Oracle Argus Interchange

Japan User's Guide

Release 8.4.1
F89772-01
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Oracle Argus Interchange Japan User's Guide, Release 8.4.1

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Preface

This preface contains the following sections:

Documentation accessibility

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

Diversity and Inclusion

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

Related resources

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

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

Access to Oracle Support

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

Cloud customers receive support assistance through Support Cloud

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

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

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

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

On-premises customers receive support assistance through My Oracle Support

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

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About Oracle Argus Interchange

Oracle Argus Interchange provides pharmaceutical manufacturers with a simple, efficient way to comply with electronic standards for transferring regulatory information through the use of an Electronic Data Interchange (EDI) gateway.

It also enables you to view:

- E2B(R2) reports in different formats, such as I-SGML, J-SGML, I-Decoded View, J-Decoded View
- E2B(R3) reports in different formats, such as HL7 View, XML View, PMDA Paper Form
- PMDA Device XML reports in different formats, such as XML View, Paper View, Decoded View

These reports can be submitted to trading partners or to regulatory authorities.

> **Note:**
>
> The features of the E2B report mentioned in this document are also applicable for the PMDA Device XML report, except for the Import ICSR feature.

The PMDA E2B supports to transmit and import ICSR reports.

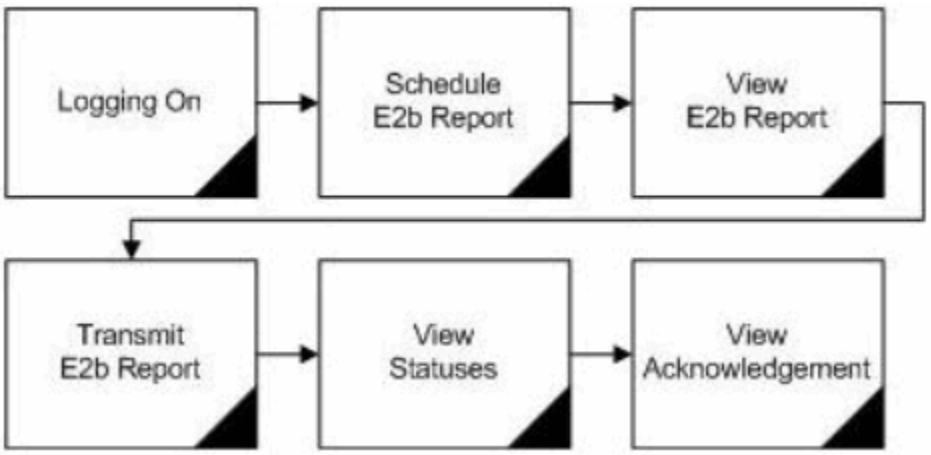
The PMDA Device only supports to transmit XML reports.

For more information, see:

- Oracle Argus Interchange Process Overview

Oracle Argus Interchange Process Overview

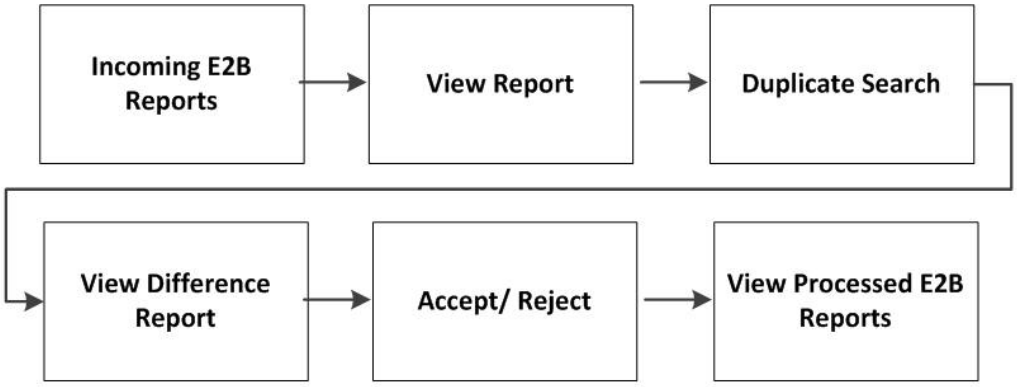
The following flowchart shows the steps to follow when using Oracle Argus Interchange.



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

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

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



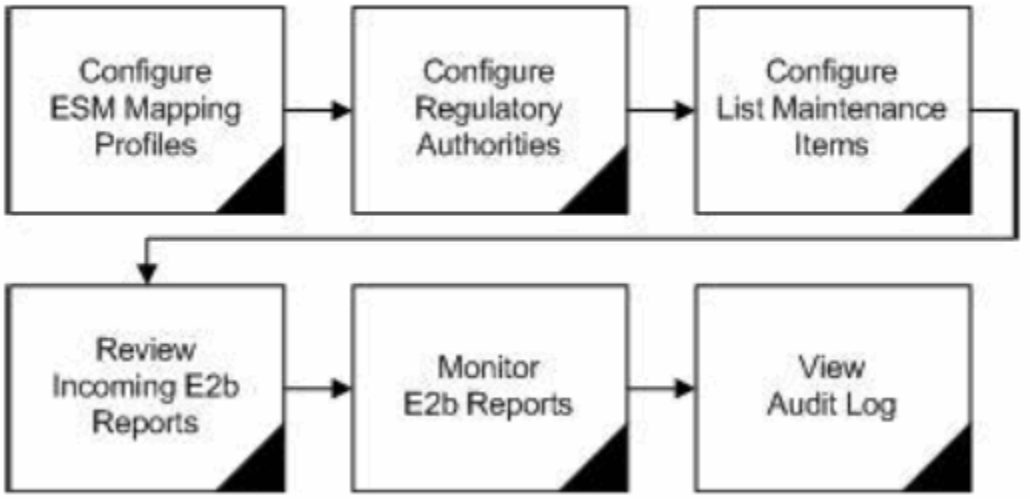
The following table describes each of the steps in the preceding flowchart.

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

2

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 Interchange Utility
- E2B Extensions (Applicable for R2 only)
- Web Console

Oracle Argus Interchange Utility

Oracle Argus Interchange utility enables you to configure the Oracle Argus Interchange Service.

- Provides a framework that allows you to configure conformance rules (validations against the ICSR reporting profiles: ICH, EMA, eVAERS and PMDA) based on the individual E2B (R3) Profiles.
- You can configure parameters for each ICSR Element Node for which data is transmitted.
- The Conformance Rules tab data is copied to the new profile when you copy any existing ICSR profile.
- The following table list the fields available in the Conformance Rules tab:

Table 2-1 Fields in the Conformance Rules tab

#	Field Name	Type	Description
1	Field Name/ Field Name (J)	Textbox	Enter the Field Name or Label of the Case Form or Console UI corresponding to the element's mapping logic. – ICH, EMA, and eVAERS: English – PMDA: Japanese – PMDA E2B R3: See *Mapping xls'Mapping(Sheet) > UI Field Name(J)*
2	Field Location	Textbox	Enter the Case Form or Console UI field location or path corresponding to the element's mapping logic. – ICH, EMA, and eVAERS: English – PMDA: Japanese – PMDA E2B R3: See *Mapping xls'Mapping(Sheet) > UI Field Name(J)*
3	Data Type	Drop Down	Select from the following options: – <blank> (Default) – Text – E2B Code – Country – Date/Time – MedDRA Version – MedDRA Term/Code – PMDA E2B R3: See *Mapping xls > Mapping(Sheet) > PMDA Data Type DTD R3*
4	Data Length	Textbox	Enter a numeric value.For PMDA E2B R3: See *Mapping xls > Mapping(Sheet) > PMDA Length DTD R3*
5	Mandatory Along with	Dropdown	Select a DTD_ELEMENT name from the list of all the elements available from the same parent of the selected element (except the selected element itself). Default value is <blank>. For PMDA E2B R3: See *Mapping xls > Mapping(Sheet) > Mandatory Along with*
6	Allowed Value Check Required	Checkbox	Unchecked by default.For PMDA E2B (R3): See *Mapping xls > Mapping(Sheet) > Allowed Values*
7	Allowed Values	Button	On Clicking this button, "Allowed value configuration" dialog box appears to configuring the allowed values for the selected elements for that profile. This button is enabled only if "Allowed Value Check Required" checkbox is selected. For PMDA E2B (R3): See *Mapping xls > Mapping(Sheet) > Allowed Values*

Table 2-1 (Cont.) Fields in the Conformance Rules tab

#	Field Name	Type	Description
8	Primary Validation Category	Drop Down	This option is available only for ICH, EMA, and eVAERS profile.This drop-down list has the values: – <blank> (Default) – Mandatory – Conditional Mandatory – Optional – Other Fatal Validation – Do not enter
9	Additional Validations	Button	On clicking this button, the "Additional Validation Configuration" dialog box appears that enables you to configure the SQL based validations for the element.This button is available only for ICH, EMA, and eVAERS.
10.1 -10. 4	--	--	*See separate table below*
11	Save	Button	On clicking the save button the changes are committed to the database and the audit logs. Saving the data also includes any changes done in the **Allowed Value Configuration** and **Additional Validation Configuration** dialog boxes. It also validates if a Primary category exists for the ICSR element. – For Non-PMDA profile: Element Level – For PMDA profile: Reporting Category Level If there exists a row with primary category as blank, an error message is displayed: "Please select a Primary Validation category for the element" Title: "ICSR Validation"
12	Print	Button	On clicking the print button, entire Conformance Rule tab data is printed.

Table 2-2 PMDA Specific Fields in the Conformance Rules tab

#	Field Name	Type	Description
10.1	Reporting Category	Label	This field represents a drop-down list containing Reporting Category LM. This is a mandatory field. Determines the report being created (ADR, Infection, Research, or Measures in foreign countries). The list values are determined at run time by the values selected in items 9,10, and 12. When Reporting Category is not selected, the license does not create the report.All the 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.
10.2	Reporting Category Description	Label	Describes the corresponding Reporting Category.

Table 2-2 (Cont.) PMDA Specific Fields in the Conformance Rules tab

#	Field Name	Type	Description
10.3	Primary Validation Category	Drop Down	This dropdown is available for PMDA profile only. This field has the values: – <blank> (Default) – Mandatory – Conditional Mandatory – Mandatory for Completion Report – Conditional Mandatory for Completion Report – Optional – Do not Enter – Other Fatal Validation For PMDA E2B (R3): See *Mapping xls > Mapping(Sheet) > Reporting Category wise Conformance*
10.4	Additional Validations	Button	On clicking this button, the "Additional Validation Configuration" dialog box appears that enables you to configure the SQL based validations for the element. This button is available against each Reporting Category.

Note:

Most features of the Interchange have been moved to the web-based console.

For more details on the service configuration, refer to the Oracle Argus Interchange User's Guide.

E2B Extensions (Applicable for R2 only)

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

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

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

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

- A switch in the Interchange utility identifies a profile as either a standard profile or an extended E2B profile but only for the Receive tab. The additional fields are formatted as follows:
  `<XXX>_EXTENSION []`

  where:

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

  When using this switch:

  - Do not enter any blank spaces or underscore characters (_) in the `XXX` naming convention.
  - In the extended E2B tags, the element number in the brackets ([ ]) is always empty. For example, `Patient Ethnicity, Event Hospitalized Start Date / Stop Date`.
  - This switch is enabled only for profiles copied from the Factory profiles (default unchecked). This flag is disabled for all factory profiles.
  - During configuration, GPS updates the DTD profile with this information before it adds any additional E2B elements.
  - The system maps extended E2B fields are mapped to existing Oracle Argus Safety fields or to user-defined fields, as appropriate. For example, the system maps the following extended E2B fields to the following Oracle Argus Safety tables.

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

E2B + Field	Argus Case Form UI Field Name	Argus Field Label Description
reactionhospstopdate_extension	EVENTS | Hospitalized Stop Date	Hospitalized Stop Date

  - The system sends an acknowledgment if the message import is successful and a rejection if the message import is not successful.

You can view the extended elements for the following:

- E2B Viewer
  - No updates to the CIOMS / MedWatch Reports
  - The Decoded View / SGML View displays the additional elements added as a part of the Extended E2B
- E2B Difference Report
  - When imported, the system displays the additional fields in the current difference report viewer.
- E2B Selective Intake for Initial and Follow up E2B Reports
  - You can selectively import the additional fields the system adds to the Extended E2B in the Oracle Argus Safety case.
  - The PDF reports display the additional fields added to the Extended E2B.
- The E2B Warnings/Errors display the warnings/errors if warnings or errors defined for the fields added to the Extended E2B.

Web Console

The Web 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:

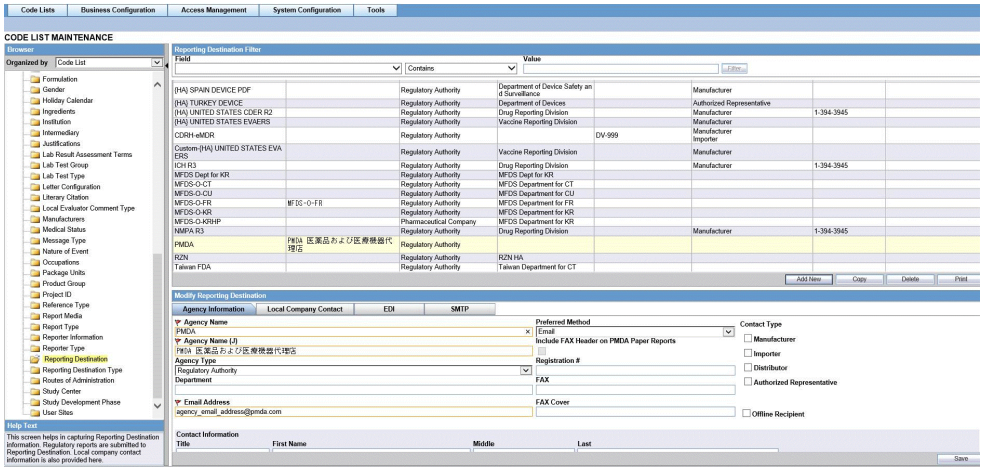
- Configure Regulatory Authorities

Configure 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:

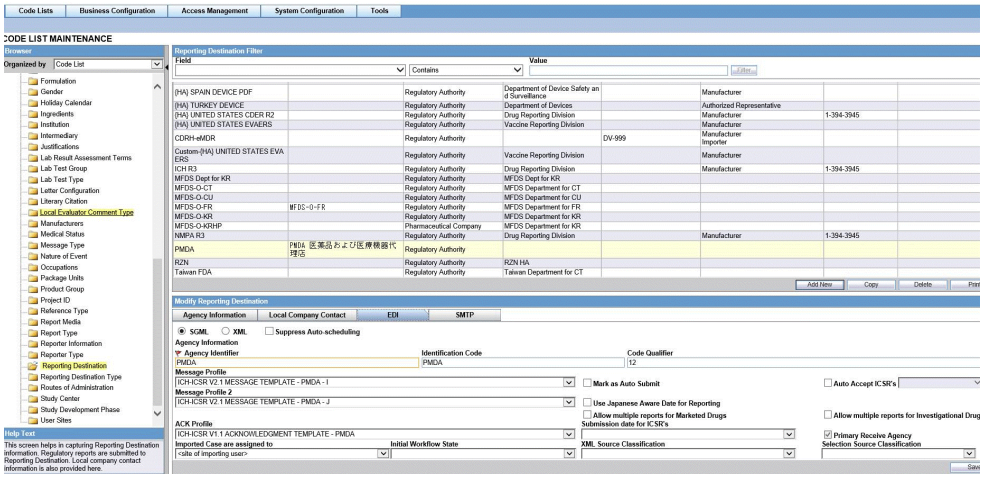
1. On the Oracle Argus Safety Console, click **Code Lists** > **Argus**.
2. When the system opens the Code List Maintenance screen, select **Reporting Destination** from the list.



> **Note:**
>
> If a report has already been generated for a Regulatory Authority, the system disables the Delete button in the Code List dialog box for the particular Regulatory Authority. However, it is still possible to modify these reports there.

Refer to the *Oracle Argus Safety User's Guide* for information on using the first three tabs of the Reporting Destination.

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



Note:

When the **Message Profile** field is set to **PMDA Device**:

- The following parameters are automatically set in the Reporting Destination codelist:
  - XML Version is set to 1 and disabled.
  - Encoding is set to UTF-8 and disabled.
  - The Attachments parameter under the Report Transmissions options in the Agency Information tab is defaulted to Single and disabled.
- The following parameters are disabled in the Reporting Destination codelist:
  - ICSR Attachment Outgoing Folder
  - Identification Code(Agency Information and Local Company Contact)
  - Code Qualifier
  - SGML Declaration File
  - Maximum # of reports to include in the msg
  - File Name
  - Method
  - EDI Header Required
  - URL for Message Schema
  - URL for Ack Schema
  - Primary Receive Agency
  - Auto Accept ICSR's
  - Submission date for ICSR's
  - Imported Case are assigned to
  - Initial Workflow State
  - XML Source Classification
  - Selection Source Classification

For more information, see:

- EDI Tab Fields

EDI Tab Fields

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

Field	Purpose
SGML/XML	Enables you to select whether to send the report in SGML or XML format.
Mark as Auto Submit	Enables you to mark the report for auto submission.

Field	Purpose
Imported Cases are assigned to	Enables you to select the country where imported cases need to be assigned. **Note:** This list contains the configured Oracle Argus Safety sites. The default value is the site of the importing user.
Initial Workflow State	Enables you to configure the initial workflow state for the case. **Note:** This list contains Oracle Argus Safety workflow states. The default value is blank. If you select blank as the workflow state, the system treats the case as a new case being booked-in.
Agency Identifier	Enables you to enter the routing ID configured in Cyclone for the sender community.
Identification Code	Enables you to enter the agency Duns code, a unique code that identifies a trading partner.
Code Qualifier	Enables you to enter the code qualifier. The system uses the code qualifier to interpret the identification code.
XML Source Classification	Defines the E2B source file classification during the E2B import. The system populates this drop-down from the Attachment Classification code list.
Selection Source Classification	Defines the classification of the PDF for initial intake or the difference report during E2B import. The system populates this drop-down from the Attachment Classification code list.
MIR Report Format	Enables you to select MIR report format. This drop-down is applicable only for MIR reports. For more information, see the *Oracle Argus Safety Administrator's Guide.*
Message Profile	Enables you to select a message profile.
Message Profile 2	Enables you to select a message profile for Japan elements required for the E2B(R2) profile. This profile is enabled for Oracle Argus Safety Japan users and only when Message Profile is selected as PMDA - I profile.
ACK Profile	Enables you to select the acknowledgement profile.
Primary Receive Agency	Indicates that this is the primary agency receiving E2B reports.
Auto Accept ICSR's	Enables or disables the auto-accept E2Bs for the agency.
Transmit E2B Attachments	Enables or disables transmission of E2B attachments for the agency.

Field	Purpose
Use Japanese Aware Date for Reporting	Check this check box to use Japanese Aware Date for reporting.
Identification Code	Enables you to enter the company Duns code, a unique code that identifies a trading partner.
Company Identifier	Enables you to enter the company identifier.
Code Qualifier	Enables you to enter the code qualifier. The code qualifier is used to interpret the identification code.
File Name	Enables you to enter the file name
SGML Declaration File	Enables you to enter the SGML Declaration File.
Maximum # of reports to include in the msg	Enables you to enter the maximum number of reports that will be transmitted in one message.
Method	Enables you to select a method. This field contains E2B-EDI Gateway, E2B Physical Media, and E2B-XML Transmission values.
EDI Header Required	Enables you to generate the required EDI Header.
XML Version	Enables you to enter the XML Version.
URL of Message DTD	Enables you to enter the path where the message DTD resides on the Internet or to enter the full path, if it is located on the disk.
Encoding	Enables you to select the character set encoding used in XML
Use Japanese Aware Date for Reporting	Enables you to ensure that reporting is based on the Japanese Aware Date. If this check box is not checked, reporting is based on the English Aware Date.
Allow multiple reports for Marketed Drugs	Check this check box to allow the system to schedule multiple reports for marketed drugs.
Allow multiple reports for Investigational Drugs (Clinical Trial)	Check this check box to allow the system to schedule multiple reports for investigational drugs of the reporting category DA, DB, DC, DD.
Allow multiple reports for Investigational Drugs (Research and Measure)	Check this check box to allow the system to schedule multiple reports for investigational drugs of the reporting category DE, DF, DG.
URL of ACK DTD	Enables you to enter the path where the ACK DTD resides on the Internet or enter the full path, if it is located on the disk.

Note:

In the **File Name** field, be sure to enter the appropriate naming convention followed by `####` before the transmission extension.

3

ICSR Check

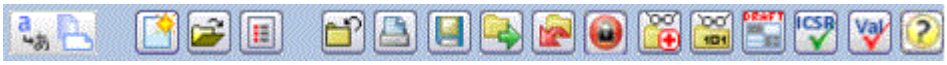
In order to successfully transmit any E2B Report, it must validated for its mandatory components before transmitting the report.

For more information, see:

- Why perform an ICSR Check

Why perform an ICSR Check

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.

Running an ICSR check validates if the E2b report has all these mandatory elements present that is required for its successful processing.This check performs the function that prints the “E2B Report – DTD Length Check Warnings" and “E2B report – DTD Validation".

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

ORACLE HEALTH SCIENCES

ICSR報告データ・チェック・エラーと警告

2018/06/28 00:33 GMT -5.00

症例番号: 18JP000019

検証されたプロファイル:

1. ICH-ICSR V2.1 MESSAGE TEMPLATE
2. ICH-ICSR V2.1 MESSAGE TEMPLATE - EMA
3. ICH-ICSR V2.1 MESSAGE TEMPLATE - FDA
4. ICH-ICSR V2.1 MESSAGE TEMPLATE - PMDA - I
5. CBER EVAERS V1.0 MESSAGE TEMPLATE
6. CDRH EMDR V1.0 MESSAGE TEMPLATE
7. ICH-ICSR V3.0 MESSAGE TEMPLATE
8. ICH-ICSR V3.0 MESSAGE TEMPLATE - EMA

検証の種類	データ項目	DTD項目	症例フォーム・フィールド	エラー・メッセージ	プロファイル
その他の検証	B.1.2.2a	PATIENTONSETAGE	症例フォーム / 患者 / 患者 / 患者の詳細 / 年齢	" 子のみ" はチェックボックスで選択されていませんが、PATIENT ONSETAGE (B.1.2.2) が入力されていません。	4
	B.2.i.8	REACTIONOUTCOME	Events Tab / Event Information / Outcome of Event	Value of element tag [REACTIONOUTCOME] does not satisfy the condition [At least one outcome must be recorded. Additionally, if the outcome (Fatal) is recorded against any of the reactions, One of the following must be reported Cause of Death or Determine Autopsy]	1, 2, 3
	A.2.1.3	REPORTERCOUNTRY	症例フォーム / 一般 / 報告者情報 / 国	以下の項目の内最低一項目が報告に含まれている必要があります。reportercountry (A.2.1.3), qualification (A.2.1.4), literaturereferenoe (A.2.2), studyname (A.2.3.1), sponsorstudynumb (A.2.3.2), observestudytype (A.2.3.3).	4
コード化に関する検証	B.2.i.1.b	REACTIONMEDDRALLT	Events Tab / Event Information / LLT	Encoded value of element tag [REACTIONMEDDRALLT] missing.	1, 2, 3
	B.2.i.1.b	REACTIONMEDDRALLT	症例フォーム / 有害事象 / 有害事象 / 有害事象情報 / 有害事象のコード化 / 下層語 (LLT)	項目タグ [REACTIONMEDDRALLT (B.2.i.1.b)] のエンコードされた値が未入力です。[有害事象情報 | 下層語 (LLT) (コード)].	4
	B.2.i.2.b	REACTIONMEDDRAPT	Events Tab / Event Information / Preferred Term	Encoded value of element tag [REACTIONMEDDRAPT] missing.	1, 2, 3

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

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

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

For more information, see:

- ICSR Validation

ICSR Validation

This report has 5 main sections:

1. Mandatory Elements
2. Mandatory Elements for Completed Reports
3. Do Not Enter Elements
4. Elements for which English Characters are not allowed
5. Other Validation Errors

4

Transmit and Monitor ICSR Reports

Oracle Argus Safety provides utilities that enable you to schedule and transmit E2B reports. Using these utilities, you can also track the status of the transmitted E2B reports.

For more information, see:

- Schedule an E2B Report
- View a Scheduled E2B Report
- Transmit E2B Reports

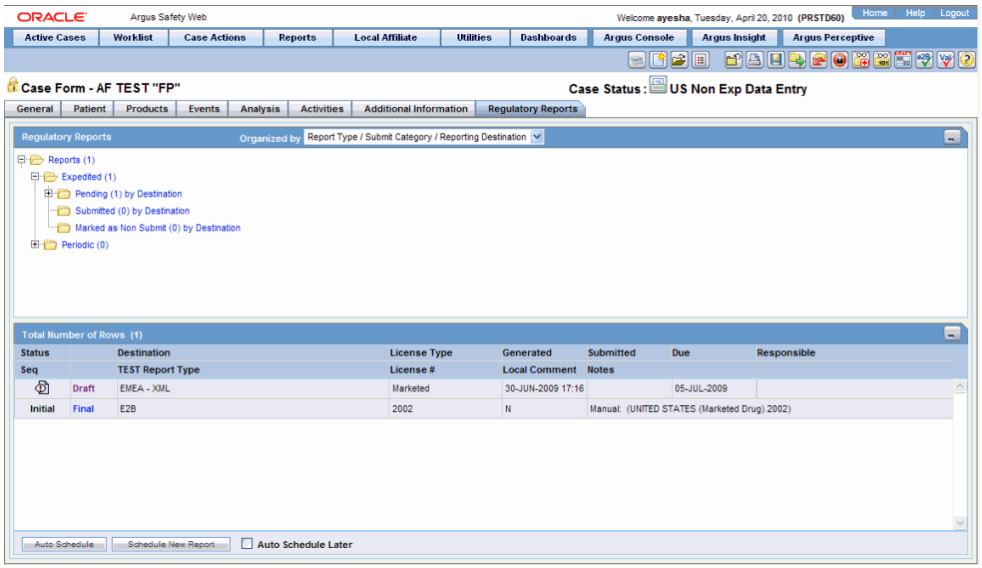
Schedule an E2B Report

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

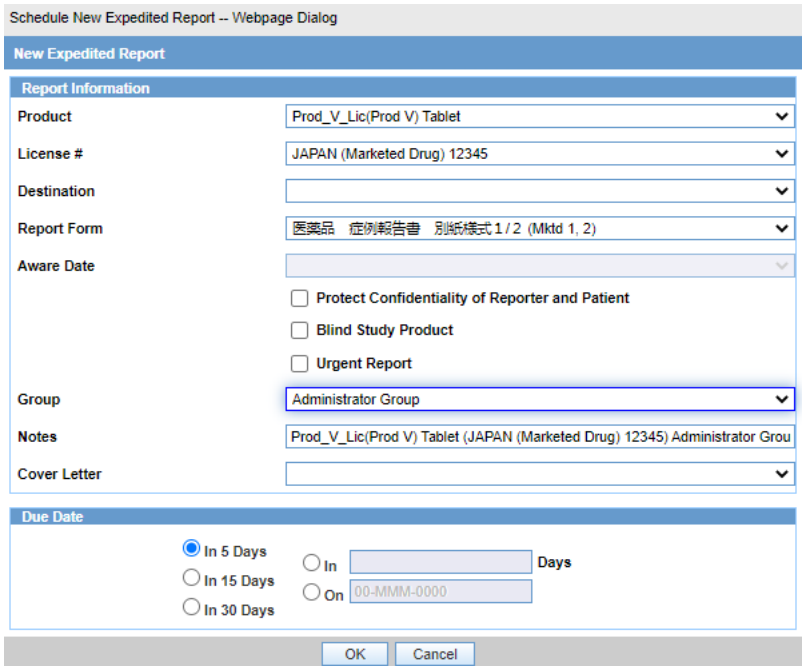
> **Note:**
>
> When you generate an E2B report, some characters entered by the user in the case form may not be display in the same way in the E2B report. Some characters are represented differently in the E2B report.

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**.



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

New Expedited Report Dialog Fields

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

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

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

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.
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 Oracle 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.`

View a Scheduled E2B Report

Use the following procedure to view a scheduled E2B report.

1. In the **Regulatory Reports** tab, click the row (draft/final) that corresponds to the scheduled E2B Report to generate the report.

The report is generated and can be viewed in the E2B Viewer. If a validation error occurs during E2B report generation, the validation details are stored in the Report Details dialog.

2. Right-click the report icon and select **View Report Details** to open the **Report Details** dialog box.

Transmit E2B Reports

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

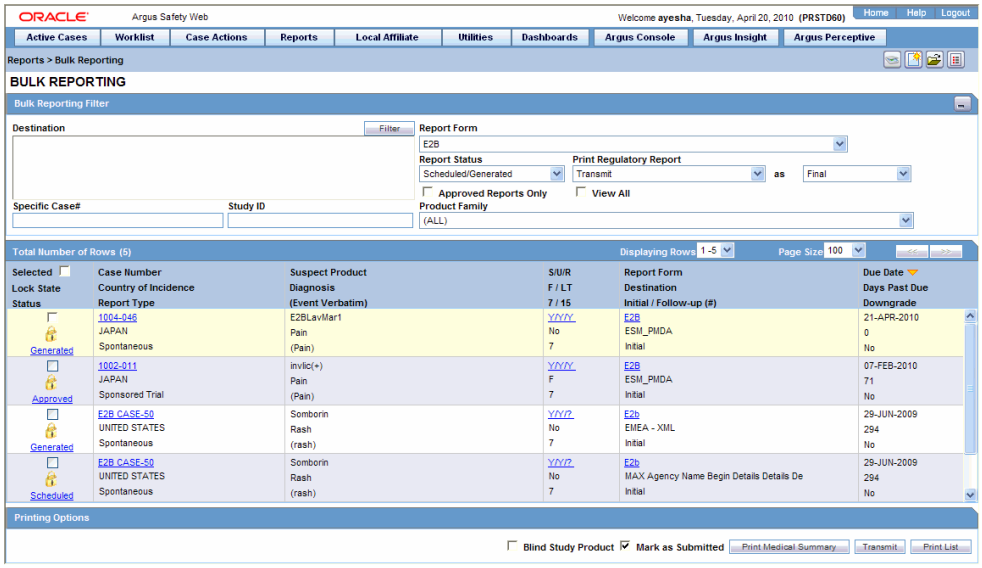
For more information, see:

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

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**.
4. Under Printing Options, select **Transmit**.

5. Select the **Mark as Submitted** check box if it is required to mark the report as "submitted" after the transmission is successful.
6. Click **OK** after all the required items in the dialog have been entered. Use the table at the end of this topic to understand the function of each item in the dialog.
7. When the system opens the **Transmission Comments** dialog box, enter the notes for transmission.
8. Click **OK** to transmit the report(s).

   OR

   Click **Cancel** to close the dialog box without transmitting the report.
9. If the Marked as Submitted check box was selected in step 5, the system opens the **Report Submission Information** dialog box.

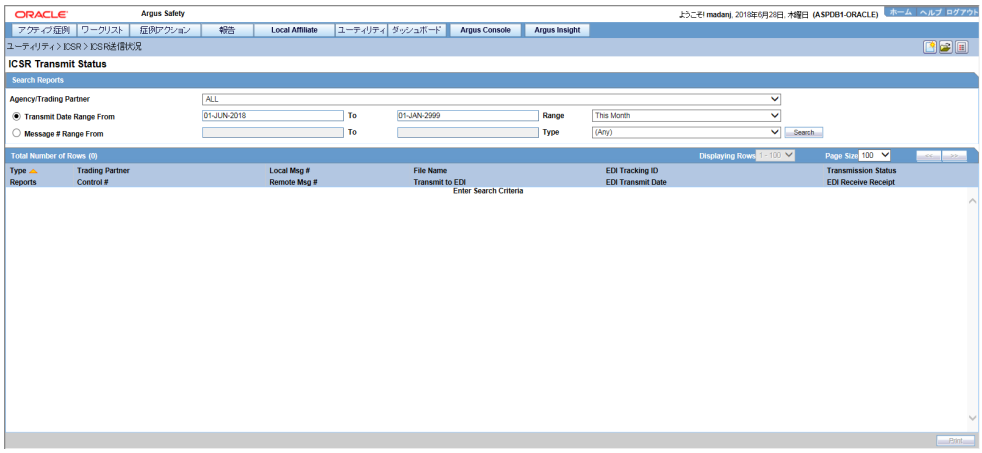
   Enter the submission notes in the **Notes** field and click **OK**.

> **Note:**
>
> If the Marked as Submitted check box was not selected, the Report Submission Information dialog does not appear automatically. In this case, once the report has been successfully transmitted, it can be marked as "submitted" from the Worklist as follows:
>
> 1. Go to **Worklist** > **Bulk 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**.

Monitor ICSR Transmit Status

Use the following procedure to monitor ICSR Transmit Statuses:

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
- PMDA ACK Import Logic

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.
Agency / Trading Partner	Enables you to filter data by selecting the Agency / Trading Partner from the list.
Transmit Date Range From	The search start date.
Transmit Date Range To	The search end date
Range	A pre-defined date that you select from the list.
Message # Range From	The beginning message number for the search.
Message # Range To	The ending message number for the search.
Type	Enables you to filter data by selecting the pre-defined Type of Message (MSG, ACK) from the list.
Print	Enables you to print the current view.
Search	Enables you to perform the search.

Note:

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

1. Select the appropriate agency or trading partner from the **Agency/Trading Partner** list.
2. Select the appropriate option, **Transmit Date** or **Message #** to search by transmit date or by message number.
3. Enter the appropriate search criteria beside the selected option and click **Search**.
4. In the search results, click the appropriate report.
5. The **Message Acknowledgement Status** dialog appears.
6. This dialog provides detailed information about the transmission status of the report. Enter the data for each field as required.

Message Acknowledgement Status Dialog Fields

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

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

PMDA ACK Import Logic

E2B (R2) Reports

The MARK AS SUBMITTED logic has been updated for PMDA E2B reports.

The following scenario is being used to explain the requirement,

The PMDA E2B Report and PMDA ACK element are being referred using the Data Element Numbers in the requirement:

PMDA E2B (R2) ACK:

- A.1.6 (TRANSMISSIONACKNOWLEDGMENTCODE)
  Possible Values as per ICH:

  01= All Reports loaded into database

  02= ICSR Error, not all reports loaded into the database, check section B

  03= SGML parsing error, no data extracted
- B.1.8 (REPORT ACKNOWLEDGMENTCODE)
  Possible Values as per ICH:

  01=Report Loaded Successfully

  02=Report Not Loaded
- B.1.9(ERRORMESSAGECOMMENT)

The application has been enhanced such that, when an ACK is received against PMDA E2B report with A.1.6 = 01, B.1.8 = 02, the application treats it as a Positive ACK with warning and marks the report as submitted.

The report submission behavior for different combination of ACK's against PMDA E2B Reports is:

- Ack: A.1.6 = 01, B.1.8 = 01 - Positive Ack, Report is marked as submitted
- Ack: A.1.6 = 01, B.1.8 = 02 - Positive Ack with Warning, Report is marked as submitted
- Ack: A.1.6 = 02, B.1.8 = 01 or 02 - Negative Ack, Report is not marked as Submitted.
- Ack: A.1.6 = 03, B.1.8 = 01 or 02 - Negative Ack, Report is not marked as Submitted.

This behavior of marking PMDA E2B Report as submitted against the positive ACK is applicable only when the report submission is set to any of the following values:

- Use MDN Date as Submission Date and Mark report as submitted only on Positive ACKs.
- Use Business Level ACK Date as Submission Date and Mark report as submitted only on Positive ACKs.
- Use Submitted date as entered by the user and Mark report as submitted only on Positive ACKs.

E2B (R3) Reports

A separate ACK profile is available for the PMDA E2B R3 ACK "ICH-ICSR V3.0 ACKNOWLEDGMENT TEMPLATE - PMDA". It consists of all the Export and Import mapping logic in the OOTB Acknowledgment profile.

The following section explains the import of ACK:

1. PMDA Number (B.r.2)
    a. PMDA number (B.r.2) element in the PMDA E2B R3 ACK corresponds to the B.1.3 element in the PMDA E2B R2 ACK.
    b. PMDA has made some modification to structure/information in PMDA Number that is sent against the E2B R3 report as compared to the corresponding information for PMDA R2 ACK; the PMDA number format for PMDA E2B R3 is: XX-YYYYYYYY-ZZ

        XX: represents the 2 digit E2B (R3) code of reporting category of the original ICSR submitted by the company.

        YYYYYYYY: represents the 8 digit unique PMDA ID provided to a successfully loaded ICSR.

        ZZ: represents the count of successfully loaded initial and follow-up reports for that case and reporting category. This is sent by PMDA to the company for information purposes only.
    c. Application logic for ACK import has been enhanced such that application identifies the ACK that is getting imported is against the PMDA E2B R3 report, the import logic has been enhanced to handle the newly added ZZ component in the such a way that it is loaded in the ESM schema and is available for user to view in the Report Details Dialogue *View ACK* Acknowledgment Report Tracking # and Bulk E2B Transmit *Messages* (tab) View Acknowledgment (context menu).
    d. The Case Form > PMDA Tab > PMDA Number displays only the 8 digit YYYYYYYY number as it does for the PMDA E2B R2 report.
2. Transmission Acknowledgement Code (A.4) and Acknowledgement Code for a ICSR Message (B.r.6)
   The above elements in the PMDA E2B R3 ACK indicate the status of the PMDA E2B R3 report, and the values for the code are in line with that of ICH. For ready reference, below are the values for these elements:

   Allowed Values for A.4

   - AA - Application Acknowledgement Accept (message successfully processed, no further action)
   - AE - Application Acknowledgment Error (error detected, error response has additional detail, some ICSR message(s) need further action)
   - AR - Application Acknowledgment Reject (parsing error, no data extracted, re-send the entire transaction)

   Allowed Values for B.r.6

   - CA - Commit Accept (the ICSR message successfully loaded)
   - CR - Commit Reject (the ICSR message contains fatal error that prevents the ICSR from being loaded)

   The similar codes A.1.6 and B.1.8 exists in the PMDA E2B R2 ACK file as

   Allowed Values for A.1.6

   - 01= All Reports loaded into database

- 02 = ICSR Error, not all reports loaded into the database, check section B
- 03= SGML parsing error, no data extracted

Allowed Values for B.1.8

- 01=Report Loaded Successfully
- 02=Report Not Loaded

a. Currently while importing the ACK for PMDA E2B R2 if the ACK File is received such that the value of A.1.6 = 01 and B.1.8 = 02 the application interpret it to ACK with a warning i.e. the PMDA has loaded the report in there system but are some warnings for which a follow-up report is required.

b. As per the PMDA E2B R3 guideline the same warning situation is indicated with A.4 = AE and B.r.6 = CA, and application logic shall be enhanced to handle the warning ACK similar to that of PMDA E2B R2

c. The warming ACK shall be handled across the application not limited to the following locations:
- *ACK Import*

- *Worklist* ' Bulk E2B Transmit (Reports & Messages Tab)

- *Report Details Dialogue*

The following table explains the possible combinations for A.4 and B.r.6 in a PMDA E2B R3 ACK file:

A.4	B.r.6	Results
AA	CA	Positive
AE	CA	Warning
AE	CR	Negative
AR	CR	Negative
AA	CR	Invalid
AR	CA	Invalid

When both the transmission ACK code and report ACK code is 01, then the ACK shows a green tick mark in the Argus Report Status window.

When the transmission ACK code is 01, the report ACK code is 02 & PMDA R2, then the ACK shows an orange tick mark in the Argus Report Status window.

When the transmission ACK code is 02, the report ACK code is 01 & PMDA R3, then the ACK shows an orange tick mark in the Argus Report Status window.

In case of any other combination of transmission ACK code and report ACK code, the ACK shows a red X mark in the Argus Report Status window.

Monitor ICSR Receive Status

Use the following procedure to monitor ICSR Receive Statuses:

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.
Rejected Reports	The number of rejected reports.
File Name	The name of the received file.
Received from EDI	The date and time the file was received.
Transmission Status	The transmission status for the file.
Print	Enables you to print the current view.
Search	Enables you to initiate the search.

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

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

Message Acknowledgement Status Dialog Fields

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

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

Validation Check of Incoming Message

Prior to updating the transmission status of the reports, the application identifies the type of incoming message and validates the incoming message. The E2b service processes all the incoming messages located in a folder either in incoming EDI directory or physical media directory. Incoming E2b Messages are retrieved as SGML from a shared directory. The incoming folder is configurable in INI file. E2b message is parsed to check the validity of the SGML file using the correct version of DTD. The incoming message is saved after checking that message is in compliance with DTD.

The recipient of the E2b message acknowledges receipt of message and notifies the sender about the validity and usability of the data in the reports. The acknowledgment message is called as ICSR Acknowledgment Message. When a message is

acknowledged, workflow status of the E2b report is updated with one of the following three status:

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

The acknowledgement contains two sections, one concerning the validity of the message as a whole and the second containing comments on the validity of the individual reports within the message. Create a folder and configure the INI file where all the incoming messages can be stored. The E2b service processes the received message and copies it in the incoming Physical media folder.

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

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

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

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

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

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

Process	Error message	Possible Reason of error
Read the Incoming message from the folder	XML File not in path.	File is removed.
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 '2.1', DTD release '1.1', Active profile = 'Y' and profile type starts 'ACK%'	Profile does not exist in cfg_profile table.

Process	Error message	Possible Reason of error
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	Not valid ICH ICSR message Tag '<messageacknowledgment>' not found	File does not contain the valid ICH Acknowledgment Header.
Processing acknowledgment	Record not found in MESSAGES table for the ICSRMESSAGE number <<MessageNum>> ICSRMESSAGE receiver identifier <<receiver info>> for the received acknowledgment	Record is deleted from the database.
Processing acknowledgment	Duplicate acknowledgment received for ICSRMESSAGE number <<message number>> and ICSRMESSAGE RECEIVER IDENTIFIER <<receiver info>>	Acknowledgment already exists for this message number.
Processing acknowledgment	<reportacknowledgment> section is missing from the received acknowledgment, MESSAGE number <<message number>>	Acknowledgment does not contain the report acknowledgment body.
Processing acknowledgment	Record not found in SAFETYREPORT table for company number <<Company Number>> and msg_id <<message id>>	Record is deleted from SAFETYREPORT table from database.

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

- In case of invalid XML format:

```
From: E2b service user
Subject: <<file name>> not valid XML formats file
Content: This mail has been sent by the system to notify that the system has
failed to identify the file <<file name>> as a valid XML file.
Error has occurred on Line: <<line no>>, Source Text <<Error Text>>, Error
Code <<Parsing Error Code>>, Error Reason <<Error Reason>>
Thanks,
<< E2b service user >>
```

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

```
From: E2b service user
Subject: Failure to Identify the Type of Incoming Message.
Content: This mail has been sent by the system to notify that the system has
failed to identify the type of the incoming message (Acknowledgement or a
Message) present in the file <<Incoming Message File Name>>.
Thanks,
<< E2b service user >>
```

- In case of validation failure of the incoming acknowledgement:

```
From: E2b service user
Subject: Validation Failure of the Incoming Acknowledgement.
Content: This mail has been sent by the system to notify that the system has
failed to further process the incoming acknowledgement present in the file
<<Incoming Message File Name>>.
The following are the reasons for this failure:
#<n>. <<Insert the corresponding relevant error message.>>
```

```
Thanks,
<< E2b service user >>
```

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

The status of the each E2b report is updated based on the information extracted from the ICSR acknowledgment, irrespective of the transmission status (Success or Failure). Refer to the section View Acknowledgement Information for viewing the acknowledgement information.

Nullification Reports

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

- When a case is deleted and an E2B Report is submitted to a reporting destination based on the Profile switch for sending E2B nullifications.
- When an E2B report is submitted and marked as unsubmitted from Reports | Compliance | Submitted Reports:
  - The Reason for Unsubmitting the report is sent as the nullification reason for the report.
  - If the user selects the **Send Nullification** on **Unsubmission of E2B Reports** check box, the system also sends a nullification to the reporting destination where the E2B Report was previously submitted.
  - If the user does not select the **Send Nullification** on **Unsubmission of E2B Reports** check box, the system does not send a nullification to the reporting destination where the E2B Report was previously submitted unless the user deletes the case.
  - If a previous nullification for the E2B Report or an unsubmitted report is sent for a case and the case is deleted at a later date, the system does not send a duplicate nullification for the previous report.
  - When the system generates the Nullification report, the system updates the following E2B items with updated values from the previous report.

Updated E2B Items	Update Content
M.1.4	System uses a different unique number from that used in the last report.
M.1.7a	System enters the message date format.
M.1.7b	System enters the message date.
M.2	System increments this value every time it transmits the report.
A.1.3a	System enters the message date format.
A.1.3b	System enters the message date.
A.1.13	System enters 1=Yes on the Nullification report.
A.1.13.1	System enters the reason for the Nullification report.

- 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.`
- PMDA E2B(R3) report transmits data in the nullification report based on the nullification report conformance for that element, only if that element is eligible to be transmitted in the Initial, FUP, Downgrade, or Amendment reports as per the conformance for that reporting category.
  For example, The Patient block (D) is not transmitted for the reporting category AE as the conformance is X = Do not enter. Hence, when a nullification report is generated for the reporting category AE, then the Patient block (D) is not transmitted.
- In the PMDA E2B(R3) nullification report, you need to have at least one company product with a value populated in MHLWADMICSRNEWDRUGCLASS (J2.4.k).

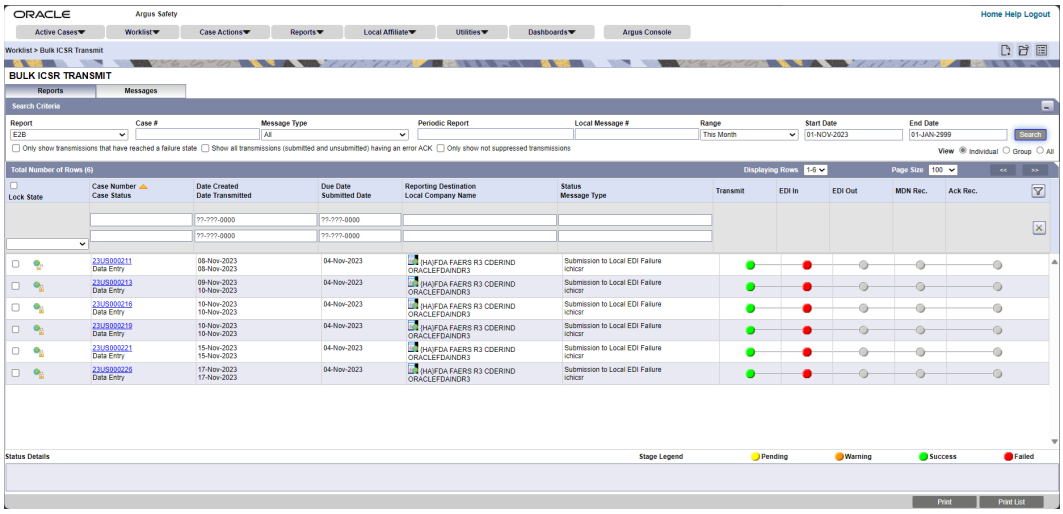
If the nullification report is generated due to a change of a company product with a Oracle Argus Safety Japan license by a company product without any Oracle Argus Safety Japan license, then the latest case data does not have any Oracle Argus Safety Japan product license listed in the PMDA tab with the MHLWADMICSRNEWDRUGCLASS (J2.4.k) value. The application fetches MHLWADMICSRNEWDRUGCLASS (J2.4.k) from the first drug block of the previously submitted E2B report for which nullification report is being generated.

View Status

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

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

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



2. Click the **Bulk ICSR Transmit** tab to view the status of transmitted reports.

> **Note:**
>
> Viewing the transmission status of E2B reports is a feature available only in Oracle Argus Safety Web.

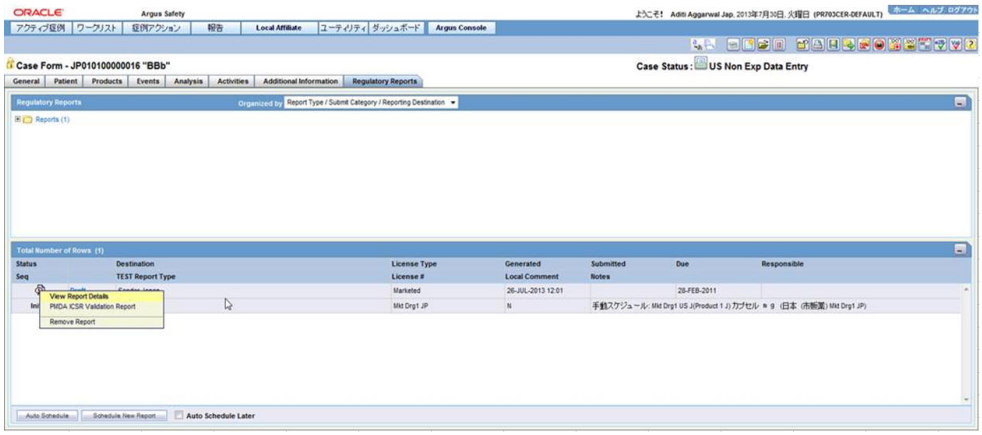
View Acknowledgement Information

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

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

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

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



2. When the system opens the **Report Details** dialog, click **View ACK Information** to view the acknowledgement details for that report. If the report is rejected, an error message or a comment appears in the **Notes** area of the dialog
3. When the **Acknowledgement Information** dialog opens, perform one of the following:
   - Click **Print** to print the acknowledgement details
   - Click **OK** to close the dialog box.

5

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.

For more information, see:

- Open the ICSR Viewer
- Export an SGML File

Open the ICSR Viewer

The ICSR Viewer enables you to view your E2B reports in the following views. A new switch is added to identify the default viewing format of the PMDA E2B R3 report in the ICSR viewer.

View	Description
SGML	Displays the E2B report in the SGML format. This view is applicable for non-Japanese E2B reports.
Decoded View	Displays all the E2B elements in groups and subgroups. Elements eligible for decoding with their decoded values in parentheses. Decoded View supports the following Oracle Argus Safety Japan specific views for Japanese E2B reports: • I - Decoded View • J - Decoded View I and J Decoded Views display following information on the screen in Japanese language: • Field Labels on the screen • Folder Tree Values • Decoded description values wherever there is a text. In this view, the application lists the ICH and PMDA element in the decoded formats as per the applicable decoded value based on the allowed values set for the element against the profile.
CIOMS	For details on the CIOMS view, refer to the "E2BCIOMSMapping" document. This view is applicable for non-Japanese E2B reports.
HL 7 View	In this view, the application opens the report within the HL7 message format as per the PMDA Guidance (as explained in the report generation section).
MedWatch	For details on the MedWatch view, refer to the "E2BMedWMapping" document. This view is applicable for non-Japanese E2B reports.
I-SGML	Displays ICSR I data items in SGML format.
J-SGML	Displays ICSR J data items in SGML format.
I-Decoded	Displays the Decoded view for all the I elements of a PMDA E2B report.
J-Decoded	Displays the Decoded view for all the J elements of a PMDA E2B report.
PMDA Report Form	Displays the appropriate PMDA form, as per the reporting category.

View	Description
XML View	In native XML view, the application lists all the ICH and PMDA specific elements as per the PMDA E2B R3 Mapping.

The **PMDA Device Viewer** enables you to view your PMDA Device reports in the following views:

View	Description
XML	This view is displayed by default.

> **Note:**
>
> In future releases, common profile switches will be available to set the default view.

Decoded	Displays all the elements in groups and subgroups. Elements eligible for decoding are displayed with their decoded values in parentheses.
Paper View	Allows you to view the PMDA Device report as Form 8 or Form 10 PDF, depending on the report form.

For more information, see:

- PMDA E2B Report Mapping for SERIOUSNESS [A.1.5.2]

PMDA E2B Report Mapping for SERIOUSNESS [A.1.5.2]

The PMDA profile E2B transmission logic for SERIOUSNESS [A.1.5.2] tags considers on those events which have been included in the PMDA E2B based on event reportability criteria. This is applicable to the following tags:

- SERIOUSNESSDEATH
- SERIOUSNESSLIFETHREATENING
- SERIOUSNESSHOSPITALIZATION
- SERIOUSNESSCONGENITALANOMALI
- SERIOUSNESSDISABLING
- SERIOUSNESSOTHER

The E2B transmission logic for SERIOUSNESSDEATH tag which currently looks at death details even though it is not related to any event included in the E2B has been removed. It is transmitted as 1 (Yes), only if at least one event which is included the E2B report has Death associated with it. Otherwise, it will be transmitted as 2.This is applicable to all E2B profiles - ICH, FDA, EMEA and PMDA.

The transmission logic for SERIOUSNESSDEATH tag has been removed. It is transmitted as 1 (Yes), only if at least one event which is included the E2B report has Death associated with it. Otherwise, it shall be transmitted as 2.This is applicable to all E2B profiles - ICH, FDA, EMEA and PMDA.

All the E2B check validations for all profiles - ICH, FDA, EMEA and PMDA, related to the following tags will be corrected to only refer to seriousness of the events which are included in the E2B report:

- SERIOUS
- SERIOUSNESSDEATH
- REACTIONOUTCOME

For PMDA E2B reports, if there are no reportable events for the E2B / PMDA Paper Reports, then instead of opening PMDA ICSR Validation Report with missing mandatory tag errors for REACTIONMEDDRAPT and REACTIONMEDDRALLT tags, application shall display an Oracle Argus Safety standard messagebox with **OK** button and error message: *No reportable event exists for the report*.

> **Note:**
>
> For additional details, refer to the *Oracle Argus Safety Report Mapping Guide* (Available from My Oracle Support) that is part of the Technical Reference Manual, as part of this release.

Export an SGML File

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

1. Click the **Final E2B** report type on the **Regulatory Reports** tab.
2. When the system opens the E2B Viewer window, Select **SGML** from the **View Format** drop-down list.
3. When the system displays the contents of the SGML file, click **Export**.
4. When the system displays the SGML report, click **File** > **Save As**.
5. When the system opens the **Save As** dialog box:
   a. Enter a name for the file.
   b. Browse to the folder where the file is to be saved
   c. Click **Save** to save and export the SGML file.

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

6

Import ICSR Reports

This chapter discusses the following:

- Incoming ICSR Reports
- Processed ICSR Reports

Incoming ICSR Reports

Incoming ICSR Reports can be viewed from the Incoming ICSR Report screen. This section includes discussions on the following:

- Search for Duplicate Cases
- Use the View Differences Report
- View the E2B Report
- Accept Single/Multiple E2B Reports
- E2B Initial/Follow-up Intake
- E2B Follow-up Acceptance for Closed/Locked Cases
- Source XML Received for the Case
- Import E2B (R3) Messages
- ICSR Pending Screen for (R3) Report
- PMDA E2B R3 ACK

Search for Duplicate Cases

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 E2B Reports** dialog, right-click a case to perform a duplicate search.
3. The system displays the search results at the bottom of the dialog box.

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 Safety received the report and saved it in the system.
Center ID	The ID of the center.
Sal.	The salutation, such as Mr. or Mrs.
Suffix	The suffix, if applicable, that follows the name (e.g., Jr., Sr.,III, etc.)
First Name	The first name of the patient.
Last Name	The last name of the patient.
Country of Incidence	The country where the incident occurred.
State	The state where the incident occurred.
Postal Code	The postal code of the area where the incident occurred.
Patient Name	The name of the patient.
Event Desc.	A description of the adverse event.
Initials	The initials of the patient.
Onset Date	The date from the first reaction or adverse event occurred.
Pat. ID	The unique value that identifies the patient.
Age/Units	The age of the patient.
Pat. DOB	The patient's date of birth.
Gender	The gender of the patient.
Reference #	National Regulatory Authority's Report Number, used as a Reference Number.
Journal	The journal name of the literature reference.
Keyword	Select the check box and enter a keyword to be searched, if required.
Title	Select the check box and enter a title to be searched, if required.
Nullification Reason	The reason the case was nullified.
Accept Initial E2B as Follow-Up	Enables you to accept initial E2B as a follow-up to an existing case.
Search	Finds results matching the specified search criteria.
View E2B	Enables you to view the E2B report.
Accept E2B Case	Enables you to accept an E2B case.

Field	Description
Reject E2B Case	Enables you to reject an E2B case.
View Warning	Enables you to view warnings associated with the case.
View Differences	Enables you to view the differences between the XML to be imported (a message that is not yet imported into the database), the current case data in the database, and the last imported case.

> **Note:**
>
> This button is available only for follow-up and nullification reports.

Case Number	The case number of the case matching the search criteria.
Pat. Initials	Displays the initials of the patient in the case matching the search criteria.
Action	Enables you to view the Case Summary dialog.
Project ID	Displays the Project ID of the case matching the search criteria.
Study ID	Displays the Study ID of the case matching the search criteria.
Date	Displays the date of the case matching the search criteria.
Country	Displays the country name of the case matching the search criteria.
Product	Displays the product name involved with the case matching the search criteria.
Event	Displays the event involved with the case matching the search criteria.
Report Type	Displays the report type of the case matching the search criteria.
Reporter	Displays the reporter involved with the case matching the search criteria.

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

Use the View Differences Report

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

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

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

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

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

For more information, see:

- Displaying Differences

Displaying Differences

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

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

For PMDA R3:

- The Difference report viewer lists all the ICH and PMDA regional elements in one single view similar to that of EMA R3 (unlike the PMDA E2B R3 where there were two I and J views).
- All the concepts for the R3 import frameworks such as deletion, primary key matching of the records, and custom comparison logic are also available for PMDA E2B R3 ICSR import.

View the E2B Report

Use the following procedure to view the E2B Report:

1. Select **Reports** > **Duplicate Search** and right-click to the **Duplicate Search** dialog box.
2. Click **View E2B** to view the E2B report in the **ICSR Viewer**.

Accept Single/Multiple E2B Reports

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

1. Select **Reports** > **E2B Pending** to open the **Incoming ICSR Report** dialog box.
2. When the system opens the Incoming ICSR Report dialog box, perform one of the following:
   - Select **Accept ICSR** to accept a single report
   - Select the check boxes for each report and click **Accept ICSRs** to accept multiple reports.
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:**
>
> Accept ICSRs can be performed only when the system numbering is set to Automatic.

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

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

For PMDA R3:

The case acceptance procedure supports the batch import of the R3 message (unlike PMDA E2B R2).

E2B Initial/Follow-up Intake

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

- The Selective Acceptance feature is enabled only for single initial ICSRs and is a right-click option.
- If you select multiple ICSRs, the system disables this button.

- If you select a single follow-up or nullification ICSR, the system disables this button.
- When the system displays the **E2B Difference Report** dialog, you can select the elements required to create or update a case without the system displaying the Case Number and Follow-up Number in the difference report dialog for initial reports.
- The following changes have been made to the Initial Intake and the Follow-up Difference Report dialogs:
  - The system displays the decoded view to enable you to select the elements (e.g., US [United States]).
  - The system prints the check box options for the **Initial Intake** and **Follow-up Difference Report** dialogs.
  - The label is updated to **Select** when selecting elements for the **Initial Intake** and the **Follow-up Difference Report** dialog.
- You must select the following fields before the system will permit you to accept the Initial case. By default, all the fields are selected.
  - Country of Incidence (default and grayed out)
  - Report Type (default and grayed out)
  - Initial Receipt Date (default and grayed out)
  - Any one Product
  - Any one Event Term
- If you fail to select these fields, the system displays the following message: `E2B cannot be imported as it does not meet minimum Argus requirements.`
- The system permits you to print the Initial ICSR report.
- When you click **Accept Initial**, the system displays the **Accept E2B Case** dialog. When you complete the data elements and click **OK**, the system displays the **Error/Warning** message dialog for any elements you have selected.
- Once you accepts 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.
- 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 (E2B Viewer).
- Initial Selection PDF
  - Attachment Classification - As specified in the Reporting Destination for the Selection Source Classification.
  - Date - The system date when you accepted XML for the case.
  - Description - The date you entered acceptance notes for XML.

- Follow-up Source XML
  - When you click the **Source ICSR PDF** or the **E2B Difference Report**, you can view the Initial Selection PDF or the E2B Difference Report in a different IE window.
- Once you accept a case as an initial or a follow-up ICSR, the system prefixes the Business Level Acknowledgement Notes with the case number in the following format:
  `Imported Case #: XXXXXX`

  where:

  `XXXXXX` is the case number
- The system attaches the current notes sent in the Business Level Acknowledgement. If the system receives the ICSR via the physical gateway (configured at the reporting destination level), the system sends a low level ACK to indicate the file was received by the Oracle Argus Interchange Service.
- For Auto Accepted ICSRs, the system does not attach the source PDF in the case because the source XML is attached.
- 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 Oracle Argus 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 Oracle Argus Interchange Service.

E2B Follow-up Acceptance for Closed/Locked Cases

- If you try to accept follow-up information for a closed or locked case, the system prompts you to unarchive or unlock the case for processing after entering the password and acceptance notes.
- If the system archives a case while you are accepting the report, the system displays the **Case Re-open** dialog to enable you to open the case.
- If the system locks a case while you are accepting a report, the system displays the **Case Unlock** dialog to enable you to unlock the case.
- After the you reopen the case, the system accepts all updates as defined in the follow-up information you selected.
- If the 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.

Source XML Received for the Case

Once Oracle Argus Safety accepts a 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 as follows:

- Initial/Follow-up Source XML
  - Attachment Classification &endash - As specified in the Reporting Destination for XML Source Classification.
  - Date &endash - The system date when the user accepted the case for XML.
  - Description &endash - The acceptance notes entered by the user for XML.
  - When the user clicks the **Source ICSR**, the system permits the user to view the ICSR by opening the ICSR Viewer (E2B Viewer).
- Initial Selection PDF
  - Attachment Classification - As specified in the Reporting Destination for Selection Source Classification.
  - Date - The system date when you accepted the case for XML.
  - Description - The acceptance notes you entered for XML.
- Follow-up Source XML
  - When you click the **Source ICSR PDF** or the **E2B Difference Report**, the system enables you to view the Initial Selection PDF or the E2B Difference Report in a different IE window.
- When you accept the case as an initial or follow-up ICSR, the system inserts the case number before Business Level Acknowledgement Notes in the following format: Imported Case #: xxxx
- If the system receives the ICSR via the physical gateway, it sends a low level ACK to indicate that the file was reviewed by Oracle Argus Interchange Services.
  - The system places the file in the Physical Out folders as defined in the reporting destination configured in the E2B Mapping.
  - When the system receives files from EDI, the system continues to let the EDI Gateway send the low level ACK.
  - The Oracle Argus Interchange Services does not process the Low Level ACK in the Physical In destination folder but enters any errors in the log file because the file will always be rejected by the Oracle Argus Interchange Service.

Import E2B (R3) Messages

- The import process for PMDA E2B R3 imports a single XML file similar to that of a EMA R3 message (unlike PMDA E2B R2 which consists of two files I & J).
- ICSR Import logic for PMDA E2B R3 enables you to import an incoming ICSR file using PMDA E2B R3 profile that consist of only ICH elements i.e. if there are only the ICH elements present in the incoming message, the files would still be imported for ICH elements.
- In the incoming ICSR message for both PMDA E2B R2 and R3, if there is no J2.1a (for R3) and J.4a (for R2) value in the incoming ICSR message then it is considered as Marketed ADR report, and either domestic or foreign is decided based on the COI identified on the data in the incoming ICSR (Primary reporter country or the Reaction occur country).
- Similar to that of PMDA E2B R3 export (same as ICH and EMA) the incoming PMDA E2B R3 messages is expected to be in UTF-8 format rather than the Shift-

jis. In case of PMDA E2B R2 (in Oracle Argus Safety the encoding is governed based on the Reporting Destination configuration).

- The following are the PMDA E2B R3 specific rules applied to validation logic during import of PMDA E2B R3 file:
  - During validations, the special internal logic of considering the Nullification report as Completion Report (J2.7.1-MHLWADMICSRCOMPLETECLASSR3="completed") is considered applicable for PMDA E2B R3. Additionally, the same logic is extended for the Downgrade report for the PMDA E2B R3 message.
  - The following is the Minimum case creation validation logic for Reaction for PMDA E2B R3 Research & measure (AE, AF, DE,DF, BC, BD, AG, or DG) category of report:
    If the incoming file does not comprise a Reaction than a Dummy relation is used during executing the minimum case validation.

    (For details on the profile switch, refer to *Oracle Argus Safety Japan Administrator's Guide*).

    (For details on minimum case validation, see section ICSR Import Framework in the *Oracle Argus Interchange User's Guide*.
  - The following is the COI Identification logic for Minimum case validation:
    If Reporting Category is AE, AF, DE, DF, BC, BD, AG, or DG, then fetch the value based on the availability in the following order:
    1. Fetch COI from the Primary Reporter C.2.r.5= 1.
    2. Fetch COI from E.i.9.
    3. Fetch the country from the First reporter which has valid C.2.r.3 value.
- In the incoming PMDA E2B R3 message file the following date elements might contain the time zone component. In case these date elements contain the time zone offset, then adhere to that time zone offset in the element value while converting it in the GMT.
  - J2.2.1 - Date of Reporting
  - N.1.5 - Date of Batch Transmission
  - N.2.r.4 - Date of Message Creation
  - C.1.2 - Date of Creation
  - C.1.4 - Date Report Was First Received from Source
  - C.1.5 - Date of Most Recent Information for This Report

  Oracle Argus Safety supports time component for N.1.5, N.2.r.4, and C.1.2 only.

  In case C.1.4, C.1.5, and J2.2.1 values are in CCYYMMDD precision i.e. without the time component then consider the incoming value to be in GMT and store it without any transformation.

  Sample date formats:

  - 23-Jan-2017 08:30 +3.5
    EMA & PMDA: +3.5 for converting it to GMT: > If Oracle Argus Safety support's time, then save the converted date. > If Oracle Argus Safety does not support's time, then strip the time from converted date, and save.
  - 23-Jan-2017 08:30
    EMA & PMDA:

> If Oracle Argus Safety support's time, then save the incoming date as-is. > If Oracle Argus Safety does not support's time, then strip the time from as-is date, and save.

  - 23-Jan-2017
    EMA & PMDA: Save the date as-is.

- PMDA E2B R3 regulation have introduced as a new concept of Urgent Report (J2.3 (MHLWFLAGFORURGENTREPORT) = 1). The Urgent Report is treated as regular initial or a follow-up report as applicable.
- The application logic for attachment import supports the compression algorithm as per the profile switch "Compression algorithm for file attachments in PMDA E2B R3".
- Similar to that of EMA E2B R3, if the Reporting destination is configured to transmit the Attachments then the PMDA E2B R3 import logic imports all the valid attachments that are allowed to be added into the case form as configured in the profile switch "Case Processing > Valid Attachment File Types".

ICSR Pending Screen for (R3) Report

- Pending screen filter displays an additional value "Urgent Report" in the existing **Reports** > **ICSR Pending** > **Report Type** drop-down list.
- The search grid indicates the Urgent reports by appending "(Urgent)" in the "Initial / F-U / Nullification/ Amendment" column after the actual report type. For example, if the Initial report is an urgent report then the column value is displayed as **Initial (Urgent)**.
- In the Pending screen context menu, the E2B Viewer displays the same options as in PMDA E2B R3 Report export i.e. it supports the viewing of the PMDA Paper report. Besides, the default view settings for E2B Viewer remains same as for PMDA E2B R3 export.

PMDA E2B R3 ACK

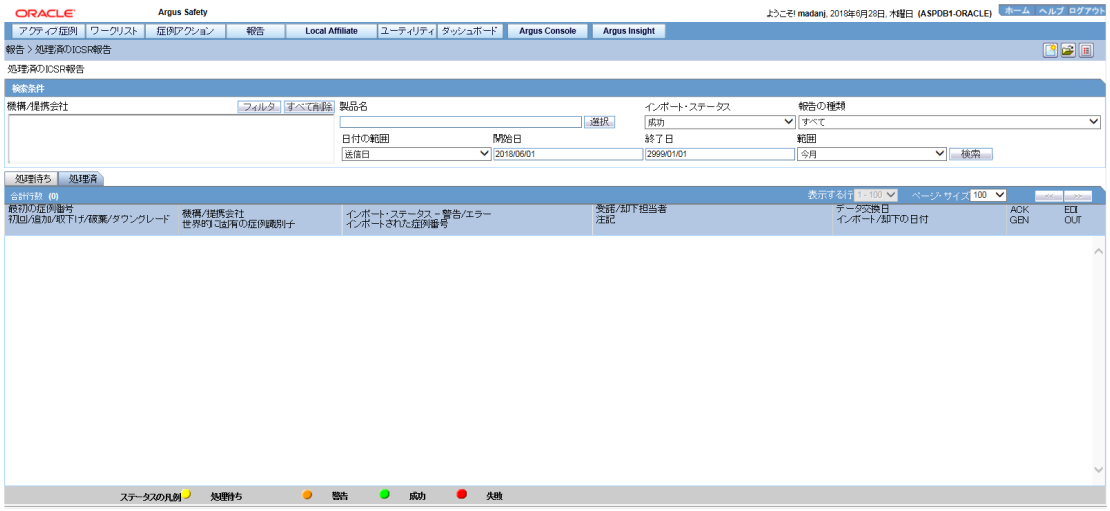
- PMDA E2B R3 Acknowledgment Template profile "ICH-ICSR V3.0 ACKNOWLEDGMENT TEMPLATE - PMDA" is available in the application.
- Similar to EMA R3, PMDA E2B R3 supports Batch Acknowledgement transmission. The acknowledgements pertaining to ICSR received in the batch are sent only after processing all the ICSRs present in the XML file.
- The application supports the generation of the low level ACK for the PMDA E2B(R3) ICSR message imported in Oracle Argus Safety using physical media option at Agency level.
- The application generates PMDA E2B(R3) ACK as an XML file with the following file name format (unlike PMDA E2B R2 where it was a SGML):
  `A-<Company's Abbreviation>-<Date of Reporting>-<unique number>.xml`

Attribute	Description
Company's Abbreviation	Code List > Reporting Destination > EDI Tab > Company Identifier

Attribute	Description
Date of Reporting	System date in Japan Time zone (using profile switch JPN_OFFSET) "YYYYMMDDHHMIss" format.
Unique number	This unique number must be alpha-numeric value constructed by concatenating the Case Number and last 2 characters of SAFETYREPORTID tag value (i.e. AA, AB, and AC etc.). For example if the case number is "15JP000236" and Safety Report ID is "JP-SENDER-JAPAN-15JP000236AA" then the Unique number will be "15JP000236AA". In case of a batch ACK, use the case number form the first case of the batch.

Processed ICSR Reports

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

For more information, see:

- Total Number of Rows Fields

Total Number of Rows Fields

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.

Field	Description
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.