incoming E2B Reports	View the incoming E2B reports.
View E2B Reports	View an incoming E2B report in the ICSR Viewer.
Duplicate Search	Search for possible duplicate cases in Oracle Argus Safety.
View Difference Report	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	Accept or reject single or multiple E2B Follow-up/Initial reports.
View Process ICSR Reports	View the processed ICSR reports.

For more information, see:

- Minimum Requirement for Electronic Report Generation

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), eMDR 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

eMDR reports are built using HL7 version 3 (V3) messaging standards with the following sections:

A - Patient Information

B - Adverse Event or Product Problem

C - Suspect Product Information

D - Suspect medical device

E - Initial Reporter

F - For Use by User Facility/Importer (Devices Only)

G - All manufacturers

H - Device manufacturers only

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.

MIR Process Overview

Manufacturer Incident Reports (MIRs) contain information about adverse events, serious injuries, deaths, or malfunctions related to medical devices.

The following flowchart shows the steps to follow when working with MIR reports.

The following table describes each step process.

Task	Description
Log in	Log in to Oracle Argus Safety.
Device Data Entry	Enter device information.
Schedule MIR Report	Schedule an MIR report for a case manually or using auto-schedule.
View and Validate MIR Report	View a scheduled MIR report in the MIR Viewer and check for validation errors.
Transmit MIR Report	Transmit the MIR report by using the Bulk Reporting screen in Oracle Argus Safety.
View Report Status	View the status of a transmitted MIR report.

For more information, refer to the *EC Manufacturer Incident Report (MIR) Best Practices* document.

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Configure Oracle Argus Interchange

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

For more information, see:

- Oracle Argus Console

Oracle Argus Console

The Oracle 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.

For more information, see:

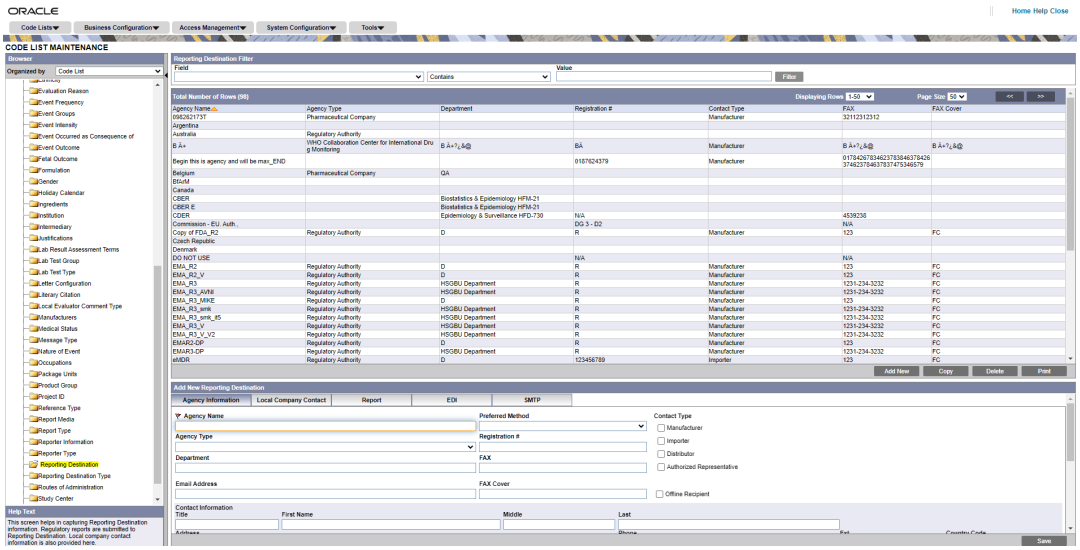
- Configure Regulatory Authorities
- Configure Code List Items

Configure 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 Oracle 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 *Oracle Argus Safety Administration Guide*, Configuring Reporting Destination section for information on using Reporting Destination.

Configure Code List Items

Oracle Argus Codelist values are associated with 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.

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Configure the Interchange Utility

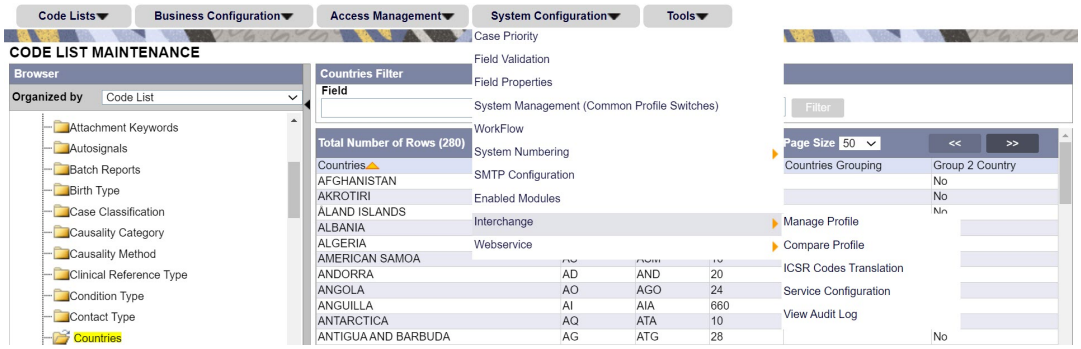
This chapter provides information on configuring and mapping the web-based Oracle Argus Interchange.

For more information, see:

Navigate to Interchange

To navigate to the Interchange menu:

1. Open the Oracle Argus Console.
2. Go to **System Configuration** > **Interchange**.



Message and Acknowledgement Profiles

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

- CBER EVAERS V1.0 MESSAGE TEMPLATE
- CDRH EMDR V1.0 MESSAGE TEMPLATE
- ICH-ICSR V1.1 ACKNOWLEDGMENT TEMPLATE
- ICH-ICSR V1.1 ACKNOWLEDGMENT TEMPLATE - FDA
- ICH-ICSR V1.1 ACKNOWLEDGMENT TEMPLATE - EMA

- ICH-ICSR V1.1 ACKNOWLEDGMENT TEMPLATE - PMDA
- ICH-ICSR V2.1 MESSAGE TEMPLATE
- ICH-ICSR V2.1 MESSAGE TEMPLATE - EMA
- ICH-ICSR V2.1 MESSAGE TEMPLATE - FDA
- ICH-ICSR V2.1 MESSAGE TEMPLATE - PMDA - I
- ICH-ICSR V2.1 MESSAGE TEMPLATE - PMDA - J
- ICH-ICSR V2.1 MESSAGE TEMPLATE - FDA PIP
- ICH-ICSR V2.1 MESSAGE TEMPLATE - PMDA PIP
- ICH-ICSR V2.2 MESSAGE TEMPLATE - FDA
- ICH-ICSR V3.0 ACKNOWLEDGMENT TEMPLATE - ICH
- ICH-ICSR V3.0 ACKNOWLEDGMENT TEMPLATE - EMA
- ICH-ICSR V3.0 ACKNOWLEDGMENT TEMPLATE - FAERS
- ICH-ICSR V3.0 ACKNOWLEDGMENT TEMPLATE - PMDA
- ICH-ICSR V3.0 MESSAGE TEMPLATE
- ICH-ICSR V3.0 MESSAGE TEMPLATE - EMA
- ICH-ICSR V3.0 MESSAGE TEMPLATE – FAERS
- ICH-ICSR V3.0 MESSAGE TEMPLATE - MFDS
- ICH-ICSR V3.0 MESSAGE TEMPLATE -NMPA
- ICH-ICSR V3.0 MESSAGE TEMPLATE - PMDA
- PMDA-DEVICE MESSAGE TEMPLATE
- FDA MEDWATCH 3500A DRUG TEMPLATE
- EC-MIR MESSAGE TEMPLATE
- EC-MIR V7.3.1 MESSAGE TEMPLATE

For more information, see:

- Import profiles for EMA and PMDA E2B(R3)

Import profiles for EMA and PMDA E2B(R3)

The following import profiles for EMA and PMDA E2B(R3) are available:

- EMA (R3) profile with OOTH Export and Import mappings with all standard features such as Copy, Edit, Print and Audit.
- EMA (R3) acknowledgment with default mappings and with all standard features such as Copy, Edit, Print and Audit.

All conformance rules are added to the OOTB EMA (R3) profile.

Low level Ack generation is supported for EMA (R3) import using physical media.

Manage Profiles

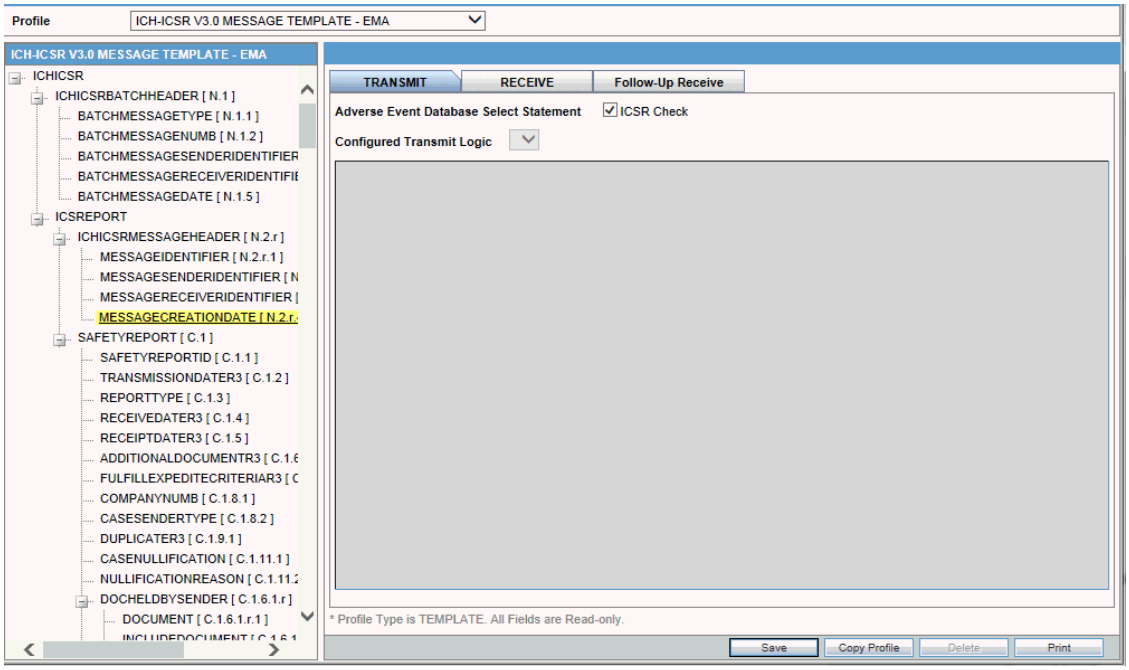
This section provides information on how to work on profiles:

- Define a Profile

- Use the Follow-up Receive Tab
- Print a Profile
- Copy a Profile
- Delete a Profile

Define a Profile

This section describes viewing or modifying the rules of a profile in the Interchange Mapping. You can view profile details by selecting a Profile from the Interchange Mapping screen.



On selecting a Profile from the drop-down, the system displays the following information:

- The tree view structure of ICSR elements
- The Transmit and Receive tabs

The following notes are displayed at the bottom of the screen:

- When a profile provided as part of the factory data is selected, ** Profile Type is TEMPLATE. All Fields are Read-only*.
- When a custom profile is selected, ** Profile Type is User DEFINED. Fields with white background are editable*.

For more information, see:

- Use the Transmit Tab
- Use the Conformance Rules Tab
- Use the Receive tab

Use the Transmit Tab

Use the following procedure to view details on the **Transmit** Tab:

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

The following table lists and describes fields 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 profile from the AE database.
ICSR check checkbox	Indicates whether the selected profile is used in the ICSR check functionality in Argus. The ICSR check function validates E2B reports based on the validation rules defined for the profiles. Only profiles that have the ICSR checkbox selected are used for validation.
Blind in PMDA AE Paper Report	Select this check box if the selected profile must be blind in the PMDA AE Paper Report. This check box is available only for PMDA E2B R2 Profiles for Japanese user and if the Japanese version is enabled.
Configured Transmit Logic	This drop-down lists the descriptive names (alphabetical order) for all the configured Transmit Mapping logic for the particular element across all the HL7 based ICSR profiles. The first value is blank and the last value is (Add New). This drop-down value is available for editing for all custom profiles and is read-only for OOTB Template profile.

Use the Conformance Rules Tab

The **Conformance Rules** tab is available to the users for the E2B (R3), PMDA E2B (R3), and PMDA Device XML Report profiles. The Japanese DTD tab is not available to PMDA E2B (R3).

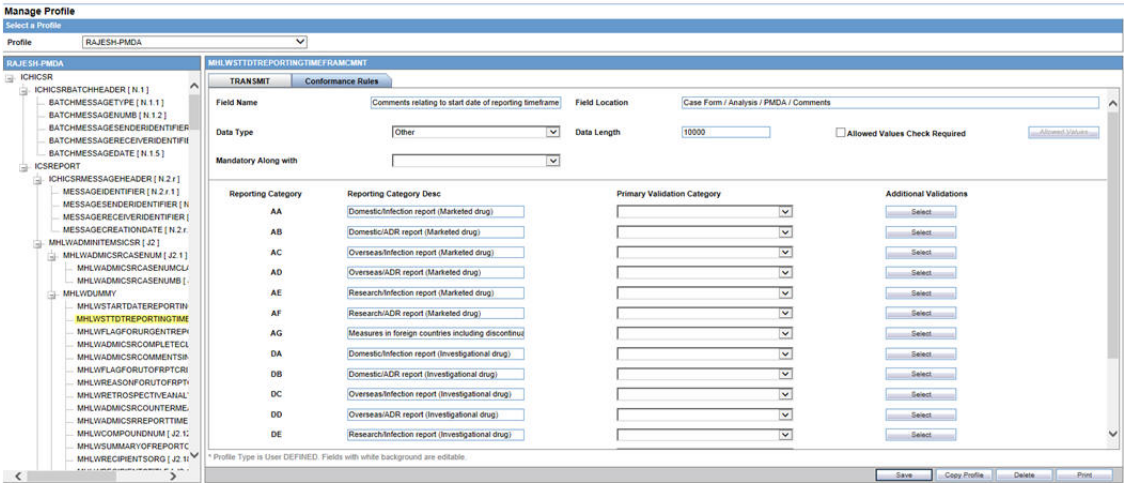
The tab allows user to configure the following parameters against each ICSR Element node for which data is transmitted (as it is applicable only for E2B export logic). It is available only for the ICSR Element Nodes (except for the Message & Batch Header tags - N) for which data is transmitted and is not available for parent element, as the attributes specific to validations are applicable only at root element level.

This configuration remains un-editable (read only) for all out-of-the-box E2B (R3) based ICSR template profiles (EMA, PMDA, FAERS) but is allowed to be edited for custom/copied profiles. (The configuration data for out-of-the-box mapping profiles is available with the mapping of that profile).

The Conformance Rules tab data is also copied to the new profile when user copies any existing ICSR profile.

Editing Conformance rules is allowed only for custom profiles.

The following is the Conformance tab for PMDA profile:



To configure the validations rule against the ICSR element, following fields have been made available to user under the Conformance Rules tab:

Field	Type	Description
Field Name / Field Name (J)	Textbox Length:255 AN	Field Name/Label of the Case form or Console UI field to which the element's mapping logic corresponds to is specified in this field. EMA: English PMDA: Japanese For PMDA E2B (R3): Refer Mapping xls > Mapping(Sheet) > UI Field Name(J)
Field Location	Textbox Length:255 AN	UI Fields Location/path of the Case form or Console UI field to which the element's mapping logic corresponds to is specified in this field. EMA: English PMDA: Japanese For PMDA E2B (R3): Refer Mapping xls > Mapping (Sheet) > UI Field Name(J)
Data Type	Drop-down list	This drop-down list has the following options in the below specified order: Blank (Default) Country Date/Time E2B Code MedDRA Term/Code MedDRA Version Text For PMDA E2B (R3): Refer Mapping xls > Mapping(Sheet) > PMDA Data Type DTD (R3)
Data Length	Textbox Length: 9 chars	This text box allows user to enter only Numeric Values For PMDA E2B (R3): Refer Mapping xls > Mapping(Sheet) > PMDA Length DTD (R3)

Field	Type	Description
Mandatory Along with	Drop-down list	This drop-down list contains the DTD_ELEMENT names that are present under the same parent of the selected element (except the selected element itself), with blank as the first and the default option Format: DTD_ELEMENT(DATA_ELEMENT) Display Order: Same as they are listed in the Element navigation tree on the left For PMDA E2B (R3): Refer Mapping xls > Mapping(Sheet) > Mandatory Along with
Allowed Value Check Required	Checkbox	This checkbox is left unchecked by default For PMDA E2B (R3): Refer Mapping xls > Mapping(Sheet) > Allowed Values
Allowed Values	Button	Clicking this button opens up *Allowed value configuration* Dialog for configuring the allowed values for the selected elements against that profile This button is enabled only if *Allowed Value Check Required* checkbox is checked For PMDA E2B (R3): Refer Mapping xls > Mapping (Sheet) > Allowed Values
Primary Validation Category	Drop-down list	This drop-down list is available for EMA profiles only. The following option is listed in the drop-down list in the below specified order: Blank (Default) Mandatory Conditional Mandatory Do not enter Other Fatal Validation Optional
Additional Validations	Button	On clicking this button, the Additional Validation Configuration Dialog opens up, this Dialog enables users to configure the SQL based validations for the element. This button is available for EMA.
Print	Button	On clicking the print button, the application prints all the Conformance rule tab data.

PMDA-E2B specific fields

Field	Type	Description
Reporting Category	Label	All Reporting Category (R3) Codes (AA, AB, AC, AD, AE, AF, AG, DA, DB, DC, DD, DE, DF, DG, BC, BD) as configured in the Reporting_category (flex code list) are listed here, along with Nullification.
Reporting Category Description	Label	Description of the corresponding Reporting Category is listed here.

Field	Type	Description
Primary Validation Category	Drop-down list	This drop-down list is available for PMDA profile only. The following option is listed in the drop-down list in the below specified order: Blank (Default) Mandatory Mandatory for Completion Report Conditional Mandatory for Completion Report Conditional Mandatory Do not Enter Other Fatal Validation Optional For PMDA E2B (R3): Refer Mapping xls > Mapping (Sheet) > Reporting Category wise Conformance
Additional Validations	Button	On clicking this button *Additional Validation Configuration*, the Dialog opens. This Dialog enables users to configure the SQL based validations for the element. Available button available against each Reporting Category.
Save	Button	On clicking the Save button, the changes are committed to Data base and audit logged. This committing of data includes any changes done in the *Allowed Value Configuration* and *Additional Validation Configuration* Dialogs as well. On clicking the Save button, the application logic validates that there exists a Primary category for the ICSR Element • In case of Non-PMDA profile: Element Level • In case of PMDA: Reporting category level If there exists a row with primary category as blank, the application displays an error message: `Please select a Primary Validation category for the element`, Title: ICSR Validation with **OK** Button.
Print	Button	On clicking the print button, the application prints all the Conformance rule tab data.

The Allowed Values Configuration Dialog

On clicking **Allowed Values**, the Allowed Values Configuration Dialog (modal Dialog) opens. The Allowed Values Configuration Dialog lets users View, Add, Update, Delete and Associate/De-associate the Codes and Description attribute of the Allowed values for the particular ICSR element for that profile.

Description for fields/buttons on the Allowed Values Configuration Dialog:

Table 3-1 Allowed Values Configuration Dialog fields

Type	Description
Code textbox	This is a textbox where user enters the Code value that is being transmitted in the ICSR report. For example, E2B R3 Codes, ISO code and so on.
Description textbox	This is a textbox where user enters the description against the Code that is being transmitted in the ICSR report.
Description (J) textbox	This is a textbox where user enters the Japanese description against the Code that is being transmitted in the ICSR report. This is visible only to J user (when J module is enabled) and only for PMDA Profile
Edit button	On clicking the edit button, the Code and Description textboxes become enabled for user to edit

The Additional Validation Configuration Dialog

Clicking **Additional Validations** displays the Additional Validation Configuration Dialog which lets the user View, Add, Update, Delete, Associate/De-associate, categorize and mark a validation to be Primary for the ICSR element of that profile.

If user marks any validation as Primary, the Associated drop-down list is disabled by default.

On unchecking the **Primary Validation** checkbox, the Primary validation checkbox for all other validations and the Associate and Validation Category drop-down lists for this particular validation are enabled.

For EMA profiles, the Additional Validation can be configured at the element level, whereas for the PMDA profile the validation can be configured individually against each reporting category for that element.

The OOTB validations are only allowed to be Associate, Disassociate, categorized or marked as primary for the element, and the Edit button always remains disabled for all such OOTB validations.

Description for fields/buttons on the Additional Values Configuration Dialog:

Table 3-2 Additional Values Configuration Dialog fields

Type	Description
Message Text area	In this text area, the user specifies the message that is printed in the validation report in case of a failure validation.
Message (J) Text area	In this text area, the user specifies the Japanese message that is printed in the validation report in case of a failure validation. This is visible only to J user (when J module is enabled) and only for PMDA Profile.
Validation SQL Text area	In this text area, the user specifies the SQL condition for the validation that is executed in order to run this particular validation.
Edit button	On clicking the edit button, the Message and Validation SQL text areas becomes enabled for user to edit.

Table 3-2 (Cont.) Additional Values Configuration Dialog fields

Type	Description
Associate Drop-down list	Lets the user associate or de-associate the allowed value for an element for the profile and has the following set of values: (R3) profiles that supports both Export & Import, that is, EMA (R3) a. Blank (Validation not associated with this profile) b. Transmit (Validation only applicable during export) c. Receive (Validation only applicable during Import) d. Transmit & Receive (Validation applicable for both Export & Import) (R3) profiles that support Export but do not support the Import a. Blank (Validation not associated with this profile) b. Transmit (Validation only applicable during export)
Validation Category	User specifies the category of validation by selecting an option from this drop-down list.
Primary Validation checkbox	User marks a validation as primary validation against an element for the profile by checking this checkbox.
Add button	On clicking the Add button, a new row is added to the grid, with Message, Description text areas, Associate drop-down list and Validation Type drop-down list (blank) enabled by default.
Delete button	Deleted button is disabled by default, and is enabled only if user selects a user created custom validations row in the grid.

Use the Receive tab

Use the following procedure to view details on the **Receive** tab:

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

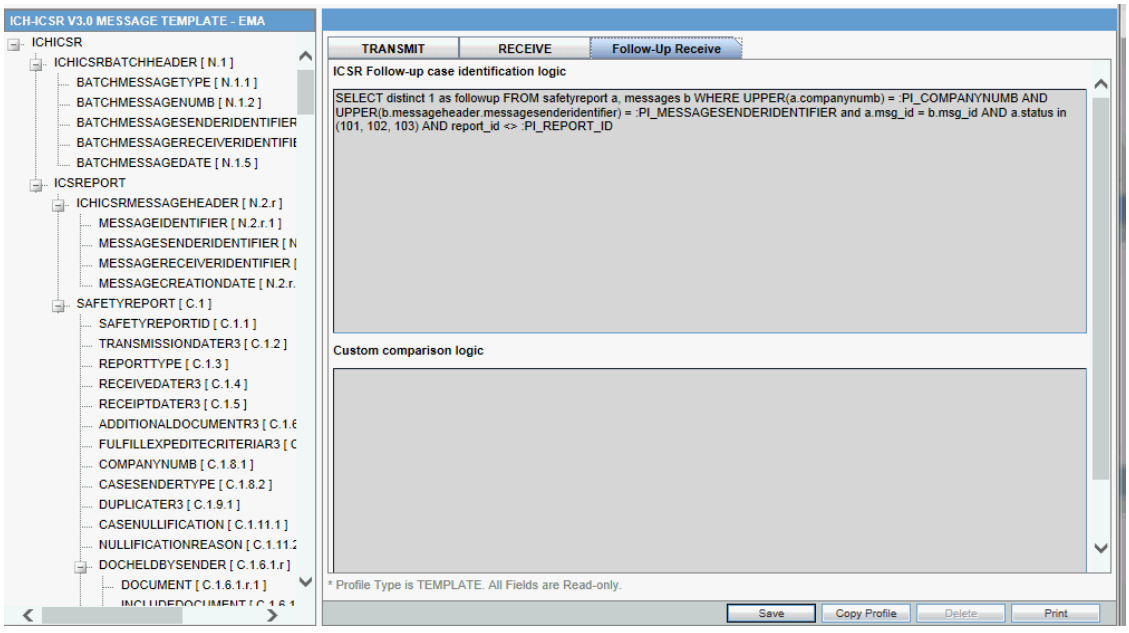
The following table lists and describes the fields on the **Receive** tab:

Item	Description
Import Mapping Logic: PL/SQL Code	Enables you to enter and view the PL/SQL code to be processed for the selected element of the profile during the import.
Enable Post-Save checkbox	Enabled for Template and Custom profiles and is a profile level switch. When this checkbox is marked, then post-save routines are executed while importing an ICSR message.
Extended ICSR	Enabled only for Custom profiles and is a profile level switch. When this checkbox is marked, the profile is considered as an Extended ICSR Profile (ICSR+ Profile).
Current Element is part of Primary Key	When this checkbox is marked, this field is treated as part of the Primary key. Values in Primary keys are used for matching data in an existing case while importing Follow-up reports. Based on the results, either a new record is created or an existing record is updated.

Item	Description
Select AE column as a part of Primary Key	Displays the Argus Case Form Database column name to which the current primary key E2B element is mapped. This relationship compares the E2B element from the incoming follow-up report to the related Case Form database column name value in the target case to identify matching records in repeater sections.
Always Import for Initial/ Follow-up reports	Governs the default UI behavior of the Import checkbox that appears against each element in the E2B Difference Report screen. If this checkbox is checked for an element, the corresponding checkbox on the E2B Difference Report screen also appears as checked and disabled. By enforcing the behavior of always importing that element, the user cannot uncheck the checkbox on the E2B difference screen.
Configured Receive Logic	This drop-down lists the descriptive names (alphabetical order) for all the configured Import Mapping logic for the particular element across all the HL7 based ICSR profiles. The first value is blank and the last value is (Add New). This drop-down value is available for editing for all custom profiles and is read-only for OOTB Template profile.

Use the Follow-up Receive Tab

The **Follow-up Receive** tab enables you to configure the configuration attributes for the ICSR profile that are specific for the Follow-up imports of the ICSR file. This tab is available for R3 based ICSR profiles that support the import (currently applicable for EMA and PMDA (R3)).



To configure the validations rule against the ICSR element, following fields have been made available to user under the Follow-up Receive tab:

Field	Type	Description
ICSR Follow-up case identification logic	Text Area	Profile level logic to identify the Follow-up case against the incoming ICSR. OOTB default logic: Current Argus embedded logic
Custom comparison logic	Text Area Default : Blank	Profile level option to specify the logic to customize the OOTB PK driven Difference report data such that user can define a PL/SQL block with this section to control the Difference report data that will be further used during the case acceptance. The order of execution for the Custom logic is that, first all the embedded OOTB system logic to build the comparison data are executed with application of Default deletes, and then once the embedded logic for Difference report execution is completed the configured custom comparison logic is invoked and the result of that custom logic is reflected on the difference report UI and further will be consumed during case data acceptance. The Configured custom logic is executed under the same DB user level access right as application does for import mapping SQL logic. Validate that under the same access right user is able to update, insert and delete the data of the Difference report table. Any changes to the custom logic are audit logged and are supported in the copy profile and print as well. Application provides all the possible Bind variable that this custom logic would require in order to define the business specific logic.
PK Element configuration	Download (Button)	This button facilitates the user to configure the PK's for identifying the repeater records in the ICSR file, so that those can be used while building the Difference report such that, if for a repeater record the configured PK elements are same in the incoming ICSR and the ICSR from the Case data then that record shall be treated as the same record. On clicking of the Download button application will export a CSV file with all the PK's for that profile as per the attached sample.

Field	Type	Description
PK Element configuration	Upload (Button)	On clicking the upload button the standard Argus upload dialogue appears with fowling title and label: Title: ICSR Mapping Utility Label: ICSR PK Element Configuration Allowed File Types: CSV As soon as user uploads the CSV file with the application executes a validation over the uploaded file to in order to validate that the uploaded CSV file is as per the application expectations. • Profile: column lists only the name of the profile for which file is getting uploaded. In case of any mismatch an error is pushed into Val_error column (<Profile Name> is different than the current profile). • PARENT_ELEMENT: The data in this column is validated to list down only those elements which have child elements to them in the current profile. In case of any incorrect entry an error is pushed into Val_error column (<Parent Element> is not a valid Parent element as per the current profile). • DTD_ELEMENT: The data in this column is validated to list down only those elements are true child elements i.e. they are the exact root node of the xml. In case of any incorrect entry an error is pushed into Val_error column (<DTD Element> is not a valid Child element as per the current profile). • DTD_ELEMENT: The data in this column is validated that the elements belongs to the Parent element as per the current profile. i.e. DRUGCHARACTERIZATION - Parent element is "DRUG" as per the EMA R3 OOTB Profile whereas in the uploaded CSV the parent for the same is mentioned as DRUGINDICATIONR3 then the error is pushed to the VAL_Error column (<DTD Element> doesn't belong to <Parent Element> as per the current profile).

Field	Type	Description
PK Element configuration	Upload (Button)	• DEFAULT_DELETE: The data in this column is validated to see if it contains any value other than "Y" or "N". Where "Y" denotes that the repeater element will be marked for Deletion by default in case of no match with the incoming file. And "N" denotes that the repeater block will not be marked for deletion by default. In case of any other value in the columns the error is pushed to the VAL_Error column (Incorrect value. Value should be either "Y" or "N"). • DEFAULT_DELETE: The data in this column is validated to see the same value exist for all the rows for a particular PARENT_ELEMENT i.e. for all the rows for a particular parent element the value for DEFAULT_DELETE should be same. In case of validation failure the error is pushed to the VAL_Error column (All the values corresponding to <PARENT_ELEMENT> should be same). • None of the four columns "PROFILE", "PARENT_ELEMENT", "DTD_ELEMENT" & "DEFAULT_DELETE" are blank for either of the row. In cases any of them is blank the error is pushed to the VAL_ERROR column(<Column Name(comma separated)> cannot be blank). • As soon as user upload the CSV file all the above validation is executed and in case there are any errors the file with the error listed in VAL_ERROR column is pushed to user from the browser (all these operations shall be performed within the upload user action). Also, if there are any validation errors the uploaded file data is not reflected into the DB configurations i.e. only a file without any validation errors can be committed to DB. • All the changes to the PK's are audit logged. The VAL_ERROR column is only present in CSV file only when there are any errors to the uploading file. It is not be present in the normal downloaded or uploaded file.

Print a Profile

Use the following procedure to print a profile.

1. Select the profile to print from the Profile list.
2. Click **Print**. This prints a PDF of the selected profile.

Copy a Profile

> **Note**
>
> The Copy Profile option can be used to create custom ICSR profiles with customized Export/Import mapping logic for any ICSR element. However, any new changes or fixes applied to factory ICSR profiles are not automatically applied to the custom ICSR profiles. For this reason, custom profile logic may be made obsolete by any Oracle Argus Safety upgrade which has changes or fixes applied to factory ICSR profiles. In such a scenario, you should re-create your custom ICSR profile again by copying the new factory ICSR profile and applying your custom Export/Import mapping logic manually.

Use the following procedure to copy a profile.

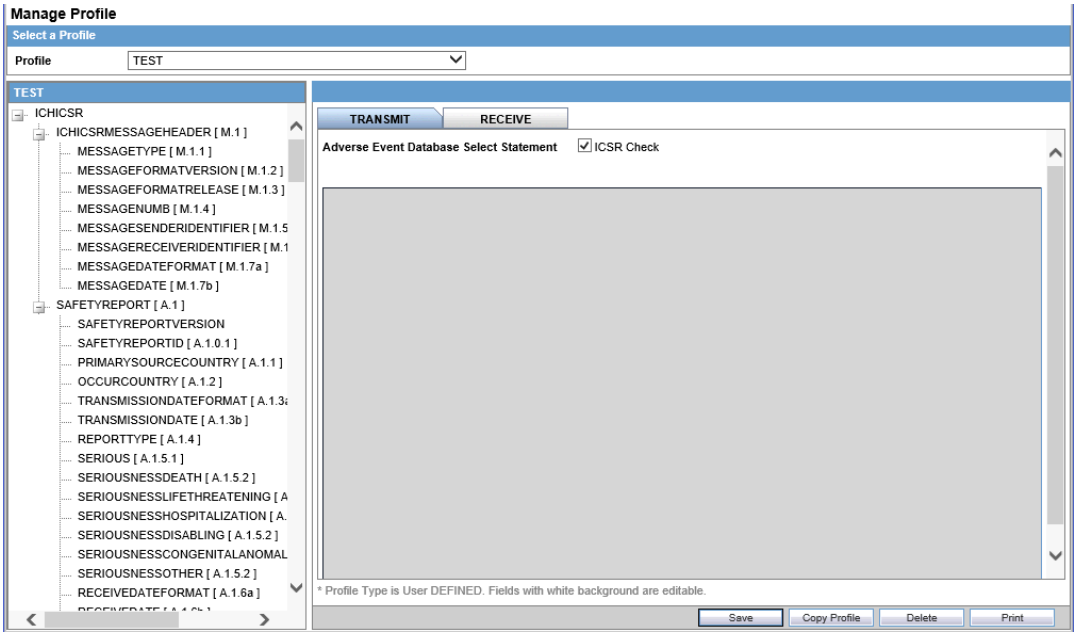
1. Select the profile to copy from the Profile list.
2. Click **Copy Profile** to open the Copy Profile dialog box.
3. Type the profile name in the To Profile field, and click **Save**.

Delete a Profile

You can only delete profiles created or modified in the Interchange Mapping interface. You cannot delete Template profiles.

Use the following procedure to delete a profile.

1. Select a custom profile to delete from the Profile list. The system enables the **Delete** button.



2. Click **Delete**.

3. Click **Yes** to confirm.

Compare Profiles

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

To compare profiles:

1. On the Oracle Argus Interchange Mapping menu, click 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.

For more information, see:

- Compare Profile Dialog Box Fields

Compare Profile Dialog Box Fields

The following table lists and describes the fields on 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 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.

Item	Description
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.
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 are 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 appears: "No differences found and no report is 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 appears: "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.

ICSR Codes Translation

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

Go to Oracle Argus Console > **System Configuration** > **Interchange Mapping** > **ICSR Translation Codes** to open the ICSR Code Translation screen.

> **Note**
>
> Oracle Argus Console > **Interchange Mapping** > **ICSR Code Translation** has been enhanced to list all (R3) elements in addition to the existing elements in the DTD Element Name drop-down list as specified in Codelist Translation column of the Import Mapping xls. The values in this drop-down list are filtered based on what is selected in the newly added ICSR Type drop-down list, that is, if (R2) is selected, then all (R2) elements are listed and if (R3) is selected, all (R3) elements are listed.

For more information, see:

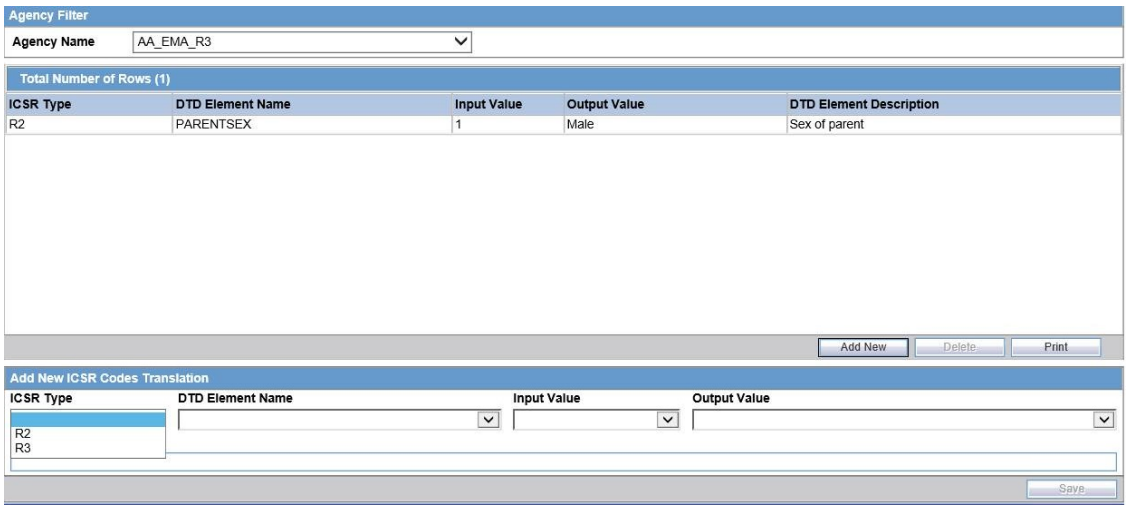
- Configure ICSR Codes Translation
- ICSR Codes Translation Fields

Configure ICSR Codes Translation

Use the following procedure to configure ICSR Codes Translation.

1. Select the Agency Name from the drop-down list box to display the Elements and their descriptions.
2. Click on the respective field to edit the **Element Name**, **Input Value**, **Output Value**, and **Element Description**.
3. Click **Save** to save your changes.

ICSR Codes Translation Fields



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

Item	Description
Agency Name	Enables the user to select an agency name from the drop-down list box. This drop-down lists the agencies configured with the (R3) profile (that supports the import of ICSRs) under the EDI tab (applicable for PMDA (R3) and EMA (R3) along with the (R2) agencies.
#	Displays the serial number.
ICSR Type	Enables the user to configure the translation code at the ICSR message type level. It lists two values (R2) (default) and (R3), and is enabled by default when the user creates any new entry to translation configuration.
Element Name	Displays the element name.
Input Value	Displays the type of input value.
Output Value	Displays the type of output value.

Service Configuration

Use this menu option to configure the Interchange service, manage the Interchange profiles and ICSR code translations, compare profiles, and view audit log information for the Interchange mappings.

This menu is available only if you have access to the ESM admin user role.

To set up the configurations, go to `Argus Console > System Configuration > Interchange > Service Configuration`, and enter the details in each section of this screen as described below.

Transmit Configuration section

The following table provides details of the fields required to configure transmit requirements. You can enter any number between 1 to 99999 in these fields, except Queue Size that has the value range from 10 to 99999.

On fresh installation or upgrade, the default value for these fields is auto-populated.

Field name	Default value
Process Elapse Time in Mins	1
EDI Transmit Time Out Value (File not picked up by gateway) in Mins	60
Binary Transmit Time Out Value (File not picked up by gateway) in Mins	60
Receive ACK Time Out Value (ACK is due for transmitted reports) in Mins	1440
Physical Media Transmit Time Out Value(File not picked up manually) in Mins	1440
MDN Time Out Value (For ICSR reports which have received business ACK) in Hours	24
Queue Size	1000 **Note:** This field controls the transmission queue size and allows minimum value as 10.

Gateway section

Select a gateway for interaction with other servers. The available options are Blank, Oracle B2B, and Axway Cyclone. By default, this field is left blank. When you select gateway as Oracle B2B or Axway Cyclone, the following fields appears and are mandatory to be set.

Field name	Default value	Allowed maximum length of value in characters
EDI Database Name	Blank	64
EDI User ID	Blank	30
EDI Password	Blank **Note:** The value you enter in this field appears as for each character.	-
EDI Password Confirmation	Blank **Note:** The value you enter in this field appears as for each character. The value in both EDI Password and EDI conformation password fields must be same.	-

Import Configuration section

Enter the server details that will be used for import.

Field name	Default value
Max Files Per Run	1000 **Note:** This field defines the maximum number files allowed to be picked by the Interchange Service to allocate them to E2BReceive.
Number of Receive Process	3
Processing Time Out Value(ICSR incoming report not processed by user) in Mins	60
Archive Folder	Blank **Note:** You must enter a value in this field before proceeding further.

Email section

In this section, the default value of all the fields is !. You can enter multiple email address in all the email fields except for the sender email.

Field name	Default value
IT Email	!
User Email	!

Field name	Default value
Sender Email	! **Note:** If you do not enter any value in this field and the value is left as default, then the application uses the sender email as defined in the `Console > System Configuration > SMTP configuration > Global From Address` as the from address, when sending emails pertaining to the Interchange.
Business Email	!

Updates made to the Server Configuration screen are auditable and details can be printed in the audit log report from `Console > System configuration > Interchange > View audit log`.

The changes made to this fields are applied from the subsequent process cycle.

The configuration set up through this screen is common to all enterprises and is displayed for the users with ESM admin user role when logged into any enterprise (not specifically the default enterprise). When the Interchange servers are deployed on multiple machines connecting to the same database, the individual Interchange servers uses the same configuration as configured here.

View the Audit Log

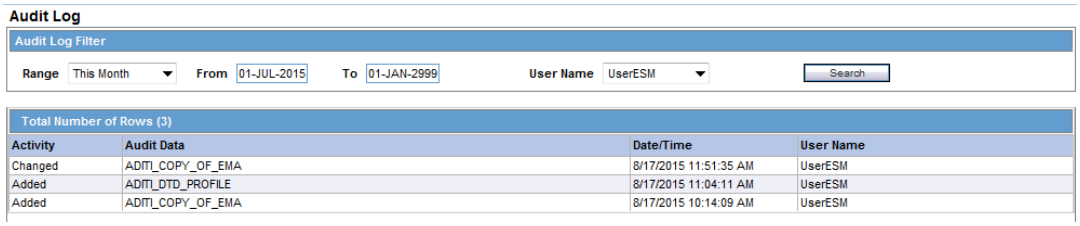
The Audit Log stores changes made to the system from the application. You can also view and filter individual changes.

Use the following procedure to view the Audit Log:

1. On the Oracle Argus Interchange Mapping menu, click **View Audit Log**.
2. When the system opens the **Audit Log** dialog box, enter the appropriate data in each field and click **Search**.

> **Note**
>
> For more information on **Audit Log** Dialog box fields, see Audit Log Dialog Box Fields.

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 and new values of the selected item.

For more information, see:

- Audit Log Dialog Box Fields

Audit Log Dialog Box Fields

The following table lists and describes the fields on 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 for the search.

> **Note**
>
> When the Oracle Argus Interchange Audit log is invoked, it shows the default range of the last 7 days.

User Name	Select a user from the list of users.
Print	Prints the current view.
Search	Performs the search.

ICSR Extensions

For more details, from the Argus Safety OHC page, download the Technical Reference Manuals, and refer to the *Oracle Argus Interchange ICSR Extensibility Guide*.

4

Validate Reports

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

For more information, see:

- Why perform an ICSR check?
- Report Generation Validations
- Validation Rules

Why perform an ICSR 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 ICSR check, the system performs a validation and lists the following types of validation errors for the data elements that are failing the validations in the ICSR Report data check errors and warnings:

E2B (R2), eVAERS, and eMDR:

1. Mandatory
2. Mandatory Optional
3. Together DTD Element Validation
4. Other Validation
5. Date Validation
6. E2B Generation Validation (only E2B(R2) reports)
7. Encoding Validation
8. Length check Validation

E2B (R3):

1. Mandatory
2. Conditional Mandatory
3. Other Validations
4. Together DTD Validation

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

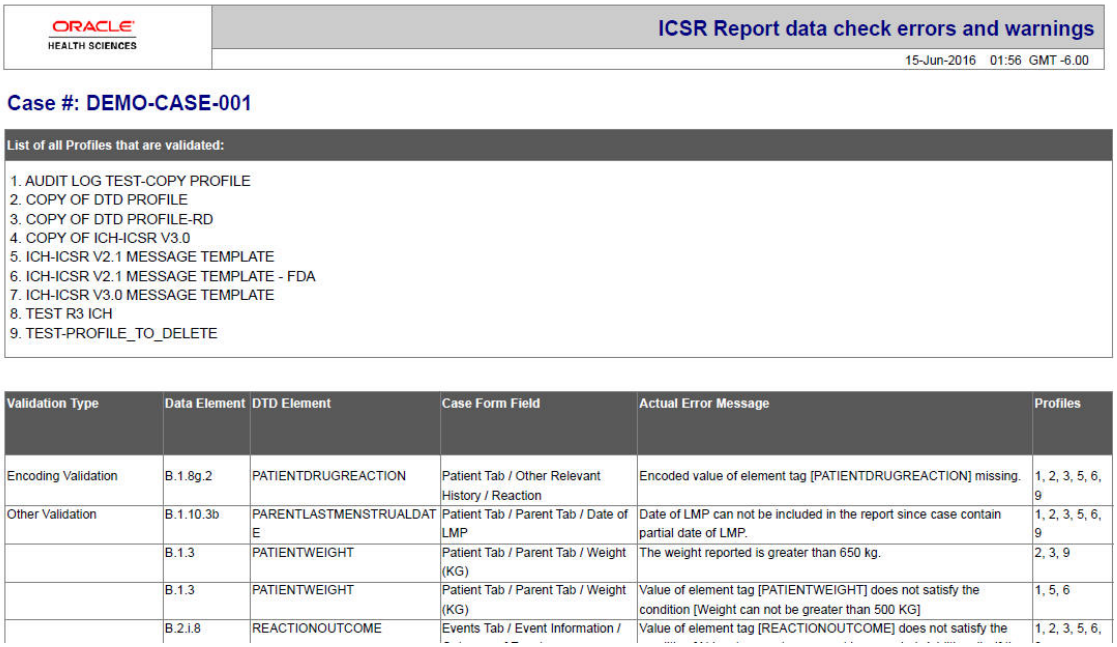
> **Note**
>
> The ICSR check icon is visible on the Quick Launch Toolbar ONLY if a case is open and active on the user session.

ICSR check can be used to validate E2B(R2), eVAERS and eMDR reports, provided the ICSR check flag is marked in the Interchange Mapping Utility.

ICSR check can be used to validate EMA E2B(R3), PMDA E2B(R3), FDA E2B(R3), NMPA E2B(R3) and MFDS E2B(R3) profiles provided the following conditions are met:

- ICSR check flag is marked in the Interchange Mapping Utility
- Profile is configured with at least one of the reporting destinations

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



ORACLE HEALTH SCIENCES

ICSR Report data check errors and warnings

15-Jun-2016 01:56 GMT -6.00

Case #: DEMO-CASE-001

List of all Profiles that are validated:

1. AUDIT LOG TEST-COPY PROFILE
2. COPY OF DTD PROFILE
3. COPY OF DTD PROFILE-RD
4. COPY OF ICH-ICSR V3.0
5. ICH-ICSR V2.1 MESSAGE TEMPLATE
6. ICH-ICSR V2.1 MESSAGE TEMPLATE - FDA
7. ICH-ICSR V3.0 MESSAGE TEMPLATE
8. TEST R3 ICH
9. TEST-PROFILE_TO_DELETE

Validation Type	Data Element	DTD Element	Case Form Field	Actual Error Message	Profiles
Encoding Validation	B.1.8g.2	PATIENTDRUGREACTION	Patient Tab / Other Relevant History / Reaction	Encoded value of element tag [PATIENTDRUGREACTION] missing.	1, 2, 3, 5, 6, 9
Other Validation	B.1.10.3b	PARENTLASTMENSTRUALDATE	Patient Tab / Parent Tab / Date of LMP	Date of LMP can not be included in the report since case contain partial date of LMP.	1, 2, 3, 5, 6, 9
	B.1.3	PATIENTWEIGHT	Patient Tab / Parent Tab / Weight (KG)	The weight reported is greater than 650 kg.	2, 3, 9
	B.1.3	PATIENTWEIGHT	Patient Tab / Parent Tab / Weight (KG)	Value of element tag [PATIENTWEIGHT] does not satisfy the condition [Weight can not be greater than 500 KG]	1, 5, 6
	B.2.i.8	REACTIONOUTCOME	Events Tab / Event Information /	Value of element tag [REACTIONOUTCOME] does not satisfy the	1, 2, 3, 5, 6,

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 following are not covered by the ICSR check:

- Attachment size validations are not supported as part of the ICSR check for any of the E2B (R3), eMDR, and eVAERS Profiles.
- The ICSR check does not validate data elements pertaining to the Batch and Message headers of the ICSR.
- Validations are not provided for elements that are mandatorily captured in Oracle Argus.
- Validations related to follow-up and Nullification reports are not displayed in the ICSR check report.

To perform an ICSR check, the system requires some reference data based on which validations can be performed. The system uses the following (existing) logic:

Element	Description
Agency	Considers the first available Agency that was configured with the Profile in Reporting Destination.
Product License	Considers the License used in the first available Product in the Case Form.
Reporting Category (for PMDA (R3))	Uses the Reporting Category data for the first available Product in the Case Form.

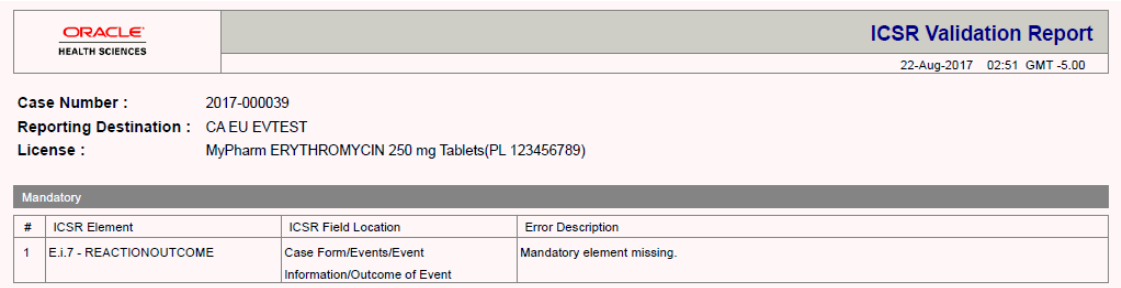
Report Generation Validations

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. Report File Size validation (for HL7 Reports only)
6. File type of attachments that qualify to be included

The system displays an error message in the following scenarios:

1. While generating draft E2B or eVAERS or eMDR report using Draft tool button, if the default Reporting Destination is not specified for E2B or eVAERS or eMDR in Common Profile Switches.
2. While generating draft/final E2B or eVAERS or eMDR report for the Reporting Destination which is not configured with valid Message Profile as E2B or eVAERS or eMDR respectively.
3. While generating E2B(R3) or eVAERS or eMDR report, if the size of inline attachments or overall size of xml file exceeds the maximum file size limit specified in the Reporting Destination configuration.
4. While validating the file type of the attachments that qualify to be included in the E2B(R3) report and displays a validation message to indicate the file type provided for the attachment does not confirm with the allowed file types for the report.



ORACLE HEALTH SCIENCES

ICSR Validation Report

22-Aug-2017 02:51 GMT -5.00

Case Number : 2017-000039
Reporting Destination : CA EU EVTEST
License : MyPharm ERYTHROMYCIN 250 mg Tablets(PL 123456789)

Mandatory

#	ICSR Element	ICSR Field Location	Error Description
1	E.i.7 - REACTIONOUTCOME	Case Form/Events/Event Information/Outcome of Event	Mandatory element missing.

Validation Rules

Validation Rules for all profiles can be viewed from Oracle Argus Console > **System Configuration** > **Interchange Mapping** > **Manage Profile**.

E2B Generation validation rules are executed on the generated ICSR report data.

The validation rules that are applicable to individual element is governed by configuration in the Conformance Rules tab for that element for the respective profile.

Validation Rule the elements is categorized amongst the following categories:

- **Basic Data Validation**: This category covers all the applicable validation based on the Length of the field.
  Length - This validation check validates if the data type length of output is within with the configured Data length or not. If the data length is exceeding the configured length then validation error is listed in the validation report.
- **Allowed Values Data Check:** The element for which the *Allowed Value Check Required* checkbox is checked is validated against the allowed values codes associated with them using *Allowed Values Configuration* Dialog for the respective profile.
- **Mandatory Along with (Together):** Elements for which the *Mandatory along with* element is specified, validation rule validates for such elements in the generated ICSR the element itself and the configured Dependent element co-exist or none of them exists in the report.
- **Validation Category Based:** The element is validated as per the value configured for that element in the *Validation Category* drop-down list in the Conformance rule tab.
  The elements for which there exists a SQL based validation for which *Primary Validation* checkbox is checked in the *Additional Validation Configuration* Dialog, the framework based validation is not executed for them; rather the configured SQL based validations is executed for them.

  These validations are categorized in two sub categories, one for the ICSR reports for the EMA/ MFDS/ NMPA/FAERS profile, and the other ICSR Report for the PMDA profile.

  The validation for the PMDA report is fired at each reporting category level:

  – **EMA/ MFDS/ NMPA/FAERS**

    Mandatory: The element which is configured as Mandatory should be present in the ICSR Report; if it is not present in the report output then application displays the validation failure in the validation report.

    Conditional Mandatory: The element which is marked as Conditional Mandatory is present based on certain condition, hence it is expected that user will configure a Validation for it in the *Additional Validation Dialog*. There is no framework based validation for the elements configured with this validation type in Conformance rule tab.

    Optional: The element which is marked as optional may or may not be present in the report, but still there could be a possibility that there might exist a validation under the *Additional Validation Dialog* and if any of the configured validation is failed it will be listed in the validation report.

    Other Fatal: There is no framework based validation for the elements configured as other fatal validation type in Conformance rule tab.

  – **PMDA**
    Mandatory: The element which is configured as Mandatory should be present in the ICSR Report; if it is not present in the report output then application displays the validation failure in the validation report.

Mandatory for Completion: The element which is marked as Mandatory for completion should be present in the ICSR Report if J2.7.1 (MHLWADMICSRCOMPLETECLASS) = completed for that report; if it is not present then application displays the validation failure in the validation report.

Conditional Mandatory and Conditional Mandatory for Completion: The element which is marked as Conditional Mandatory or Conditional Mandatory for Completion is present in the report based on certain condition, hence it is expected that user will configure a Validation for it in the *Additional Validation Dialog*. There is no framework based validation for the elements configured with these validation types in Conformance rule tab.

Do not Enter: The element which is marked as Do not enter are not present in the report, and if they are present than application lists the validation failure in the validation report (Argus report generation logic removes the elements that are marked as Do not enter at the time on generation itself).

Optional: The element which is marked as optional may or may not be present in the report, but still there could be a possibility that there might exist a validation under the *Additional Validation Dialog* and if any of the configured validation fails, it is listed in the validation report.

Other Fatal: There is no framework based validation for the elements configured as other fatal validation type in Conformance rule tab.

- **Additional Validations:** The Additional SQL based validations associated with elements in the respective ICSR profile (element level for E2B other than PMDA and Reporting category level for PMDA E2B), the validation is fire based on the SQL logic specified under the Validation SQL.

Validations for MIR:

- When you click the **Draft** button for the MIR Report, the validations are performed based on conformance rulesfor EC, and lists failed validations in the MIR Validation Report.
- The MIR Validation Report can be viewed as a PDF report.
- If the case data has the necessary data to meet the conformance rules for EC, a draft MIR XML (default) or PDF is generated in a separate window. You can **MIR PDF** from the **View** format.
- When the MIR report is generated by the AG Services, validation check is performed and the validation errors are logged in the log file.

5

Transmit and Monitor Reports

Oracle Argus 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.

For more information, see:

- Schedule Reports
- Generate Reports
- Attachments in Reports
- Transmit Reports
- Nullification Reports

Schedule Reports

Oracle Argus enables you to schedule the generation of your E2B, eMDR and eVAERS reports.

> **Note**
>
> When you generate an E2B report, some characters entered by the user in the case form may not be displayed 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 Oracle Argus Safety and click the **Regulatory Reports** tab.
2. When the system opens the Regulatory Reports tab, click **Schedule New Report** from the bottom of the screen.
3. When the system opens the New Expedited Report Dialog box, enter the relevant information and click **OK**.

For more information, see:

- New Expedited Report Dialog Fields
- Nullification Reports
- Follow-Up eMDR Reports
- Follow-up eVAERS Reports

New Expedited Report Dialog Fields

The Schedule New Expedited Report window has a Report Information 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	Select the Aware date for which the report is required to be scheduled. Amendment reports can be scheduled by selecting the Aware date which is appended with text (A).
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.
Protect confidentiality of Reporter and Patient	Select this checkbox if you do not wish to disclose the identity of the reporter and the patient in the report.
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.

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/ N.1.2	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 / N.1.5	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/C.1.2	System enters the message date.
A.1.13/C.1.11.1	System enters 1=Yes on the Nullification report.
A.1.13.1/C.1.11.2	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.

- However, the receipt date for A.1.7 item is fetched based on the latest significant follow-up date used while generating the nullification reports instead of the date from the previous submitted 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.*
- Nullification reports are not scheduled for eMDR and MIR.

Follow-Up eMDR Reports

If an eMDR report is manually scheduled or automatically scheduled for the same reporting Destination, system either schedules Initial or Follow-up report based on the same logic (product license ID and status of previously scheduled report) that is currently existing for Device reports.

If the case was previously submitted to a Reporting Destination as MedWatch Device report and if the same reporting destination is configured for sending eMDR report:

1. System schedules the next eMDR as a follow-up report and displays the follow-up numbering in the Case Form ' Regulatory Reports ' Seq field by considering the previously reported MedWatch device report.
2. System uses the same report number (F.2 or G.9) that was used in MedWatch Device report in eMDR for the data element ufimporterrepnumber(F2) or mfrreportnumber (G8).
3. Follow-up number that is populated in (F7 uffollowupnumber or G6 gfollowupnumber) shall be incremented from (F7 or G6) of the previously submitted MedWatch Device report by considering the internal common profile switch *Allow generation of Report*.

Example : If F/p 1 report was submitted as 0000555-2014-00011 to CDRH in MedWatch format and the next follow-up report in eMDR format, then Mfr Report # shall be populated as 0000555-2014-00011 and F/p number as 2.

If the previous report was sent by eMDR and the subsequent report is being sent as MedWatch Device to the same destination, the system shall maintain the report numbering (F2 or G8) same as of previously submitted eMDR.

1. System schedules a follow-up report by populating *Follow-up' in the Case Form* Regulatory Reports' Seq column.
2. System uses the same report number (F2 or G8) from the previously submitted eMDR report in the F2 or G8 of MedWatch Device report.
3. Follow-up number that is populated in (F7 or G6) is incremented from (F7 uffollowupnumber or G6 gfollowupnumber) of the previously submitted eMDR report by considering the internal common profile switch *Allow generation of Report*.
4. The MedWatch Device scheduled after the eMDR report does not respect the Common Profile Switch "*Data to print on follow up MedWatch Device form* "and system displays a

warning message during manual scheduling of report as *Delta data will not be printed MedWatch Device form for this Device license as it was previously submitted as an eMDR*. In case automatic scheduling, this warning message is logged against the report without impacting report scheduling or generation.

Example: If F/p 1 report was submitted as 0000555-2014-00011 to CDRH in eMDR format and the next follow-up report in eMDR report fails due to some reason and company decides to send them in MedWatch device format, then MedWatch report shall print Mfr Report # as 0000555-2014-00011 and F/p number as 2

System includes complete data in follow-up eMDR as the other E2B (R3) reports.

> **Note**
>
> Common Profile Switch Data to print on follow up MedWatch Device form does not have any impact on eMDR follow-ups.

Downgrade report is scheduled automatically if the F/UP version does not satisfy the Regulatory Reporting Rules defined for eMDR for a case that was previously submitted in eMDR.

Follow-up eMDR is scheduled automatically if the Significant F/UP version is marked as Amendment for a case that was previously submitted in eMDR (existing functionality for non E2B (R3) reports).

Nullification reports are not scheduled for eMDR.

Follow-up eVAERS Reports

If an eVAERS report is manually scheduled or automatically scheduled for the same reporting Destination, system either schedules Initial or Follow-up report based on the same logic (product license type and status of previously scheduled report) that is currently existing for E2B reports.

If the case was previously submitted to a Reporting Destination in VAERS PDF format and if the same reporting destination is configured for sending eVAERS report:

1. System schedules the next eVAERS as a follow-up report and displays the follow-up numbering in the Case Form ' Regulatory Reports ' Seq field by considering the previously reported VAERS.
2. If any Follow-up reports are scheduled to the same destination at a later point of time, system schedules a follow-up report by populating *Follow-up<##> in Case Form* Regulatory Reports Seq column.
3. System uses Case Number (as printed in the Manufacturer Control Number (that is listed in Box 24) of the previously submitted VAERS report) in data elements C.1.1. and C.1.8.1.

If a reporting destination is configured for eVAERS and VAERS reports and if the previous report was sent in eVAERS format and if the subsequent report is scheduled in VAERS PDF format to the same destination:

1. System schedules an initial report by populating *Initial' in the Case Form* Regulatory Reports Seq column.
2. If any Follow-up reports are scheduled to the same destination at a later point of time, system schedules a follow-up report by populating *Follow-up<##> in Case Form* Regulatory Reports Seq column.

3. System does not use (C.1.1) from the previously submitted eVAERS report as the Manufacturer Control Number of VAERS report.

> **Note**
>
> If user tries to generate eVAERS and VAERS in parallel for a Case, then system has different MCN for eVAERS and VAERS reports for the same case.

Downgrade report is scheduled automatically if the Significant F/UP version does not satisfy the Regulatory Reporting Rules defined for eVAERS for a case was submitted in eVAERS.

System auto-schedules Amendment report instead of a follow-up report for a Reporting Destination configured with eVAERS profile, when:

a. eVAERS report was previously submitted to the same Reporting Destination for the same license type

b. if the latest record in the 'Amendment / Follow-up section' of Case Form ' General is an Amendment and the Amendment record was created for previously submitted eVAERS report

System auto-schedules a Nullification report instead of follow-up report for a Reporting Destination configured with eVAERS, under the same conditions (Case deletion and manually scheduling Nullification from Reports Compliance Submitted Reports Schedule Nullification) as per current functionality on Nullification reports for E2B profiles.

When Nullification report is generated, following data element items have updated values from the previous report.

- N.1.2 batchmessagenumb
- N.1.5 batchmessagedate
- N.2.r.4 messagecreationdate
- C.1.2 transmissiondater3
- C.1.11.1 casenullification
- C.1.11.2 nullificationreason

Generate Reports

Use the following procedure to generate a scheduled report.

1. E2B, eMDR, eVAERS, and MIR reports scan 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 report generation, the validation details are stored in the Report Details Dialog.
2. E2B, eMDR, eVAERS, and MIR reports are generated by AG Services for a locked case which has scheduled 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`.

Attachments in Reports

Case Form Attachments are sent to Reporting Destination with the 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.

> **Note**
>
> While transmitting attachments using the FDA profile in the E2B(R2) format, the system places the attachment file (PDF file created by merging all relevant attachments) in the configured Attachment folder (Reporting Destination > EDI tab > ICSR Attachment Outgoing folder) only after receiving a positive ACK for the ICSR submitted in the E2B(R2) format as an Initial or Follow-up report.
>
> The placement of Attachment files in configured folder after receipt of Positive Ack is done only for E2B(R2) generated using FDA E2B(R2) profile (CFG_PROFILE.AUTHORITY_ID=2.
>
> The system retains the ICSR Attachment in the Outgoing folder if a negative acknowledge is received for an ICSR.

Case Form Attachments are sent to the Reporting Destination with E2B(R3) report as described below:

1. Case Form Attachments are embedded within the ICSR sent in report formats such as E2B(R3), eVAERS and eMDR.
2. Attachments are encoded in the B64 format and sent in the report. The selection of attachments is based on Reporting Destination configuration.
3. Attachments for E2B(R3) are compressed using the compression algorithm configured before embedding them to ICSR. The default algorithm used is DF (Deflate). Attachments are not compressed in eVAERS, eMDR and FDA E2B(R3) reports.
4. Attachments that were sent out in previous submissions are not sent in Follow-up submission of E2B(R3), eVAERS and eMDR reports (only new and updated attachments are sent in Follow-up reports).

> **Note**
>
> Case Attachments are not sent along with the MIR Report.

5. For ICH, EMA, MFDS and NMPA attachments, the supported file formats are defined in their respective common profile switches: `ALLOWED_ATTACHMENT_FILE_TYPES`. You can configure additional file formats in `Flexible Re-Categorization Code Lists > Mediatype`, under the respective attributes.
   eMDR and eVAERS support attachment types that are configured under the FDA attribute.

   FDA E2B(R3) support attachment types that are configured under the FAERS attribute.

Transmit Reports

To learn how to monitor and transmit a report, and view status, see:

- Transmit ICSR Reports
- Transmit Bulk Reports by Form
- Monitor ICSR Transmit Status
- Monitor ICSR Receive Status
- View Status
- View Acknowledgement Information

Transmit ICSR Reports

Oracle Argus enables you to simultaneously submit multiple adverse event reports to ease the submission process.

After submission of ICSR, the Reporting Destination which receives the ICSR sends MDN and Business Acknowledgment to indicate the status of report acceptance.

The section below describes use of the Bulk Reporting screen to transmit E2B reports, MIR reports, and ICSR Transmit Status, ICSR Receive Status and Bulk ICSR transmit screen to track the report submissions and acknowledgement for E2B, eMDR, and eVAERS reports.

MIR transmission to the reporting destination is done only via email. The Bulk Transmit screen is used to track the MIR Reports.

Transmit 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, eMDR, eVAERS, or MIR.
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. When Expedited reports are selected, the Transmission Comment dialog box is displayed.

7. Perform one of the following steps:
   - Click **OK** to transmit the report(s).
   - Click **Cancel** to close the Dialog box without transmitting the report.

   If the **Marked as Submitted** check box was selected in step 5, the system opens the Report Submission Information Dialog box.
8. Enter the submission notes in the Notes field and click **OK**.Transmitting Bulk Reports by Form.

> **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:
> **For E2B, eMDR, eVAERS Reports:**
>
> 1. Go to **Worklist** > **Bulk ICSR Transmit** and verify that the **View All** radio button is selected.
> 2. 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**.
> 3. In the Report Submission Information Dialog box, enter the submission notes and click **OK**.
>
> **For MIR Reports:**
>
> 1. Go to **Worklist** > **Reports**.
> 2. Scroll in the list to locate the required report. If the report is generated, click the report icon and select **Mark Report as Submitted**.
> 3. In the Report Submission Information Dialog box, enter the submission notes and click **OK**.

Monitor ICSR Transmit Status

Use the following procedure to monitor ICSR Transmit Status:

1. Click **Utilities** > **ICSR** > **ICSR Transmit Status**.
2. When the system opens the ICSR Transmit Status Dialog, enter the appropriate data.

For more information, see:

- ICSR Transmit Status Fields
- Message Acknowledgement Status Dialog Fields

ICSR Transmit Status Fields

The following table lists and describes the fields in the ICSR 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.

Item	Description
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 Number	This is the sender's transmission message number.
Acknowledgement Message #	This is the receiver's acknowledgement 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.
ICSR Message Receiver ID	This is the receiver name or identification.
Acknowledgement Message Date	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.
Report Number	This is the report number for adverse event.

Item	Description
Authority /Company Number	If the ICSR report originates from a regulatory authority/company, this is regulatory authority's/company's report identification number.
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."
Report Type	This is the report type. It can be one of the following Initial Follow up Nullification Duplicate
Error Message/Comments	This indicates whether an error message or comments are associated with the transmission or receipt of the report.

Monitor ICSR Receive Status

Use the following procedure to monitor ICSR Receive Status:

1. Select **Utilities** > **ICSR** > **ICSR Receive Status**.
2. When the system opens the ICSR Receive Status Dialog box, enter the appropriate data in each field.

For more information, see:

- ICSR Receive Status Dialog Fields
- Message Acknowledgement Status Dialog Fields
- Validation Check of Incoming Message

ICSR Receive Status Dialog Fields

The following table lists and describes the fields in the ICSR 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.

Item	Description
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.

To update the ICSR Receive Status dialog box:

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.
Acknowledgement Message #	This is the receiver's acknowledgement 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.
ICSR Message Receiver ID	This is the receiver name or identification.
Acknowledgement Message Date	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.
Report Number	This is the report number for adverse event.
Authority /Company Number	If the ICSR report originates from a regulatory authority/company, this is regulatory authority's/company's report identification number.
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."

Item	Description
Report Type	This is the report type. It can be one of the following Initial Follow up Nullification Duplicate
Error Message/Comments	This indicates whether an error message or comments are associated with the transmission or receipt of the report.

Validation Check of Incoming Message

Before updating the transmission status of the reports, the application identifies the type of incoming message and validates it. The ICSR service processes all the incoming messages located in a folder in either the incoming EDI directory or the physical media directory. Incoming ICSR Messages are retrieved as SGML from a shared directory. The incoming folder is configurable through the Oracle Argus Interchange Mapping Utility. The ICSR 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 the message is in compliance with the DTD.

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

- 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 Oracle Argus Interchange Mapping Utility, where all the incoming messages can be stored. The Interchange service processes the received message and moves it to the Archive folder.

The message is validated based on the ICH ICSR acknowledgement specifications and the format of the message identified by the DTD version. The correctness of the receiver and sender identifiers 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 the message type (acknowledgement) and the DTD version of the message. In Oracle Argus Safety, if the application is unable to identify the message type or DTD version, the error is logged in the log table and no further processing occurs. In Oracle Safety One Argus, the failed report is marked as invalid and appears in the Intake Monitor with the applicable error message. In both environments, the application then sends an email to the configured email address indicating that the message could not be read.

The 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 a duplicate message is found in the database, and an error message is created.

The following table describes the error messages and shows the possible reasons for the errors.

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

The following are examples of the email messages that are sent to the configured email address if message validation fails:

- In the case of invalid XML formatting:

```
From: ICSR 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,
<< ICSR service user >>
```

- If the application fails to identify the incoming message:

```
From: ICSR 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,
<< ICSR service user >>
```

- For validation failure of the incoming acknowledgement:

```
From: ICSR 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,
<< ICSR service user >>
```

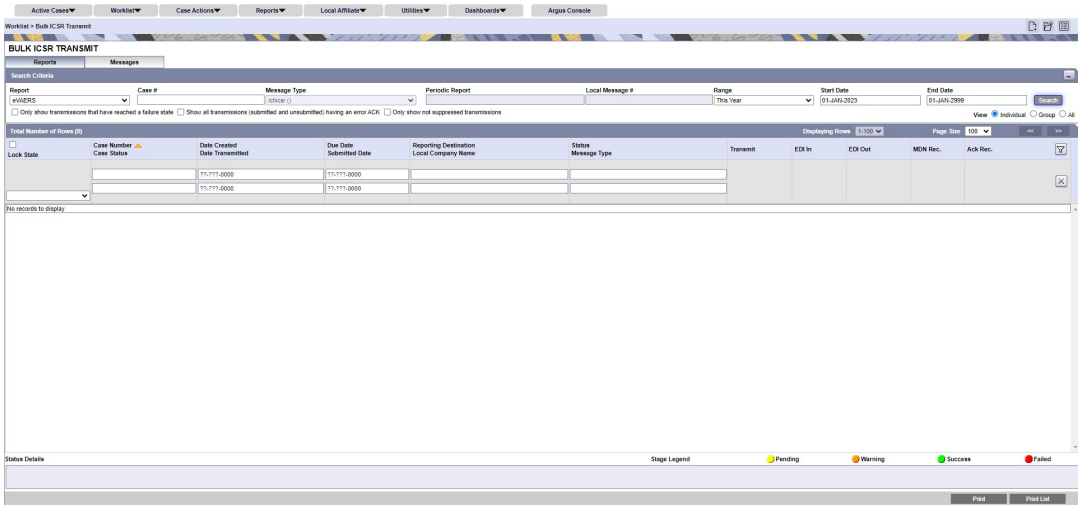
You can view acknowledgement details for a report in the Report Details Dialog. Information includes the acknowledgement message tracking number, the acknowledgement report tracking number, the date the acknowledgement was initiated, the company ICSR message, and the error reported by the receiver.

The status of the each ICSR report is updated based on the information extracted from the ICSR acknowledgment irrespective of the transmission status (Success or Failure). Refer to View Acknowledgement Information for the steps to follow to see detailed acknowledgement information for a report.

View Status

Oracle Argus provides features you can use to monitor the transmission status of E2B, eMDR and eVAERS reports. Use the following procedure to check the status of these reports.

1. Select **Worklist** > **Bulk ICSR Transmit**.



2. Select a report from the Report drop-down list. The available options are:

- E2B
- eVAERS
- eMDR
- PMDA Device

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

View Acknowledgement Information

In Oracle Argus, 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**, **eMDR**, or **eVAERS** 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.

   The Acknowledgement Information Dialog opens.
3. Perform one of the following steps:
   - Click **Print** to print the acknowledgement details.
   - Click **OK** to close the Dialog box.

Nullification Reports

After authentication, you can accept nullification reports. When you do so, the following queuing message appears: `Report queued for Processing`.

Oracle Argus Safety environments: When the nullification report is successfully processed, an information icon appears in the ICSR Processed screen. When you click the icon, the following warning message is displayed: `Please manually delete this case. Following is the Argus Case Number that is associated with the current Nullification. Argus Case Number : 2016US0000000027`.

In Oracle Safety One Argus environments, the report appears in Consolidated Intake.

6

Use the ICSR Viewer

The ICSR Viewer enables you to open E2B files and view them in different formats. You can print these files from the ICSR viewer.

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

For more information, see:

- Open the ICSR Viewer

Open 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 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. The ICSR Viewer provides the decoded view format for the eVAERS, eMDR, and E2B reports. For eMDR XML reports, the MedWatch box numbers are displayed instead of Data Element Number. The E2B(R3) Descriptive Element Name is used to populate each E2B element. For NMPA, all the regional elements contain Chinese descriptive names with parentheses along with the English descriptive names.
HL7 View	This view is applicable only for E2B(R3) eMDR, eVAERS and NMPA reports. This view displays the report in HL7 format. The data element number and data element description is displayed as a comment for all the data elements for ICH E2B(R3), EMA E2B(R3), FDA E2B(R3), eMDR, PMDA, eVAERS, NMPA and MFDS reports.
CIOMS	The E2B data is populated in the CIOMS report format, and this view is applicable only to E2B(R2) reports.
MedWatch	The E2B data is populated in the MedWatch report format, and this view is applicable only for E2B(R2) reports.

7

Use the MIR Viewer

The MIR Viewer enables you to open MIR reports and view them in XML or PDF formats based on the selected view: XML view or MIR PDF view. You can print these files for each view.

The following fields appear in the MIR viewer:

- Report Type
- Case Number
- View formart: XML and MIR PDF

The **Date and Time** field appear at the end of the MIR PDF Report for Draft and Final reports, where generation date and time of the report are populated based on the data stored in the database.

8

Import ICSR Reports

> **Note**
>
> In Oracle Safety One Argus, some of these features are available under different menu options. For details, refer to the *Oracle Life Sciences Consolidated Intake User's Guide*.

In this chapter:

Incoming ICSR Reports

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

This release does not support import of eVAERS.

For more information, see:

Import both E2B (R2) and E2B (R3) Messages

The ICSR Import functionality supports the import of both the E2B (R2) and E2B (R3) reports without any data loss of data conversions. To determine if the Sender agency is sending an (R2) or (R3) message, the application relies on the configured E2B profile for the receiving Agency in the Argus Console.

Once the application identifies the message type, the incoming message is processed in accordance with message type and the profile so that the respective data element mappings are executed to extract the data without any data loss.

The application provides the OOTB profile to import ICH, PMDA, EMA & FDA E2B (R2) message, and the EMA & PMDA E2B (R3) message.

> **Note**
>
> If the incoming message is identified as ICH E2B (R3) message, application downgrades it to ICH E2B (R2) before importing it into the system.

ICSR Import Framework

The ICSR Import framework for (R3) imports has been designed to provide greater flexibility with respect to (R2) imports. It facilitates the user in extending, configuring and customizing the Import profile in such a way that broader use cases for importing data leveraging the ICSR import framework can be met.

The Import framework has been designed to achieve more flexibility by extending, configuring and customizing the profile for the following:

1. **Extensible ICSR Profile framework**: With the current ICSR (R2) framework, E2B+ allows the user to extend the profile elements. However, extending a profile using the existing Framework has certain limitations:
   - **Linking of extended child with the Parent**: If the element is added to the node which is lower in the report hierarchy, linking of the extended node becomes difficult with the higher level node.
     For example:

     Level 1: SAFETYREPORT

     Level 2: PATIENT

     Level 3: Drug

     Level 4: Dosage

     Now, if the user wants to extend an element at Dosage level using E2B+, then the linking of that attribute with the Drug becomes complex and at times could error prone.
   - **Cannot add a new Parent/repeater**: Using the current E2B+ framework it is not feasible to add a new repeater section that is not part of the standard E2B report.
2. **Minimum Case creation validations on Incoming ICSR**: MAH uses Oracle Argus for capturing data from different sources to meet their regulatory and non-regulatory reporting needs. ICSR Import is a big platform for data capturing from various sources. MAH are expected to use Argus as an importing platform to pull the information from various sources in their Oracle Argus database and then further process it using Argus for coping with regulatory and non-regulatory purposes.

   > **Note**
   >
   > All the compliance validation is maintained in the error/warning log for user to review the regulatory gaps with the incoming ICSR file.

3. **Import F/U on non-E2B compliant Case**: The usage of the ICSR Import framework in not confined to regulatory purposes only - the purpose of the incoming ICSR file can be just the data exchange. Therefore, there can be a scenario where the case on which the ICSR

is being imported may not be regulatory complaint but the user would like to import the update from the incoming ICSR. Therefore, the application will not execute the ICSR conformance validation check before importing the data from Follow-up ICSR.

4. **Provide flexibility to user to map Incoming ICSR as Follow-up to the existing case**: As the usage of the ICSR Import framework in not confined to regulatory purposes, the logic to link an incoming report to the report with an existing case is configurable at the profile level.
5. **Comparison and data evaluation/update for an incoming Follow-up report**: As per the current implementation for comparing the Incoming ICSR file, the application provides the user a three view difference in the ICSR format:
   - Newly imported ICSR message
   - ICSR message generated using the current case data against the ICSR profile for the importing agency
   - Last imported ICSR file to the case

   This comparison logic performs a record matching based on the metadata of the internal table by performing the key based comparison of the elements in the above three ICSR files. The comparison logic can be configured by modifying the internal metadata to a certain extent with several limitations. The existing comparison and data updation logic has been enhanced for the following:
   a. Support deletion of unwanted data after F/U
   b. Flexibility in Primary key identification for F/U records
   c. Special use case to support comparison based on External applications entity Identifier
   d. Customizable comparison and updation for handling exceptional use scenarios (User Exits)

For more details, from the Argus Safety OHC page, download the Technical Reference Manuals, and refer to the *Oracle Argus Interchange ICSR Extensibility Guide*.

> **Note**
>
> Oracle Safety One Argus provides a different user interface for report comparison and data evaluation/updates. Refer to the *Oracle Life Sciences Consolidated Intake User Guide* for more information.

Interchange Accept Process

This content is specific to the E2B (R3) Import.

The application function flow for importing (R3) based ICSR messages in the Interchange accept process is similar to that of the (R2) except for the updates specified in this section.

> **Note**
>
> Any xsd/xslt/dtd validations that may apply to any of the internal processing/ massaging/ transformations of the xml message are configurable at profile level.

- The application supports the import of batch (R3) messages consisting of more than one report.
- The maximum file size you can import into Argus respects the value configured in Argus Console -> Reporting Destination -> EDI -> Allowed report size (in MB) for the receiving Agency.
- The Interchange Accept process performs the following validations on the incoming (R3) message:
  Hard Validation: In the case of a validation error under this category, the Interchange Accept process rejects the incoming message and generates a negative ACK with the required error message. For more information on ACK mapping details, refer to the ACK element level mappings. The following are the categories of hard validations:

  1. Length validation
  2. Code list data validations
  3. Minimum case creation validation

  Soft Validation: In case of a validation error under this category, the Interchange Accept process does not reject the incoming message. Instead, the process maintains a log of errors under this category for future reference in the ICSR Pending screen (for more details, refer to the ICSR Pending screen section) and in the Case Attachment (for more details, refer Case creation/updation section). The following are the categories of soft validations:

  1. Element Conformance validation
  2. Mandatory along with validation
  3. Additional validation

  > **Note**
  >
  > In Oracle Safety One Argus, E2B reports that are ready for import or are being processed are available through the Intake Worklist and Intake Monitor respectively.

  The logic to identify the case over which the Incoming (R3) ICSR message is imported as a Follow-up is configurable at the profile level.
- The accept process loads all the data from the incoming (R3) based ICSR message to staging schema without any data loss.
- The application logic to identify the Agency whose profile configuration is used during the import of the (R3) based ICSR message is as follows:

  1. Reporting Destination'EDI'Agency Identifier: N.1.3-BATCHMESSAGESENDERIDENTIFIER / N.2.r.2 - MESSAGESENDERIDENTIFIER
  2. Reporting Destination'EDI'Company Identifier: N.1.4-BATCHMESSAGERECEIVERIDENTIFIER / N.2.r.3 - MESSAGERECEIVERIDENTIFIER
  3. Reporting Destination'EDI' Primary Receive Agency: Checked
- All the respective statuses that are applicable for the existing (R2) message have been updated for the (R3) message in a similar manner. These statuses can be tracked in various screens. for example Reports > ICSR Pending (Pending & processed tabs) & Utilities > ICSR > ICSR Receive Status).

> **Note**
>
> In Oracle Safety One Argus, E2B reports that are ready for import or are being processed are available in the Intake Worklist and Intake Monitor respectively.

- Duplicate (R3) message identification is governed based on the value in the N.1.2 - BATCHMESSAGENUMB tag.
- The existing application identifies the Amendment report based on the C.1.11.1-CASENULLIFICATION. The amendment identification is only applicable for (R3) message as the concept of amendment report is specific to (R3) reports only.
- The acceptance process every stage of import evaluates the various import stages and generates the ACK in the (R3) format.

ICSR Pending screen icons

> **Note**
>
> This section applies only to Argus Safety environments. For Safety One Argus environments, refer to the *Oracle Life Sciences Consolidated Intake User Guide*.

After you accept, authenticate and queue an ICSR report, the report is then processed by background AG services. On the ICSR Pending screen, you can view the processing status of your report. Each status is depicted by an icon and a status legend is displayed at the bottom of the screen, as seen below:

To see the status changes, you can refresh your screen by using the search option.

Table 8-1 Status icons descriptions

Icon	Status	Description
	Queued	This icon is displayed when you accepted, authenticated, and queued the report for the AG service to process it. When in this status, the actual processing has not started. In addition, the check box next to the report is disabled and you can not perform any actions on this report.
	Processing	This icon is displayed when the AG service has started processing the report. **Note:** Once processing is successful, the report will move to the ICSR Processed screen. When in this status, the check box next to the report is disabled and you can not perform any actions on this report.

Table 8-1 (Cont.) Status icons descriptions

Icon	Status	Description
	Retry in progress	If a report was not processed successfully, the system will retry before it marks the report as a failure. b. The default number of retries is 3. In addition, the number of retries that can be attempted is determined by the following new profile switch in Argus Console > Common profile Switch > Background Services: **Number of retries to be done for an unsuccessful report to be picked for reprocessing by Auto Accept AG Process**. This profile switch allows values from 1-999. The time interval for re-processing is determined by the following profile switch in Argus: **Number of minutes to wait for a unsuccessful report to be picked for reprocessing by Auto Accept AG Process** The default value for this switch is 60. For the two Console profile switches above: • You can enter a 3-digit number; however, you enter zero, the following warning message is displayed: *Please enter numeric value greater than zero.* • If you enter non-numeric and negative values, the following warning message is displayed: *This field can not contain non - numeric value!* • If a save is successful, the following message is displayed: *Common profile has been saved.* The Details pop-up window shows the error link with the reason the report failed to be processed. When in this status, the check box next to the report is disabled and you cannot perform any actions on this report.
	Failed	If the report could not be processed by the background service after three retries, it is marked as **Failed**. The Details pop-up window shows the error link with the reason the report failed to be processed. When a report is in this status and the actual processing is completed, you can attempt to accept or reject the report again. The check box for these reports is enabled, so you can select Bulk Accept or Reject.

Search for Duplicate Cases

> **Note**
>
> This section applies only to Argus Safety environments. For Safety One Argus environments, refer to the *Oracle Life Sciences Consolidated Intake User Guide*.

The Duplicate Search Dialog for E2B report allows you to search for possible duplicate cases in the Oracle 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** > **ICSR Pending Report**.
2. When the system opens the Incoming ICSR Reports Dialog, right-click a case to perform a duplicate search.

   The system displays the search results at the bottom of the Dialog box.

For more information, see:

- Duplicate Search Dialog Box Fields

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 Oracle Argus received the report and saved it in the system.
Center ID	The ID of the center.
Batch/Lot #	In this field, you can enter a batch or lot number to search for duplicate cases.
Sal.	The salutation, such as Mr. or Mrs.
Suffix	The suffix, if applicable, that follows the name (for example Jr., Sr.,III)
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 at Birth	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 ICSR 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 ICSR	Enables you to view the E2B report.
Accept ICSR	Enables you to accept an E2B case.
Reject ICSR	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.

Use the View Differences Report

Note

This section applies only to Argus Safety environments.

For Oracle Safety One Argus environments, refer to the *Oracle Life Sciences Consolidated Intake User Guide*.

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 ICSR 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.

For more information, see:

- Display Differences

Display 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.

View the E2B Report

> **Note**
>
> This section applies only to Argus Safety environments. For Safety One Argus environments, refer to the *Oracle Life Sciences Consolidated Intake User Guide*.

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 ICSR Pending screen by right-clicking on a row and selecting **ICSR Viewer**.

Accept Single or Multiple E2B Reports

> **Note**
>
> This section applies only to Argus Safety environments. For Safety One Argus environments, refer to the *Oracle Life Sciences Consolidated Intake User Guide*.

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

1. Select **Reports** > **ICSR Pending** to open the Incoming ICSR Report Dialog box.
2. Perform one of the following steps when the system opens the ICSR Pending screen:
   - To accept a single report, right-click on it and select **Accept E2B**.
   - 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**
>
> Manual numbering is not supported as an option for accepted ICSR Reports. If the system numbering is marked as Manual when you accept a report in the pending screen, then the following warning message is displayed: `System must be in auto-numbering mode and not manual.`

7. When you click the icons shown next to the reports, the ICSR Accept Status - Webpage Dialog window is displayed. It details the steps in which the report is currently being processed.

   On the details window, the **Accept Initiated By** field displays the user name of the user that accepted the case and the local date and time at which the report is accepted is displayed on the **Accept Intiated On** field.
   The statuses that are displayed with a grey checkmark are the following:

Table 8-2 ICSR Accept Status

Status name	Description
ICSR Accept Request Received	Indicates that the report has been accepted by the user and it is waiting in queue for processing. It is displayed with a green check mark as a default.
ICSR Accept Process Started	Indicates that the report is picked up for processing by the background service. If the process is not running, this status has a grey check mark.
Selective Acceptance / Difference Report Generated	Indicates that the system has internally generated the selective acceptance report or difference report.
Case Created/Modified	Indicates the initial or followup case has been successfully created.
ICSR Accept request Completed	Indicates that the background process is completed. If this is successful, then the report moves to the Processed screen. In case of failure or retry, this step does not display a green checkmark.

E2B Initial or Follow-up Intake

> **Note**
>
> This section applies only to Argus Safety environments.

For Oracle Safety One Argus environments, refer to the *Oracle Life Sciences Consolidated Intake User Guide*.

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 Acknowledgment 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 Acknowledgment.
- 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 or Locked Cases

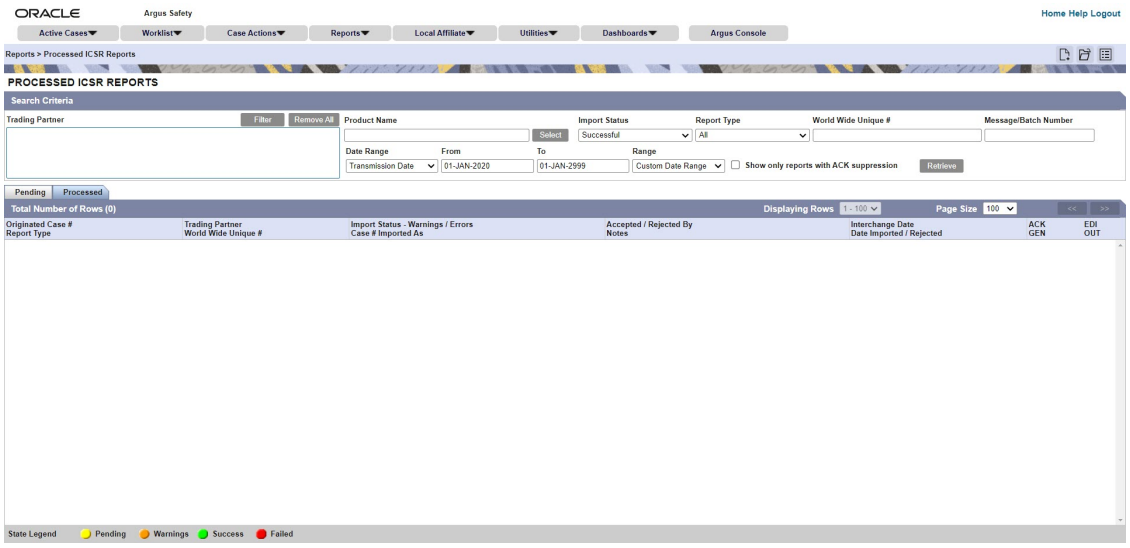
> **Note**
>
> This section applies only to Argus Safety environments. For Safety One Argus environments, refer to the *Oracle Life Sciences Consolidated Intake User Guide*.

- 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 ICSR Reports

> **Note**
>
> In Oracle Argus Cloud, the processed ICSRs are available in the Intake Monitor.

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



The Processed ICSR screen contains the following:

- Search Criteria
- Total Number of Rows

Search Criteria section

In the Search Criteria section of the Processed ICSR screen, the **Message/Batch Number** filter option can be used to retrieve reports that belong to the same batch number during bulk import. If no value is set on this field, then all batch numbers are selected.

Error and warning messages are displayed when you click the binoculars icon and when the Agency has the **Suppress ACK** option set in the Reporting Destination. To view these messages, follow the procedure below:

1. Configure a reporting agency to suppress acknowledgement.
2. Import an E2B file for the agency configured at step 1.
3. On the ICSR Pending screen, accept the imported E2B report.
4. Click the binocular icon on the ICSR Pending screen.
5. You can see any error or warning messages for the acknowledgement, even if the **Suppress ACK** option is checked.

You can use the **World Wide Unique #** filter option to retrieve reports that belong to a particular WWID. This filter supports wildcard searches (when you use the % symbol). The **World Wide Unique #** option is available in the Total Number of Rows grid as well.

Total Number of Rows section

The following table lists and describes the fields in the Total Number of Rows section on the Processed ICSR 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.
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.
Show only reports with ACK suppression	This option is unchecked by default. Check this checkbox to search reports for which ACK transmission is suppressed. When the ACK suppression is checked, the corresponding report status appears in default state, and the EDI OUT column appears in yellow color. ACK Gen column appears in orange/amber color with warning comment when ACK is unavailable.