

Oracle® Argus Interchange

User's Guide

Release 8.1

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Oracle Argus Interchange User's Guide Release 8.1

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Contents

Preface	vi
Audience	vi
The Oracle Health Sciences Safety Suite	vi
Documentation Accessibility	vii
Related Documents	vii
Checking My Oracle Support	viii
Conventions	viii
1 About Argus Interchange	
Argus Interchange Process Overview	1-1
ICSR	1-2
Minimum Requirement for Electronic Report Generation	1-3
2 Configuring Argus Interchange	
ESM Mapping Utility	2-1
Configuring Argus Interchange Service	2-1
Service INI File Setup Dialogue Box	2-2
Adding a Database for Argus Interchange Service	2-3
Service DB Setup Fields	2-3
Argus Console	2-5
Configuring Regulatory Authorities	2-5
Configuring Code List Items	2-6
3 Configuring Argus Interchange - Web	
Web-based Interchange Mapping	3-1
Navigating to Interchange Mapping	3-1
Managing Profiles	3-1
Defining a Profile	3-2
Printing a Profile	3-10
Copying a Profile	3-10
Deleting a Profile	3-10
Comparing Profiles	3-11
Comparing Profile Dialog Box Fields	3-12
ICSR Codes Translation	3-13
ICSR Codes Translation Fields	3-13

Configuring ICSR Codes Translation	3-13
Viewing the Audit Log.....	3-14
Audit Log Dialog Box Fields	3-15
E2B Extensions.....	3-15
4 Validating ICSR Reports	
Why perform an ICSR check?.....	4-1
Report Generation Validations.....	4-2
Validation Rules	4-3
5 Transmitting and Monitoring Reports	
Logging In and Out of Argus Safety	5-1
To Log Out of the Argus Application	5-2
Scheduling Reports.....	5-2
New Expedited Report Dialogue Fields	5-3
Nullification Reports	5-5
Follow-Up eMDR Reports	5-7
Follow-up eVAERS Reports	5-8
Generating Reports	5-9
Attachments in Reports.....	5-9
Transmitting Reports	5-10
Transmitting ICSR Reports.....	5-10
Transmitting Bulk Reports by Form.....	5-10
Monitoring ICSR Transmit Status.....	5-12
ICSR Transmit Status Fields	5-13
Message Acknowledgement Status Dialogue Fields	5-14
Monitoring ICSR Receive Status	5-14
ICSR Receive Status Dialogue Fields	5-14
Message Acknowledgement Status Dialogue Fields	5-15
Validation Check of Incoming Message	5-16
Viewing Status.....	5-19
Viewing Acknowledgement Information.....	5-19
6 Using the ICSR Viewer	
Opening the ICSR Viewer.....	6-1
Exporting an XML File	6-1
7 Importing E2B Reports	
Incoming E2B Reports	7-1
Conversion of E2B (R3) reports to E2B (R2) format (applicable only for E2B (R3) reports) ...	7-1
Searching for Duplicate Cases.....	7-1
Duplicate Search Dialogue Box Fields	7-2
Using the View Differences Report	7-3
Displaying Differences	7-4
Viewing the E2B Report	7-4

Accepting Single/Multiple E2B Reports	7-5
E2B Initial/Follow-up Intake	7-5
E2B Follow-up Acceptance for Closed/Locked Cases	7-7
Processed ICSR Reports	7-7

Preface

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

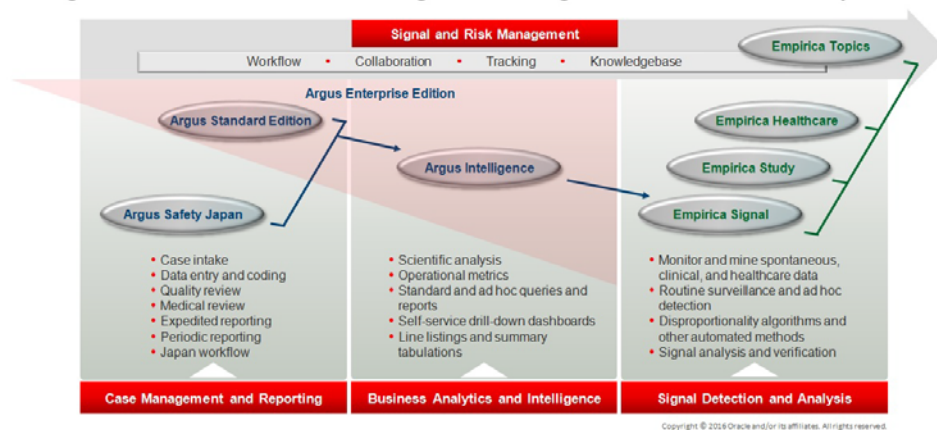
Audience

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

The Oracle Health Sciences Safety Suite

This product is part of the Oracle Health Sciences Safety Suite, an integrated solution for end-to-end vigilance from adverse event management to signal management, through the entire lifecycle of a medicinal product from clinical trials to post-marketing surveillance.

Oracle Health Sciences Safety Suite Integrated Solution for End-to-End Vigilance Through the Entire Product Lifecycle



The Oracle Health Sciences Safety Suite consists of the following components:

- Oracle Argus Standard Edition: Manage and report adverse events through a workflow including case intake, data entry, coding, quality review, medical review, expedited reporting, and periodic reporting. Modules include Oracle Argus Safety, Oracle Argus Interchange, Oracle Argus Affiliate, Oracle Argus Dossier, Oracle Argus Unblinding, and the Oracle Health Sciences Adverse Event Integration Pack for Oracle Health Sciences InForm and Oracle Argus.

- Oracle Argus Enterprise Edition: In addition to managing the adverse event workflow and reporting, employ a powerful and flexible business analytics and intelligence platform for both scientific analysis and operational metrics. Modules include Oracle Argus Analytics, Oracle Argus Insight, Oracle Argus Mart, Oracle Argus Safety, Oracle Argus Interchange, Oracle Argus Affiliate, Oracle Argus Dossier, Oracle Argus Unblinding, and the Oracle Health Sciences Adverse Event Integration Pack for Oracle Health Sciences InForm and Oracle Argus.
- Oracle Argus Safety Japan: Manage and report adverse events in Japan, and connect the global and local workflows using a single database.
- Oracle Health Sciences Empirica Topics: Manage and document safety signals through a workflow including validation, prioritization, assessment, confirmation/refutation, and resulting actions.
- Oracle Health Sciences Empirica Study: Detect and analyze safety signals in clinical trial data including adverse events, clinically significant labs, electrocardiograms, vital signs, and shifts from baseline.
- Oracle Health Sciences Empirica Signal: Detect and analyze safety signals in post-marketing spontaneous adverse reaction data including public health authority databases and/or private inhouse databases such as Oracle Argus.
- Oracle Health Sciences Empirica Healthcare Analysis: Evaluate safety signals in healthcare data including electronic medical records and administrative claims, and support pharmacoepidemiology, comparative effectiveness analysis, and health economics and outcomes research.

For more information on Argus Safety, visit the Oracle Health Sciences Safety suite page at:

<http://www.oracle.com/goto/pharmacovigilance.html>

Documentation Accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at

<http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc>.

Access to Oracle Support

Oracle customers have access to electronic support through My Oracle Support. For information, visit

<http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info> or visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

Related Documents

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

Oracle Argus Documentation

The *documentation set* includes:

- *Argus Safety Affiliate User Guide*

- *Argus Safety Administrator's User Guide*
- *Argus Safety Dossier User Guide*
- *Argus Safety Interchange User Guide*
- *Argus Safety Installation Guide*
- *Argus Safety Service Administrator Guide*
- *Argus Safety Flexible Aggregate Reporting Extensibility Guide*
- *Argus Safety BIP Aggregate Reporting User's Guide*
- *Argus Safety User's Guide*
- *Argus Safety Unblinding User Guide*
- *Argus Safety Minimum Security Configuration Guide*
- *Argus Safety Japanese Administrator's Guide*
- *Argus Interchange Japanese User's Guide*
- *Argus Safety Japanese User's Guide*

Checking My Oracle Support

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

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

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

The My Oracle Support portal opens, displaying general news from several categories. If you do not yet have an account, click **Register here** and follow the instructions given on the registration page.

3. Click **Knowledge**.
4. In the **Browse any Product, by Name** field, enter **Oracle Argus Safety**.
5. Click **Go**. My Oracle Support loads the Oracle Argus Safety Knowledge Browser Product Page.

Conventions

The following text conventions are used in this document:

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

About Argus Interchange

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

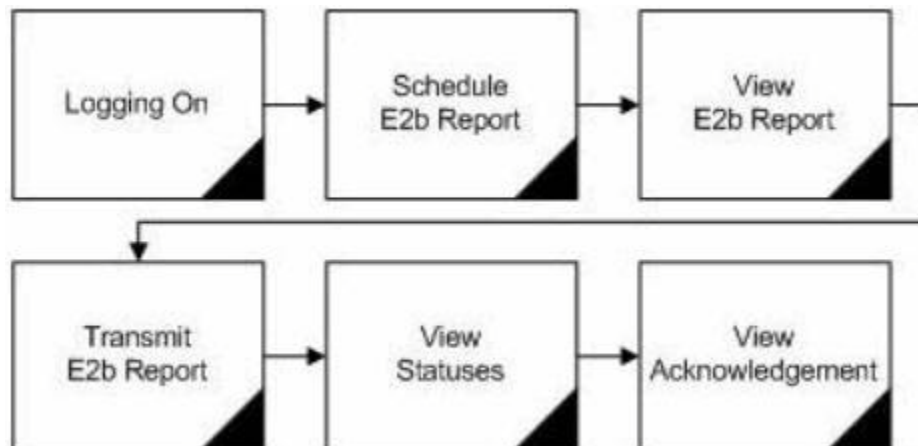
A color-coded graphical display provides peace of mind by delivering real-time insight into transmission status. Further, Argus Interchange is seamlessly integrated with Oracle Argus Safety, facilitating import, export, and transmission of cases. In addition, it supports immediate case triage upon electronic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

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

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

Argus Interchange Process Overview

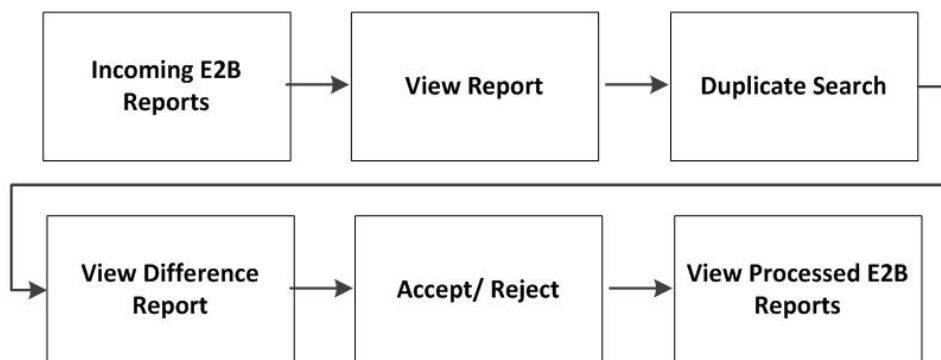
The following flowchart shows the steps to follow when using Argus Interchange.



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

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

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



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

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

ICSR

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

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

Minimum Requirement for Electronic Report Generation

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

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

Reporting Destination can be configured with a message profile for E2B(R2), E2B(R3), 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

D - Suspect medical device

E - Initial Reporter

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

G - All manufacturers

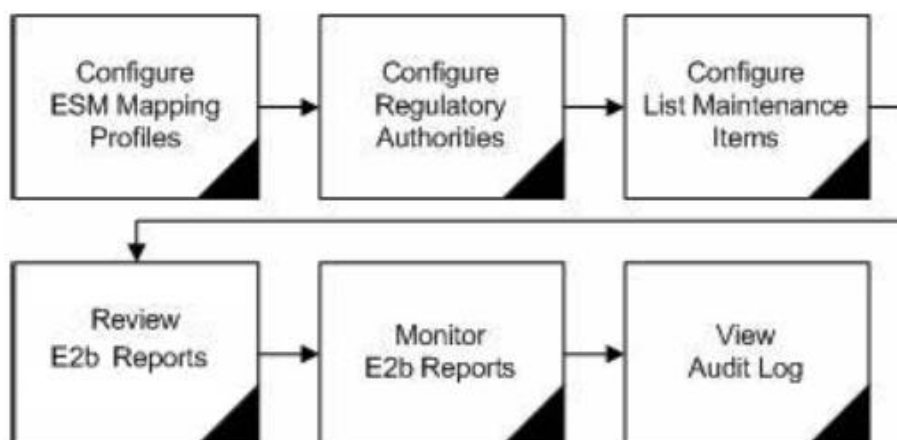
H - Device manufacturers only

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.

Configuring Argus Interchange

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



ESM Mapping Utility

Argus Interchange mapping utility helps to configure the Argus Interchange Service. This chapter provides the following information:

- [Configuring Argus Interchange Service](#)
- [Adding a Database for Argus Interchange Service](#)

Configuring Argus Interchange Service

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

1. In the Windows 2012/2012R2 server, navigate to Apps and click on ESM Mapping tool. This opens the Service INI set up Dialogue box.

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

Service INI File Setup Dialogue Box

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

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

Item	Description
Multiple Database Section	Displays all the configured databases for ESM Service.
Delete Button	Click Delete to remove the entire Database Configuration from ESM Service INI File.

Adding a Database for Argus Interchange Service

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

To configure a database:

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

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

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

Service DB Setup Fields

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

Item	Description
Database Name	Enter the name of the Adverse Event database.
Unique Database ID	Identifies each database uniquely. In the case of multiple databases, the value of this field should be unique.
User ID	Enter the user name for the Service.
Password	Enter the password associated with the User Name entered in the USER ID field.
Process	Enter the full path of the ESMProc.exe file. The system uses this path to locate the ESMProc.exe file.
Receive Process	Enter the full path of the E2BReceive.exe file. The system uses this to locate the E2BReceive.exe file.
Archive Folder	Enter the full path where the system places the file processed by Argus Interchange.
Receive Processes Count	Enables you to specify multiple E2B receive processes You can specify from 1 to 5 E2B receive processes The default is 1.
Process Elapse Time	Enter the time interval for the Argus Interchange Process to run.
Enter EDI Transmit Time out Value	The amount of time, in minutes, that must pass before the system sends an e-mail message when an E2B Report has not been transmitted within a specified time period. Note: The minimum value for the time-out is 10 minutes.
Enter Physical Media Transmit Time out Value	Enter amount of time, in minutes, that must pass before the system can send an e-mail message when an E2B Report has not been sent manually by a specified person within a specified time period. Note: The minimum value for the time-out is 10 minutes.
Enter Receive ACK Time Out Value	Enter the amount of time, in minutes, that must pass before the system can send an e-mail message when an ACK message has not been received within a specified time period. Note: The minimum value for the time-out is 10 minutes.
Enter Processing Time Out Value	Enter the amount of time, in minutes, that must pass before the system can send an e-mail message when an Incoming Report has not been processed within a specified time period. Note: The minimum value for the time-out is 10 minutes.
Enter XML Transmit Time Out Value	Enter the amount of time, in minutes, that must pass before the system can send an e-mail message when an XML file is not picked up by the Gateway. Note: The minimum value for the time-out is 10 minutes.
Enter Binary Transmit Time Out Value	Enter the amount of time, in minutes, that must pass before the system can send an e-mail message when a binary file is not picked up by the Gateway. Note: The minimum value for the time-out is 10 minutes.
Enter MDN Time Out Value	Enter the amount of time, in hours, that must pass before the system stops polling the MDN information from the EDI server after receiving the Business ACK for a transmitted report.

Argus Console

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

This section includes discussions of the following:

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

Configuring Regulatory Authorities

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

To configure a regulatory authority:

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

The screenshot shows the Oracle Argus Console interface. At the top, it says 'Welcome ayesha, Tuesday, April 20, 2010 (PRSTD60)'. Below that are navigation tabs: Code Lists, Business Configuration, Access Management, System Configuration, and Tools. The main window is titled 'CODE LIST MAINTENANCE'. On the left is a 'Browser' pane with a tree view containing various categories like 'Letter Configuration', 'Literary Citation', 'Local Evaluator Comment Type', 'Manufacturers', 'Medical Status', 'Message Type', 'Nature of Event', 'Occupations', 'Package Units', 'Product Group', 'Project ID', 'Reference Type', 'Report Media', 'Report Type', 'Reporter Information', 'Reporter Type', 'Reporting Destination' (which is highlighted), 'Reporting Destination Type', 'Routes of Administration', 'Study Center', 'Study Development Phase', and 'User Sites'. Below the browser is a 'Help Text' box.

The main content area is divided into several sections. At the top is a 'Reporting Destination Filter' with a 'Field' dropdown, a 'Value' input, and a 'Filter' button. Below that is a table showing 'Total Number of Rows (11)'. The table has the following columns: Agency Name, Agency Type, Department, Registration #, Contact Type, FAX, and FAX Cover. The data rows are:

Agency Name	Agency Type	Department	Registration #	Contact Type	FAX	FAX Cover
CBER	Other		N/A		949-453-1817	
CDER			N/A		949-453-1817	
Conv. of FDA			DG 3 -D2		949-453-1817	

Below the table are buttons for 'Add New', 'Copy', 'Delete', and 'Print'. The 'Add New Reporting Destination' section is active, showing a form with tabs for 'Agency Information', 'Local Company Contact', 'EDI', and 'SMTP'. The 'Agency Information' tab is selected. The form includes:

- Agency Name (text field)
- Agency Type (dropdown menu)
- Department (text field)
- Email Address (text field)
- Preferred Method (dropdown menu)
- Registration # (text field)
- FAX (text field)
- FAX Cover (text field)
- Contact Type (checkboxes for Manufacturer, Importer, Distributor, Offline Recipient)
- Contact Information section with fields for Title, First Name, Middle, Last, Address, Phone, Ext, Country Code, City, State/Province, Country, and Postal Code.

A 'Save' button is located at the bottom right of the form.

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

Refer to the Argus Safety Administrator's Guide, Configuring Reporting Destination section for information on using Reporting Destination.

Configuring Code List Items

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

Configuring Argus Interchange - Web

This chapter provides information on configuring web-based Argus Interchange.

Web-based Interchange Mapping

This section contains the following sections:

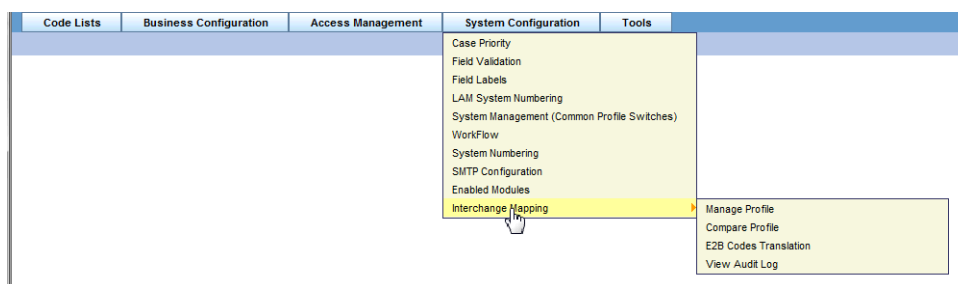
- [Navigating to Interchange Mapping](#)
- [Managing Profiles](#)
- [Comparing Profiles](#)
- [ICSR Codes Translation](#)
- [Viewing the Audit Log](#)
- [E2B Extensions](#)

Navigating to Interchange Mapping

This section provides information on navigating to the Interchange Mapping menu.

To navigate to the Interchange Mapping menu:

1. Open **Argus Console**.
2. Go to System Configuration ->Interchange Mapping.



Managing Profiles

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

- ICH-ICSR V2.1 MESSAGE TEMPLATE
- ICH-ICSR V2.1 MESSAGE TEMPLATE - EMA

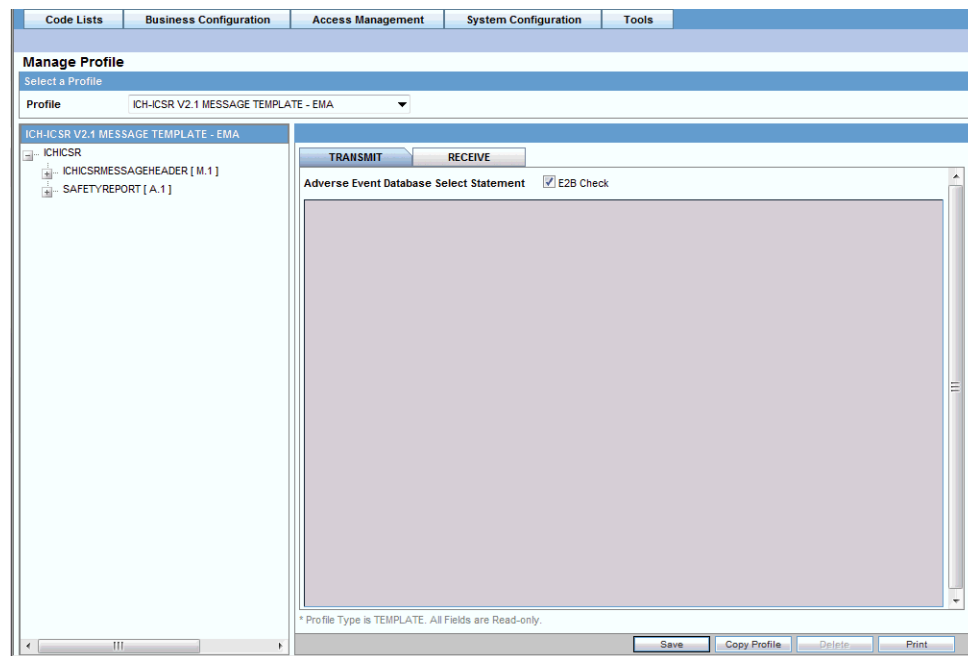
- ICH-ICSR V2.1 MESSAGE TEMPLATE - FDA
- ICH-ICSR V3.0 MESSAGE TEMPLATE
- ICH-ICSR V1.1 ACKNOWLEDGEMENT TEMPLATE
- ICH-ICSR V1.1 ACKNOWLEDGEMENT TEMPLATE - EMA
- ICH-ICSR V1.1 ACKNOWLEDGEMENT TEMPLATE - FDA
- CBER EVAERS V1.0 MESSAGE TEMPLATE
- CDRH eMDR V1.0 MESSAGE TEMPLATE

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

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

Defining a Profile

This section describes 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:

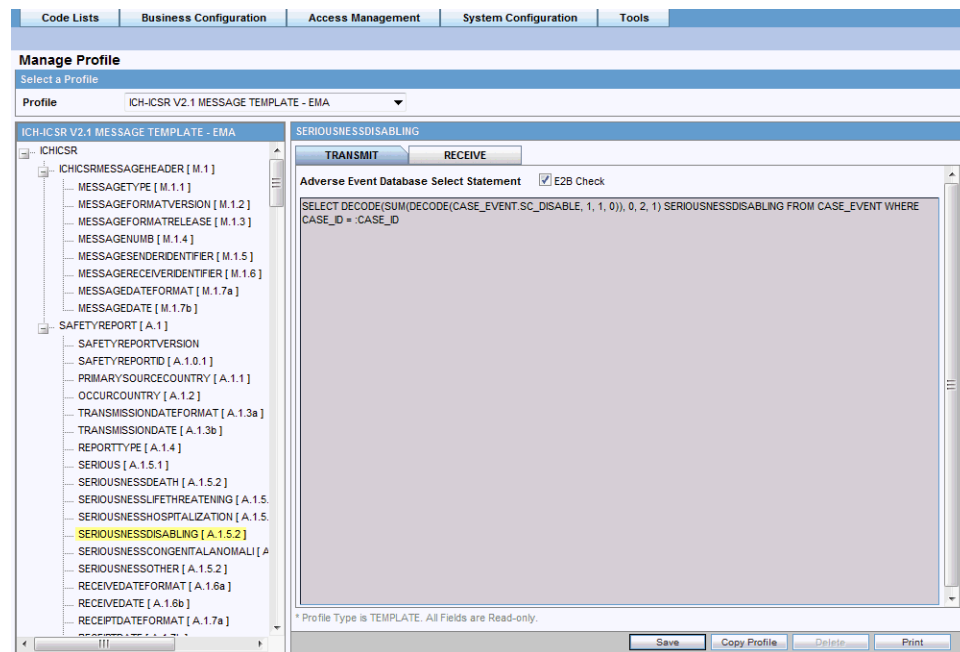
- The tree view structure of ICSR elements
- The Transmit and Receive tabs

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.

Using 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.

Using the Conformance Rules Tab

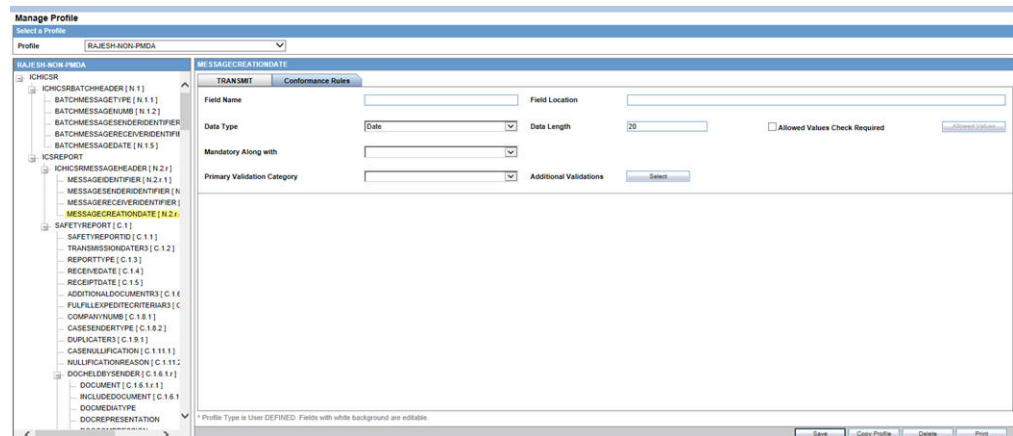
A new tab *Conformance Rules* is now available to users for all the E2B R3 based ICSR Profiles, that is, ICH, EMA, eVAERS and PMDA. The Japanese DTD tab is not available to PMDA E2B R3.

The tab allows user to configure 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.

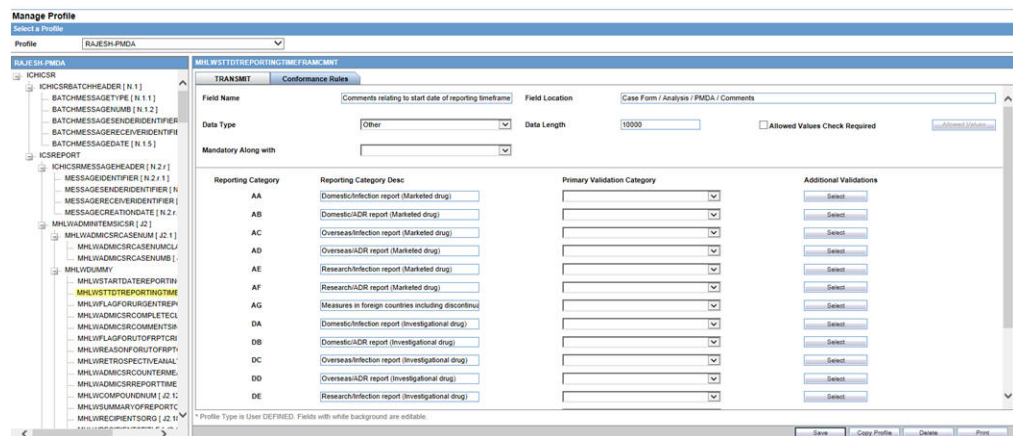
This configuration remains un-editable (read only) for all out-of-the-box E2B R3 based ICSR template profiles (ICH, EMA, PMDA, eVAERS) but is allowed to be edited for custom/copied profiles. (The configuration data for out of the box mapping profiles is available with the mapping of that profile).

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

The following is the Conformance Tab for ICH, EMA and eVAERS profile:



The following is the Conformance Tab for PMDA profile:



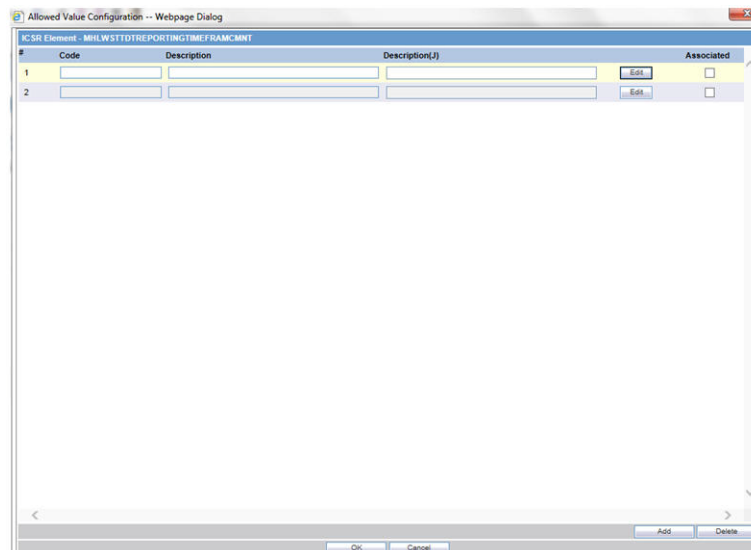
To configure the validations rule against the ICSR element, following fields have been made available to user under the Conformance Rules tab:

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. ICH, EMA, eVAERS : 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. ICH, EMA, eVAERS : 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
Mandatory Along with	Drop-down list	This drop-down list contains the DTD_ELEMENT name 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	On Clicking this button opens up <i>Allowed value configuration</i> dialogue for configuring the allowed values for the selected elements against that profile This button is enabled only if <i>Allowed Value Check Required</i> checkbox is checked For PMDA E2B R3: Refer Mapping xls > Mapping(Sheet) > Allowed Values

Field	Type	Description
Primary Validation Category	Drop-Down list	<p>This drop-down list is available for all ICH, EMA, eVAERS profiles only.</p> <p>The following option is listed in the drop-down list in the below specified order:</p> <p>Blank (Default)</p> <p>Mandatory</p> <p>Conditional Mandatory</p> <p>Do not enter</p> <p>Other Fatal Validation</p> <p>Optional</p>
Additional Validations	Button	<p>On clicking this button <i>Additional Validation Configuration</i> dialogue opens up, this dialogue enables users to configure the SQL based validations for the element.</p> <p>This button is available for ICH, EMA, eVAERS</p>
PMDA Specific		
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.
Primary Validation Category	Drop-Down list	<p>This drop-down list is available for PMDA profile only.</p> <p>The following option is listed in the drop-down list in the below specified order:</p> <p>Blank (Default)</p> <p>Mandatory</p> <p>Mandatory for Completion Report</p> <p>Conditional Mandatory for Completion Report</p> <p>Conditional Mandatory</p> <p>Do not Enter</p> <p>Other Fatal Validation</p> <p>Optional</p> <p>For PMDA E2B R3: Refer Mapping xls > Mapping (Sheet) > Reporting Category wise Conformance</p>
Additional Validations	Button	<p>On clicking this button <i>Additional Validation Configuration</i> dialogue opens up, this dialogue enables users to configure the SQL based validations for the element.</p> <p>Available button available against each Reporting Category.</p>

Field	Type	Description
Save	Button	<p>On clicking the Save button the changes are committed to Data base and audit logged.</p> <p>This committing of data includes any changes done in the <i>Allowed Value Configuration</i> and <i>Additional Validation Configuration</i> dialogues as well.</p> <p>On clicking the Save button, the application logic validates that there exists a Primary category for the ICSR Element</p> <ul style="list-style-type: none"> ■ In case of Non-PMDA profile: Element Level ■ In case of PMDA: Reporting category level <p>If there exists a row with primary category as blank, the application displays an error message: <i>Please select a Primary Validation category for the element</i> Title: <i>ICSR Validation</i> with OK Button.</p>
Print	Button	On clicking the print button, the application prints all the Conformance rule tab data.

The Allowed Values Configuration Dialogue



On clicking *Allowed Values*, the *Allowed Values Configuration* dialogue (modal Dialogue) opens. The *Allowed Values Configuration* dialogue 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 dialogue:

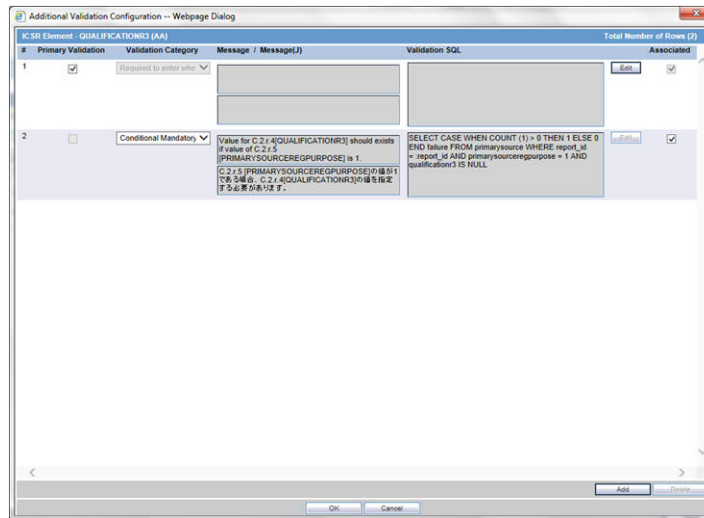
Table 3-1 Allowed Values Configuration dialogue fields

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

Table 3-1 Allowed Values Configuration dialogue fields

Edit button	On clicking the edit button, the Code and Description textboxes become enabled for user to edit
Associate checkbox	User associates or de-associates the allowed value for an element for the profile by checking and un-checking this checkbox.
Add button	On clicking the Add button, a new row is added to the grid, with Code, Description text boxes and Associate checkbox (unchecked) enabled by default.
Delete button	Deleted button is disabled by default, and is enabled only if user selects a user created custom allowed value row in the grid

The Additional Validation Configuration Dialogue



Clicking *Additional Validations* displays the *Additional Validation Configuration* dialogue 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 checkbox is checked and disabled by default.

On unchecking the *Primary Validation* checkbox, the Primary validation checkbox for all other validations and the Associated checkbox and Validation Category drop-down list for this particular validation is enabled.

For ICH, EMA and eVAERS profiles 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 dialogue:

Table 3-2 Additional Values Configuration dialogue fields

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.
-------------------	---

Table 3–2 (Cont.) Additional Values Configuration dialogue fields

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.
Associate checkbox	User associates or de-associates a validation against an element for the profile by checking and un-checking this checkbox.
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 checkbox (unchecked) 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.

Using 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 E2B	Enabled only for Custom profiles and is a profile level switch. When this checkbox is marked, the profile is considered as an Extended E2B Profile (E2B+ 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.
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.

Item	Description
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.

Printing a Profile

Use the following procedure to print a profile.

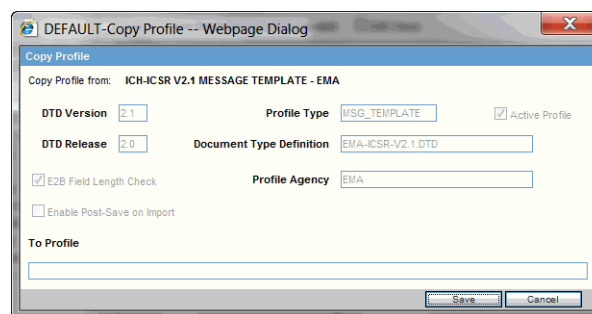
1. Select the profile to print from the Profile list.
2. Click **Print**. This prints a PDF of the selected profile.

Copying 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 / fixes applied to factory ICSR profiles are not automatically applied on the custom ICSR profiles. Hence, the custom profile logic may get obsolete by any Argus Safety version upgrade which has changes / fixes applied to factory ICSR profiles. In such a scenario, customers should re-create their custom ICSR profile again, by copying the new factory ICSR profile and applying their 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**.

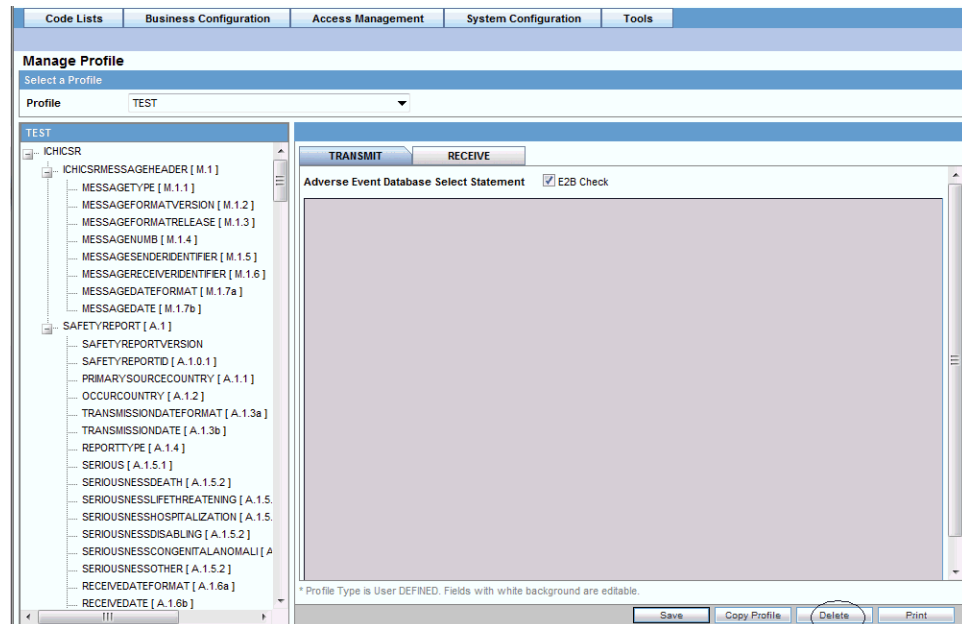


Deleting a Profile

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.



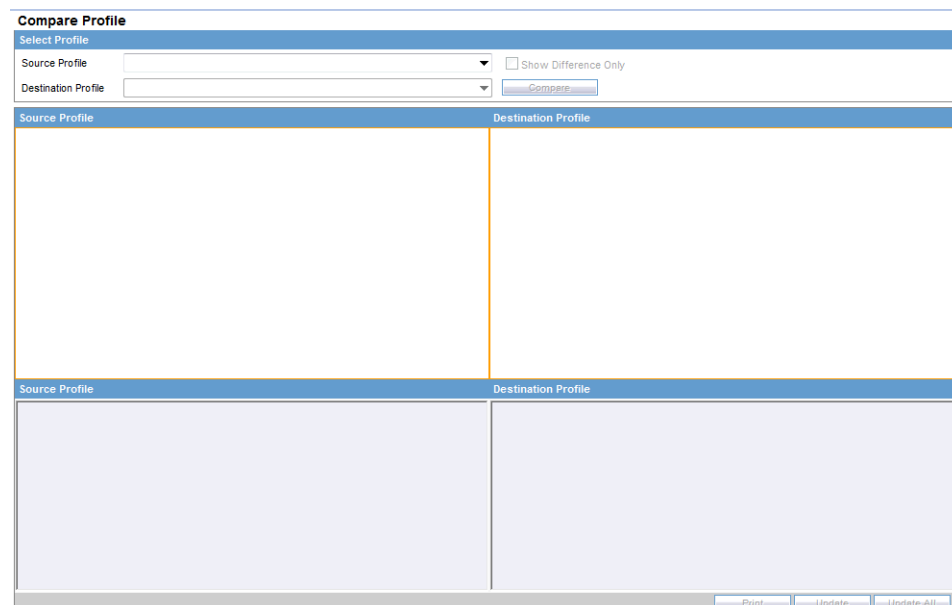
2. Click **Delete**.
3. Click **Yes** to confirm.

Comparing Profiles

You can compare two profiles to find element-level differences. Select a source profile in the left pane and a target profile in right pane, and run Compare Profiles 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 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.

Comparing 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.
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 Interchange Mapping -> ICSR Translation Codes to open the ICSR Code Translation screen.

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.
#	Displays the serial number.
Element Name	Displays the element name.
Input Value	Displays the type of input value.
Output Value	Displays the type of output value.

Configuring 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.

Viewing 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 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.

Audit Log Filter

Range: This Month (dropdown) From: 01-JUL-2015 To: 01-JAN-2999 User Name: UserESM (dropdown) Search (button)

Note: For more information on Audit Log dialogue 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.

Audit Log

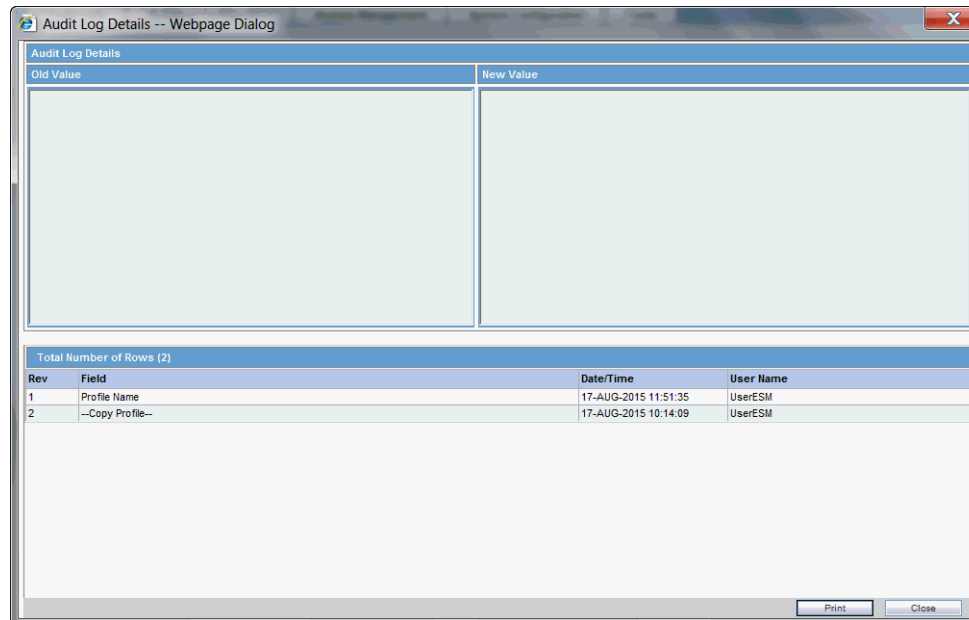
Audit Log Filter

Range: This Month (dropdown) From: 01-JUL-2015 To: 01-JAN-2999 User Name: UserESM (dropdown) Search (button)

Total Number of Rows (3)

Activity	Audit Data	Date/Time	User Name
Changed	ADITL_COPY_OF_EMA	8/17/2015 11:51:35 AM	UserESM
Added	ADITL_DTD_PROFILE	8/17/2015 11:04:11 AM	UserESM
Added	ADITL_COPY_OF_EMA	8/17/2015 10:14:09 AM	UserESM

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.



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 on for the search. Note: When the 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.

E2B Extensions

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

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

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

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

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

```
<XXX>_EXTENSION []
```

where:

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

When using this switch:

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

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

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

You can view the extended elements for the following:

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

Validating ICSR Reports

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

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 'E2B Report data check errors and warnings':

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

You can run an 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.

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

	ICSR Report data check errors and warnings
<small>15-Jun-2016 01:56 GMT -6.00</small>	

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

Report Generation Validations

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

1. Missing Mandatory Elements
2. Missing Mandatory Optional Elements
3. Length Validation for character data
4. M2 Code validation
5. Report File Size validation (for HL7 Reports only)

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 Common Profile Switches.

Validation Rules

E2B Generation validation logic has been enhanced such that rather than executing the validations directly on the case/LM data the validation rules is 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* Dialogueue 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* Dialogueue, 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 ICH, EMA and eVAERS Profile and other ICSR Report for PMDA profile

- **ICH, EMA and eVAERS**

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

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 Dialogueue*. 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 Dialogueue* 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 E2B**

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 Dialogueue*. 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 Dialogueue* 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.

Transmitting and Monitoring Reports

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

- [Logging In and Out of Argus Safety](#)
- [Scheduling Reports](#)
- [Generating Reports](#)
- [Transmitting Reports](#)

Logging In and Out of Argus Safety

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

- If you enter an incorrect username or password three (3) consecutive times, the system disables the Login button and displays the following message:
The login button has been disabled due to 3 consecutive incorrect entries of Username or Password. Please refresh the page to enable the Login button.
- The Date/Time format is DD-MMM-YYYY HH:MM:SS to reflect the 24-hour format used by the Web server.

To log in to the Argus Safety application:

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

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

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

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

To Log Out of the Argus Application

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

Scheduling Reports

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

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

To schedule an E2B report:

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

ORACLE Argus Safety Web

Welcome ayesha, Tuesday, April 20, 2010 (PRST060) Home Help Logout

Active Cases Worklist Case Actions Reports Local Affiliate Utilities Dashboards Argus Console Argus Insight Argus Perceptive

Case Form - AF TEST "FP" Case Status: US Non Exp Data Entry

General Patient Products Events Analysis Activities Additional Information Regulatory Reports

Regulatory Reports Organized by Report Type / Submit Category / Reporting Destination

Reports (1)

- Expedited (1)
 - Pending (1) by Destination
 - Submitted (0) by Destination
 - Marked as Non Submit (0) by Destination
- Periodic (0)

Total Number of Rows (1)

Status	Destination	License Type	Generated	Submitted	Due	Responsible
Draft	EMEA - XML	Marketed	30-JUN-2009 17:16		05-JUL-2009	

Initial Final E2B 2002 N Manual: (UNITED STATES (Marketed Drug) 2002)

Auto Schedule Schedule New Report Auto Schedule Later

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

Schedule New Expedited Report -- Webpage Dialog

New Expedited Report

Report Information

Product Somborin(Somobrin) Tablet 200 mg - Headache

License # UNITED STATES (Investigational Drug) 2001

Destination FRANCE (Marketed Drug) 2005
GERMANY (Marketed Drug) 2004
IRELAND (Investigational Drug) 2006
JAPAN (Marketed Drug) 2002
UNITED STATES (Investigational Drug) 2001

Report Form

Aware Date

Protect Confidentiality of Reporter and Patient

Blind Study Product

Group Administrators

Notes Manual: Somborin(Somobrin) Tablet 200 mg - Headache (UNITED STATES)

Cover Letter

Due Date

In 5 Days In Days

In 15 Days On

In 30 Days

OK Cancel

New Expedited Report Dialogue 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 Dialogue box.

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

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

Nullification Reports

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

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

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

Updated E2B Items	Update Content
J.7	System will remove the value of this tag, if it was present in the previous report.

- When you accept a Nullification report, the system creates an Action Item in the case. The action item tells you that the system will delete the case if you click OK on the acceptance Dialogue 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 Dialogue to enable you to open the archived case.
- After you reopen the case, the system displays the Accept Nullification E2B Dialogue.
- 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.

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 ufimporterreportnumber(F2) or mfrreportnumber (G9).
3. Follow-up number that is populated in (F7 ufollowupnumber or G7 gfollowupnumber) shall be incremented from (F7 or G7) 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 G9) 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 G9) from the previously submitted eMDR report in the F2 or G9 of MedWatch Device report.
3. Follow-up number that is populated in (F7 or G7) is incremented from (F7 ufollowupnumber or G7 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 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 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

Generating Reports

Use the following procedure to generate a scheduled report.

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

Attachments in Reports

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

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

Case Form Attachments are embedded within the ICSR that are sent in report format such as E2B(R3), eVAERS and eMDR. Attachments are encoded in B64 format and sent in the report, selection of attachments are based on Reporting Destination configuration. Attachments for E2B(R3) are compressed before embedding to ICSR using compression algorithm configured. Default algorithm used in DF(Deflate). Attachments are not compressed in eVAERS and eMDR reports

Transmitting Reports

Transmitting ICSR Reports

Argus Safety 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 and ICSR Transmit Status, ICSR Receive Status and Bulk ICSR transmit screen to track the report submissions and acknowledgement.

Transmitting Bulk Reports by Form

Use the following procedure to transmit Bulk Reports by Form:

1. Click Reports ->Bulk Reporting.

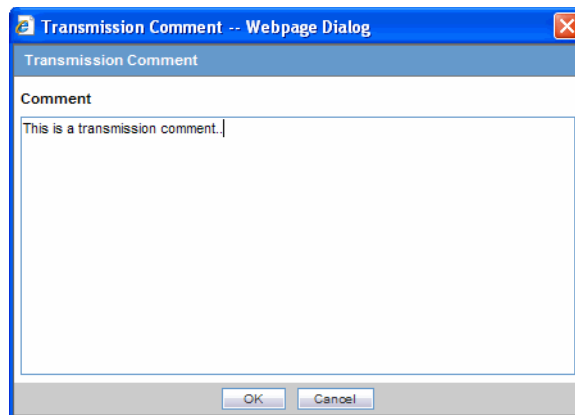
The screenshot shows the Oracle Argus Safety Web interface for Bulk Reporting. The top navigation bar includes 'Active Cases', 'Worklist', 'Case Actions', 'Reports', 'Local Affiliate', 'Utilities', 'Dashboards', 'Argus Console', 'Argus Insight', and 'Argus Perceptive'. The main content area is titled 'BULK REPORTING' and contains a 'Bulk Reporting Filter' section with fields for 'Destination', 'Report Form' (set to E2B), 'Report Status' (Scheduled/Generated), 'Print Regulatory Report' (Transmit), and 'as Final'. Below the filter is a table with the following data:

Selected	Lock State	Case Number	Country of Incidence	Report Type	Suspect Product	Diagnosis	SUIR	Report Form	Destination	Initial / Follow-up (#)	Due Date	Days Past Due	Downgrade
<input type="checkbox"/>	Generated	1004-046	JAPAN	Spontaneous	E2B LaviMar1	Pain (Pain)	Y/Y/Y	E2B	ESM_PMDA	Initial	21-APR-2010	0	No
<input type="checkbox"/>	Approved	1002-011	JAPAN	Sponsored Trial	invic(+)	Pain (Pain)	Y/Y/Y	E2B	ESM_PMDA	Initial	07-FEB-2010	71	No
<input type="checkbox"/>	Generated	E2B_CASE-50	UNITED STATES	Spontaneous	Sombrin	Rash (rash)	Y/Y/Y	E2b	EMEA - XML	Initial	29-JUN-2009	294	No
<input type="checkbox"/>	Scheduled	E2B_CASE-50	UNITED STATES	Spontaneous	Sombrin	Rash (rash)	Y/Y/Y	E2b	MAX Agency Name Begin Details Details De	Initial	29-JUN-2009	294	No

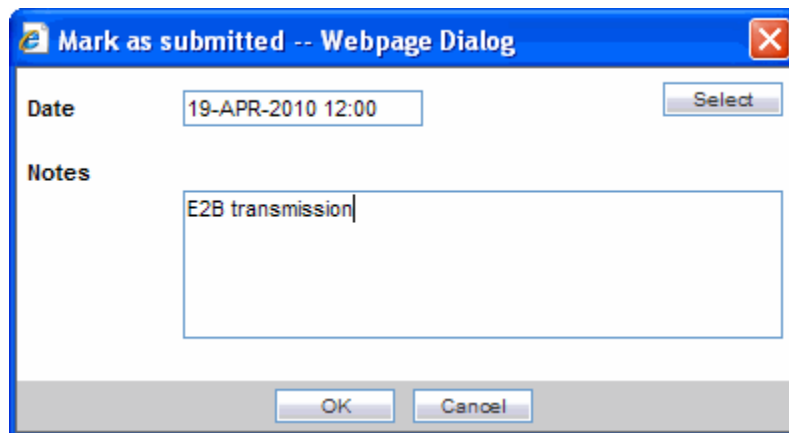
At the bottom of the interface, there are 'Printing Options' including checkboxes for 'Blind Study Product' and 'Mark as Submitted', along with buttons for 'Print Medical Summary', 'Transmit', and 'Print List'.

2. When the system opens the Bulk Reporting Dialogue box, enter the appropriate data in the fields.
3. In the Report Form list, select E2B, eMDR or eVAERS.
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. If Only eMDR or eVAERS are selected, then Mark as Submitted checkbox is disabled.
6. Click OK after all the required items in the Dialogue have been entered. Use the table at the end of this topic to understand the function of each item in the Dialogue.
7. For selection of single report eVAERS or eMDR, Dialogue for entering Transmission comments is not displayed. When Other Expedited reports are

selected along with eMDR or eVAERS, then the Mark as Submitted Dialogue is displayed as shown below:



8. Click OK to transmit the report(s)
OR
Click Cancel to close the Dialogue 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 Dialogue box.
Enter the submission notes in the Notes field and click OK.

Note: eMDR and eVAERS are marked as submitted on receiving successful ACK3(Business Ack) and submission date is updated with the date when the eMDR, eVAERS was submitted to the FDA ESG in ACK1(MDN).

If Successful ACK3(Business Ack) is received and ACK1(MDN) are not received, eMDR is marked as submitted and submission date is updated with ACK3(Business Ack) received date.

If ACK1(MDN) is received after receiving ACK3(Business Ack) and eMDR is already marked as submitted, then the submission date is overwritten with ACK1(MDN) date only if it is earlier than the already populated submission date and Transmission status of ACK1(MDN) is displayed in the Bulk ICSR Transmit.

If ACK1(MDN) is received after marking the report submitted manually than, manually entered submitted date is overwritten by ACK1(MDN)date only if it is earlier than the already populated submission date.

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

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

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

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

Monitoring 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 Dialogue, enter the appropriate data.

The screenshot shows the 'ICSR Transmit Status' dialog box. At the top, there are navigation tabs: Active Cases, Worklist, Case Actions, Reports, Local Affiliate, Utilities, Dashboards, and Argus Console. Below the tabs, the breadcrumb path is 'Utilities > ICSR > ICSR Transmit Status'. The main area is titled 'ICSR Transmit Status' and contains a 'Search Reports' section. This section has a dropdown for 'Agency/Trading Partner' set to 'ALL'. Below this are two search options: 'Transmit Date Range From' (radio button selected) with '01-JUN-2016' in the 'From' field and '01-JAN-2999' in the 'To' field, and 'Message # Range From' (radio button unselected) with empty fields. A 'Range' dropdown is set to 'This Month' and a 'Type' dropdown is set to '(Any)'. A 'Search' button is located to the right of the search criteria. Below the search section, there are controls for 'Total Number of Rows (0)', 'Displaying Rows 1-100', and 'Page Size 100'. The main area is a table with the following columns: Type, Trading Partner, Local Msg #, File Name, EDI Tracking ID, and Transmission Status. The table is currently empty, with a note 'Enter Search Criteria' below the columns. A 'Print' button is located at the bottom right of the dialog.

Type	Trading Partner	Local Msg #	File Name	EDI Tracking ID	Transmission Status
Reports	Control #	Remote Msg #	Transmit to EDI	EDI Transmit Date	EDI Receive Receipt
Enter Search Criteria					

ICSR Transmit Status Fields

The following table lists and describes the fields in the ICSR Transmit Status Dialogue 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 Dialogue appears.

Message Acknowledgement Status -- Webpage Dialog

Message Acknowledgement Status

ICSR Message Number: 205_AS2 Acknowledgment Message #: 214_AS1

ICSR Message Date: 15-JUN-2016 08:14 Acknowledgment Message Date: 15-JUN-2016 02:18:51

ICSR Message Sender ID: PMDA_Sender_81

ICSR Message Receiver ID: PMDA_Receiver_81

Transmission ACK Code: All reports loaded into database.

Report Number	Authority / Company Number	Other Number	Report Status	Report Type
JP-B2B1_PMDA-JP140000000000	JP-B2B1_PMDA-JP140000000000		Report loaded	Initial

Error Message / Comments

Imported Case #: JP00208. 詳細不明: 選択された報告の種類はliteratureのチェックボックスにチェックが入っていますが、文献情報が存在しません。 ; DTD項目MHLWADMICRSENUMCLASSのマッピング/ロジック尚で特定されている製造IDとライセンスIDがデータベース上で一致しません。 ; case_pmda_licenseテーブル内で、一致するPMDAライセンスを見つけ、PMDA IDフィールドをインポートしてください。モジュール: CREATE_CASE_PMDA_LICENSE ; 項目タグ[SENDERDIAGNOSIS (B.5.3b)]のエンコードされた値が未入力です。 隣接 | 症例概要 | 企業による診断 | 症例 | (Analysis Tab - Case Assessment - Company Diagnosis) ; 子のみ値チェックボックスで選択されていませんが、PATIENTONSETAGE (B.1.2.2) が入力されています。 (Patient Tab - Age) ; ワークフロー - ステータスが設定されていません。 症例のルーティングはNEW CASEステータスから最初のワークフロー - ルールを使ってシステムによって自動的に行われます。 ; モジュール: Main_Create_Case ; リスト・メンテナン스에 複数の値が存在します ; テーブル [LM_REPORT_TYPE] ; DTD項目: REPORTTYPE, E2Bコード: 1 ; リスト・メンテナン스에 複数の値が存在します ; テーブル [LM_EVT_OUTCOME] ; DTD項目: REACTIONOUTCOME, E2Bコード: 6 ; Value for SOURCE_ID not found in table LM_CAUSALITY_SOURCE for DTD element DRUGASSESSMENTSOURCE value - 第一次情報源 ; ORA-01403: no data found DRUGASSESSMENTMETHOD ; グローバルイントロスペクション not found in lm_causality_method ; Value for SOURCE_ID not found in table LM_CAUSALITY_SOURCE for DTD element DRUGASSESSMENTSOURCE value - 報告企業 ; ORA-01403: no data found DRUGASSESSMENTMETHOD ; グローバルイントロスペクション not found in lm_causality_method

Print Close

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

Message Acknowledgement Status Dialogue Fields

The following table lists and describes the fields in the Message Acknowledgement Status Dialogue 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."
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.

Monitoring 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 Dialogue box, enter the appropriate data in each field.

ICSR Receive Status Dialogue Fields

The following table lists and describes the fields in the ICSR Receive Status Dialogue 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 Dialogue, enter the appropriate data in each field.

Message Acknowledgement Status Dialogue Fields

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

Item	Description
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."
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

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

The recipient of the ICSR 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 ICSR report is updated with one of the following three status:

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

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

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

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

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

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

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

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

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

Process	Error message	Possible Reason of error
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: 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 >>

- In case 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 >>

- In case of 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 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 Dialogue.

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 the section, Viewing Acknowledgement Information, for viewing the acknowledgement information.

Viewing Status

Argus Safety provides the feature to monitor the transmission status of E2B, eMDR and eVAERS reports.

Use the following procedure to check the status of transmitted E2B, eMDR and eVAERS reports.

1. Select Worklist -> Bulk ICSR Transmit.

The screenshot shows the 'BULK ICSR TRANSMIT' interface. The search criteria section includes filters for Report (eVAERS), Case #, Message Type (ichiscr), and Start/End Dates. The table below displays the following data:

Case Number	Date Created	Date Transmitted	Due Date	Reporting Destination	Status	Message Type	Transmit	EDI In	EDI Out	MDN Rec.	Ack Rec.
20260802	15-Jan-2015	15-Jan-2015	09-Jan-2015	eVAERS_RECEIVER_01 eVAERS_SENDER_01	Submission to Trading Partner ... ichiscr		●	●	●	●	●
AA_003	19-Jan-2015	19-Jan-2015	09-Jan-2015	eVAERS_RECEIVER_01 eVAERS_SENDER_01	Submission to Local EDI Failure ichiscr		●	●	●	●	●
CASE_222	12-Jan-2015	12-Jan-2015	16-Jan-2015	eVAERS_RECEIVER eVAERS_SENDER	Received Invalid MDN Receipt f... ichiscr		●	●	●	●	●
CASE_7	16-Jan-2015	16-Jan-2015	10-Jan-2015	eVAERS_RECEIVER_01 eVAERS_SENDER_01	Submission to Trading Partner ... ichiscr		●	●	●	●	●

2. Select E2B, eMDR or eVAERS report from the Report drop-down list.
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.

Viewing Acknowledgement Information

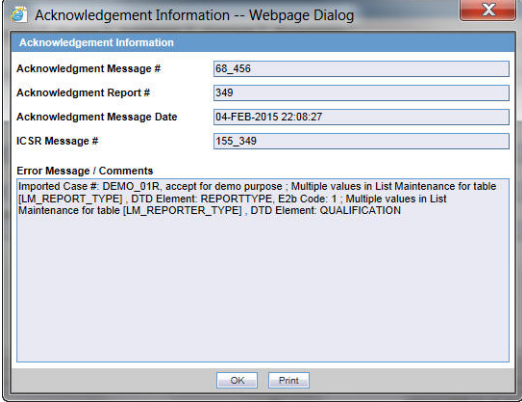
In Argus Safety, you can view detailed acknowledgement information for a report sent to a trading partner or a regulatory authority. Use the following procedure to view acknowledgement information.

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

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

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 Dialogue, 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 Dialogue

When the Acknowledgement Information Dialogue opens:



The screenshot shows a dialog box titled "Acknowledgement Information -- Webpage Dialog". It contains the following fields:

Acknowledgment Message #	68_456
Acknowledgment Report #	349
Acknowledgment Message Date	04-FEB-2015 22:08:27
ICSR Message #	155_349

Below the fields is a section titled "Error Message / Comments" containing the text: "Imported Case #: DEMO_01R, accept for demo purpose : Multiple values in List Maintenance for table [LM_REPORT_TYPE], DTD Element: REPORTTYPE, E2b Code: 1 : Multiple values in List Maintenance for table [LM_REPORTER_TYPE], DTD Element: QUALIFICATION". At the bottom of the dialog are "OK" and "Print" buttons.

Click Print to print the acknowledgement details

OR

Click OK to close the Dialogue box.

Using the ICSR Viewer

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

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

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

- Opening the ICSR Viewer
- Exporting an XML File

Opening the ICSR Viewer

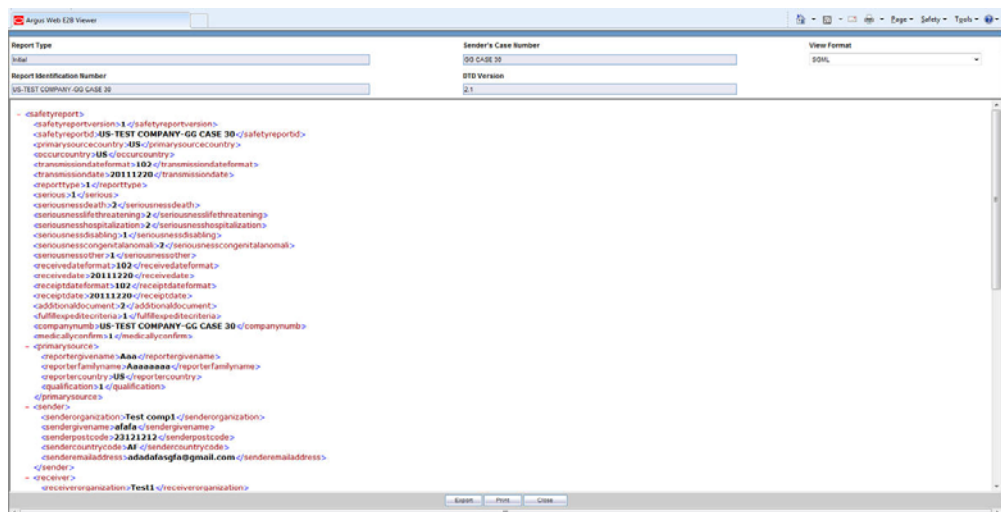
The ICSR Viewer enables you to view your E2B reports in the following views:

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

Exporting an XML File

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

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



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

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

Importing E2B Reports

Incoming E2B Reports

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

This release does not support import of eVAERS.

This section includes discussions on the following:

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

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

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

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

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

Searching for Duplicate Cases

The Duplicate Search Dialogue for E2B report allows you to search for possible duplicate cases in the Argus Safety system. You can select different combinations of

search criteria. When more than one criterion is selected, only cases that satisfy all criteria are listed. By default, only the fields that are present in the E2B Report are checked for the Duplicate Search.

Use the following procedure to perform a duplicate search.

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

Duplicate Search Dialogue Box Fields

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

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

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

Using the View Differences Report

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

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

- The last imported case.

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

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

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

Displaying Differences

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

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

Viewing the E2B Report

Use the following procedure to view the E2B Report:

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

Accepting Single/Multiple E2B Reports

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

1. Select Reports -> ICSR Pending to open the Incoming E2B Report Dialogue box.
2. When the system opens the ICSR Pending screen:
To accept a single report, right-click on it and select Accept E2B
OR
To accept multiple reports, select the check boxes for each report and click Accept E2B.
3. When the system opens the Acceptance of Initial Report Confirmation Dialogue 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 Dialogue appears with the generated case number.
6. Click OK to close this Dialogue.

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

E2B Initial/Follow-up Intake

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

- The Selective Acceptance feature is enabled only for single initial ICSRs and is a right-click option.
- If you select multiple ICSRs, the system disables this button.
- If you select a single follow-up or nullification ICSR, the system disables this button.
- When the system displays the E2B Difference Report Dialogue, 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 Dialogue for initial reports.
- The following changes have been made to the Initial Intake and the Follow-up Difference Report Dialogues:
 - 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 Dialogues.

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

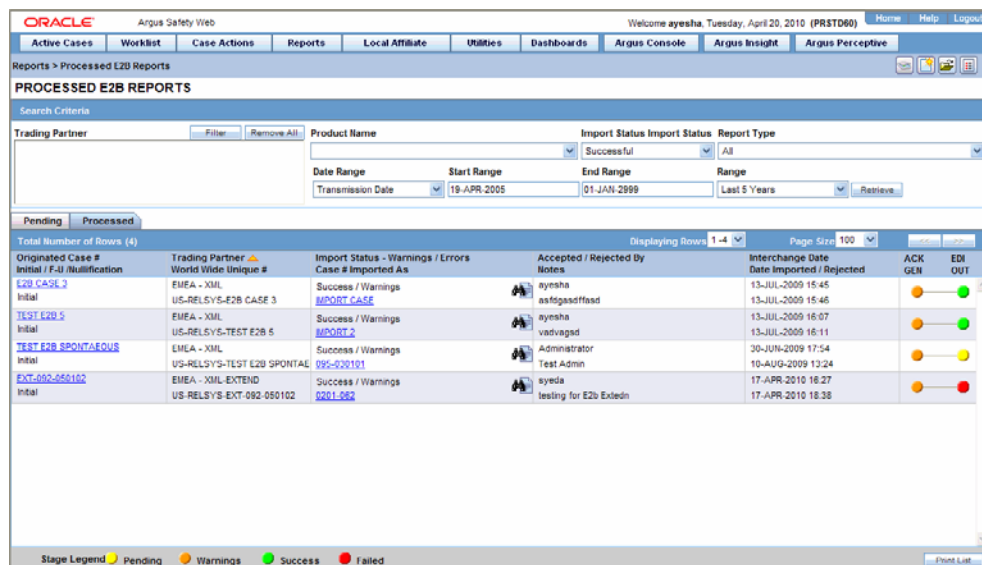
- The system attaches the current notes sent in the Business Level Acknowledgement.
- If the system receives the ICSR via the physical gateway (configured at the reporting destination level), the system sends a low level ACK to indicate the file was received by the Argus Interchange Service.
- The system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

E2B Follow-up Acceptance for Closed/Locked Cases

- If you try to accept follow-up information for a closed or locked case, the system prompts you to unarchive or unlock the case for processing after entering the password and acceptance notes.
- If the case is in archived state while you are accepting the report, the system displays the Case Re-open Dialogue 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 Dialogue 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

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

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.

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