Oracle Argus Interchange

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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.

Where to Find More Information

Oracle Help Center

The latest user documentation for Oracle Health Sciences products is available at http://docs.oracle.com/en/industries/health-sciences/.

My Oracle Support

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About Argus Interchange

Argus Interchange provides pharmaceutical manufacturers with a simple, efficient way to comply with electronic standards for transferring regulatory information through the use of an Electronic Data Interchange (EDI) gateway. It also enables you to view E2B reports in different formats, such as I-SGML, J-SGML, I-Decoded View, J-Decoded View, and PMDA Report Form. These reports can be submitted to trading partners or to regulatory authorities.

Argus Interchange Process Overview

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



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

Task	Description
Logging on	Explains how to log on to Argus Safety.
Schedule E2B Report	Explains how to schedule an E2B Report for a case using the New Expedited Report dialog.
View E2B Report	Explains how to view a scheduled E2B Report in the E2B 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 Statuses	Explains how to view and understand the status of a transmitted E2B report.
View Acknowledgement	Explains how to view the detailed acknowledgement information from a trading partner or a regulatory authority.

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



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

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

Configuring Argus Interchange

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



Argus Interchange Mapping Utility

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

- Configuring the Argus Interchange Service
- Adding a Database for Argus Interchange Service

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

Configuring the 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 the ESM Mapping tool. This opens the Service INI Set up dialog box.
- **2.** Use the items in the Service INI File Setup dialog to configure the Argus Interchange Service INI file.
- 3. Enter the data for each field as required.

EMAIL Section			EDI Section		
IT Email	1		EDI Gateway	Axway Cyclone	
Business Email	1		EDI Database Name	CYCLONE	
Jser Email	!			Terresona.	
Sender Email	ms exchange setti	ngs	EDI User ID	cyclone	
Note: Use I sign in th emails	e email fields if you	do not want to send	EDI Password	******	
DTD/LOG			1		
DTD Path Enter Full Path	C:\Program Files (x	(86)\Oracle\Argus\Interch	nangeService\DTDFiles		
Log File Path Enter Full Path	C:\Program Files (x	86)\Oracle\Argus\Interch	nangeService		
Multiple Database S	ection				
Database	User Name	Elapse Time	EDI Tx Time Out	Media Tx Time Out	XML Tx Time Out
Database Add New Process AS81CS	User Name ESM_LOGIN	Elapse Time	EDI Tx Time Out	Media Tx Time Out	XML Tx Time Out
Database Mada New Process ✓ AS81CS	User Name ESM_LOGIN	Elapse Time 1 Min.	EDITx Time Out	Media Tx Time Out	XML Tx Time Out 10 Min.

Service INI File Setup Dialog Box

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

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

Adding a Database for Argus Interchange Service

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

To configure a database:

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

Database Name	AS81CS	Unique Database ID	A2C	
Jser ID	ESM_LOGIN	Password	******	
Process	C:\Program Files (x	86)\Oracle\Argus\Interchange	Service\EsmProc.e>	Browse
Receive Process	C:\Program Files (x)	86)\Oracle\Argus\Interchange	Service\E2BReceive	Browse
Archive Folder	C:\ESM_IN_OUT\An	chive		
Receive Processes	1	Process Elapse Tim	ie 1	Minutes
Receive ACK Time Out value (ACK is due for transmitted reports)			Minutes	
Processing Time Out value (E2B Report not Processed by User) 10			Minutes	
XML Transmit Time Out value (File is not picked up by Gateway) 10			Minutes	
Binary Transmit Time	Outvalue (File is not pi	icked up by Gateway)	10	Minutes
MDN Time Out Value (For E2B Reports which	have received Bus ACK)	24	Hours

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

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

Service DB Setup Fields

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

ltem	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.

Item	Description
Receive Processes	Enables you to specify multiple E2B receive processes
Count	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.

E2B

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 system maps 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
reactionhospstartdateforma t_extension	Argus Date entry format YYYYMMDD or YYYYMM or YYYY	Hospitalized Start Date Format
reactionhospstartdate_ extension	EVENTS Hospitalized Start Date	Hospitalized Start Date
reactionhospstopdateforma t_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 if the message import is successful and a rejection if the message import is not successful.

You can view the extended elements for the following:

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



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

E2B Codes Translation

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

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

E2B Codes Tran	Common	J	-				X
# DT	D Element Name	Input Value	Output Value			Edit	
DTD Element De	scription						
		Add New	Save	P	int List	Close	

E2B Codes Translation Fields

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

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

Configuring E2B Codes Translation

Use the following procedure to configure E2B Codes Translation.

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

à.		DTD Element Name	Input Value	Output Value	Edit
	2	DRUGRESULT	Possible	Unassessible	Edit
3	3	SPONSORSTUDYNUMB	D0X001	CURE ALL CH 001	Edit
3	4	DRUGRESULT	Almost Certain	Begin Causa_END	Edit
3	5	PARENTSEX	1	Male	Edit
3	6	OBSERVESTUDYTYPE	1	Clinical Trial	Edit
3	7	QUALIFICATION	5	Consumer	Edit
3	8	REPORTTYPE	2	Post Marketing Surv.	Edk
3	9	DRUGSTRUCTUREDOSAGEUNIT	3	mg	Edit
3	10	REACTIONOUTCOME	4	Lasting Damage	Edit
3	11	REACTIONOUTCOME	2	Improved	Edit
3	12	QUALIFICATION	3	Nurse	Edit
3	13	DRUGSTRUCTUREDOSAGEUNIT	7	mg/kg	Edit
3	14	REPORTTYPE	3	Regulatory Authority	Edit
1	15	DRUGRESULT	Not Definite	Definite not	Edit

3. Click Save to save your changes.

Web Console

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

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.

ode Lists	Business Configuration	Access Management	System Configuratio	n Tools							
E LIST MAIN	TENANCE										
ser		Reporting Destination Filt	er								
ized by Code	liet v	Field			Va	lue					
			-	Contains	•				97		
- 🔁 Lab Result	Assessment Terms	Platinum FDA		Regulatory Authority	Platinum	Department	00.3-02			949-453-1817	
Lab Test G	Ronb	RECEIVER		Pharmacer fical Company	P IOLE KATI	peparanent	003-02	Manufactur		949-453-1817	15
	ype	RECEIVER 1		Pharmaceutical Company			DG 3 -D2	Manufactur	,	949-453-1817	15
Letter Con	figuration	SENDER-BINARY	SENDER-Binary-J	Pharmaceutical Company	OPD		SENDER Reg			949-453-1817	
Literary Cit	tation										Agency Cover adf
Local Eval	uator Comment Type										df asdfa sdfasdfas
Manufactu	rers										asdf*8(*8%/\$#/%\$
Medical St	atus	Sender-Janan	医薬品および医療機器	Reculatory Authority	Agency_ 34123413	dept_asdfasdf2 2341a8///8/48/4	Agency reg			Agency_fax_ajsdf	~%\$\$5%~5%~6% ^#2^#20L#20L#20L#20L
🔁 Message 1	Гуре	Server response	代理店(PMDA)	roganica y manority	@#\$asdf	asdf>_end	Agency_reg			_end	^*8% **8 *% akjahsg
Nature of 8	Event				-	-					askdjfgasdf546546
Occupation	ns										1121321321321321
— 🚞 Package U	hts						1			0	or ena
- Cal Product Gr	roup								Acanew	Copy	Zelete I Phi
Project ID		Modify Reporting Destina									
Reference	Type	Agency Information	Local Company Contact	EDI	S	MTP					
	dia 👘										
- Cal Report Typ		Y Agency Name				Preterred Me	thod		Contact Type		
	nformation	pender-Japan				Email	ander on DMDA Da	· or Deporto	Manufacture	r	
	уре	F Agency Harrie (3) 国家県たと73国際機能	(HTTP://DMDs)			Include PAA H	leader on FMDA Faj	bei Reports	E		
Reporting	Destination	Agency Type				Registration	v		Importer		
- Carl Reporting	Destination Type	Registery Authority				Agency reg	•		Distributor		
Routes of	Administration	Department			_	FAX					
Study Cerl	ter	Agency dept asdfasdf2341	23412341a8/1*8/*8/10#\$asdf	asdf> end		Agency fax a	isdf end				
Study Dev	elopment Phase	W Email Address				EAV Count					
User Sites	•	Agency email aksidefiasidf	ter hred/this/dh/dhead net			AGEOCY COVER	add to applie applies	Hardfardardfard	F		
Text		region or y _on old _on openhological	na java majava m <u>a</u> letita het				Tage to acquigence of	102010208501050	i omine Recipi	ient	
rees beins in ca	schuring Reporting										
		Contact information									

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

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

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

Code Lists Business Configuration	Access Management	System Configuratio	n Tools					
DE LIST MAINTENANCE								
owser	Reporting Destination Fill							
ganized by Code List 💌	Field			Value				
I ab Result Assessment Terms	11	•	Contains	-		mEiBAEm		
lab Test Group	Platinum_FDA		Regulatory Authority	Platinum_Department	DG 3 -D2		949-453-1817	
lab Test Orosp	RECEIVER		Pharmaceutical Company		DG 3 -D2	Manufacture	949-453-1817	15
Lattar Configuration	RECEIVER_1		Pharmaceutical Company		DG 3 -D2	Manufacture	949-453-1817	15
Celler Comparation	SENDER-BINARY	SENDER-Binary-J	Pharmaceutical Company	OPD	SENDER Reg		949-453-1817	
Local Evaluator Comment Type Manufacturers								Agency_Cover_adf fs df asdfa sdfasdfasdas asdf3/18/18/18/18/18/18/18/18/18/18/18/18/18/
Martical Status				Agency_dept_asdfasdf2	2		Annana fan aladi	~%\$8%~8%~(8%~8
Message Type	Sender-Japan	ビ来加めよび医療機器 代理店(PMDA)	Regulatory Authority	thority 34123412341a8*(*8**8*1 Agency_reg	Agency_reg	eg end		~8~8%~8%~8%~8
Nature of Event		11.2.0 (@#\$asdfasdf>_end				**&%**&*%akjahogdk
Cocumations								112132132132132132132
Deckare Lints								df end
Death at Group						Add New	Copy	Delete Print
Desired D	Martin David and Davids	et						
- Project in P	Modify Reporting Destina	tion						
Deference Tune		1						
Reference Type	Agency Information	Local Company Contact	EDI	SMTP				
Reference Type Report Media Report Media	Agency Information	Local Company Contact	EDI	SMTP				
Reference Type Report Media Report Type Report Type	Agency Information	Local Company Contact	EDI	SMTP				
Reference Type Report Media Report Type Report Type Reporter Information	Agency Information	Local Company Contact	EDI	SMTP	Code Qualifi	ler .		
Report Media Report Media Report Type Report Type Reporter Information Reporter Type	Agency Information © SGML © XML Agency Information © Agency Identifier SEPUREPENDA	Local Company Contact	EDI	SMTP	Code Qualifi	ier		
Report Notis Report Notis Report Type Report Information Reporter Type	Agency Information Good SGML SGML Agency Information Agency Identifier SENDERPMDA Message Profile	Local Company Contact	EDI Identification Code SENDERPMDA	SMTP	Code Qualifi	ler		
Report Neda Report Yype Report Yype Reporter Information Reporter Type Reporting Destination Reporting Destin	Agency Information G SGML C XML Agency Information Agency Information Agency Identifier SENDERPMDA Message Profile IDH/SSRAGE T	Local Company Contact	EDI Identification Code SENDERPMDA	SMTP	Code Qualifi	ier	⊂ Mark as Auto	Submit
Reference Type Report Media Report Media Reportsr Information Reporter Information Reporter Type Reporting Destination Reporting Destination Report Type Reporting Destination Report Type	Agency Information G SGML C XML Agency Information Agency Information SENDERMOA Message Profile ICH-ICSR V2.1 MESSAGE T Message Profile 2	Local Company Contact	EDI Identification Code SENDERPMDA	SMTP	Code Qualifi 12 Transmit E2B Attacl	ier hments	🗆 Mark as Auto	Submit
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EDI Tab Fields

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

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

Field	Purpose
SGML/XML	Enables you to select whether to send the report in SGML or XML format.

Field	Purpose
Mark as Auto Submit	Enables you to mark the report for auto submission.
Imported Cases are assigned to	Enables you to select the country where imported cases need to be assigned.
	Note: This list contains the configured Argus sites. The default value is the site of the importing user.
Initial Workflow State	Enables you to configure the initial workflow state for the case.
	Note: This list contains Argus workflow states. The default value is blank. If you select blank as the workflow state, the system treats the case as a new case being booked-in.
Agency Identifier	Enables you to enter the routing ID configured in Cyclone for the sender community.
Identification Code	Enables you to enter the agency Duns code, a unique code that identifies a trading partner.
Code Qualifier	Enables you to enter the code qualifier. The system uses the code qualifier to interpret the identification code.
XML Source Classification	Defines the E2B source file classification during the E2B import. The system populates this drop-down from the Attachment Classification code list.
Selection Source Classification	Defines the classification of the PDF for initial intake or the difference report during E2B import. The system populates this drop-down from the Attachment Classification code list.
Message Profile	Enables you to select a message profile.
Message Profile 2	Enables you to select a message profile for J elements. This profile is enabled for J users.
ACK Profile	Enables you to select the acknowledgement profile.
Primary Receive Agency	Indicates that this is the primary agency receiving E2B reports.
Auto Accept ICSR's	Enables or disables the auto-accept E2Bs for the agency.
Transmit E2B Attachments	Enables or disables transmission of E2B attachments for the agency.
Use Japanese Aware Date for Reporting	Check this checkbox to use Japanese Aware Date for reporting.
Allow multiple reports for Marketed Drugs	Check this checkbox to allow multiple reports for Marketed Drugs.
Allow multiple reports for Investigational Drugs	Check this checkbox to allow multiple reports for Investigational Drugs.
Identification Code	Enables you to enter the company Duns code, a unique code that identifies a trading partner.
Company Identifier	Enables you to enter the company identifier.
Code Qualifier	Enables you to enter the code qualifier. The code qualifier is used to interpret the identification code.
File Name	Enables you to enter the file name
SGML Declaration File	Enables you to enter the SGML Declaration File.
Maximum # of reports to include in the msg	Enables you to enter the maximum number of reports that will be transmitted in one message.
Method	Enables you to select a method. This field contains E2B-EDI Gateway, E2B Physical Media, and E2B-XML Transmission values.

Field	Purpose
EDI Header Required	Enables you to generate the required EDI Header.
XML Version	Enables you to enter the XML Version.
URL of Message DTD	Enables you to enter the path where the message DTD resides on the Internet or to enter the full path, if it is located on the disk.
Encoding	Enables you to select the character set encoding used in XML
Use Japanese Aware Date for Reporting	Enables you to ensure that reporting is based on the Japanese Aware Date. If this checkbox is not checked, reporting is based on the English Aware Date.
Allow multiple reports for Marketed Drugs	Checking this checkbox allows the system to schedule multiple reports for marketed drugs.
Allow multiple reports for Investigational Drugs	Checking this checkbox allows the system to schedule multiple reports for investigational drugs.
URL of ACK DTD	Enables you to enter the path where the ACK DTD resides on the Internet or enter the full path, if it is located on the disk.

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

Configuring SMTP

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

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

To configure SMTP:

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

System Configuration	: SMTP Configuration Webpage Dialog	×
SMTP Configuration		
Enable SMTP?		
Server IP or Name	internal-mail-router.oracle.com	
Port	25	
Authentication	No Authentication	*
SMTP UserName		
SMTP Password		
Custom SMTP Header	Confidential : Please Treat this as confidential	
	OK Cancel	

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

SMTP Configuration Dialog Box Fields

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

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

Configuring Code List Items

Argus Safety is currently shipped with E2B Codes for the applicable factory data items. If you enter new items, E2B codes must be derived from ICH guidelines and entered as described here.

Note: From Argus Console, click Code Lists -> Argus to open the Code List Maintenance screen.

Configuring an Action Taken

Use the following procedure to configure action taken:

- 1. From the Argus Console, select Code Lists -> Argus -> Action Taken.
- **2.** When the system opens the Code List Maintenance screen, click Action Taken in the Code List in the left pane.
- **3.** The system puts the corresponding data for the selected item in the right pane.

ORACLE						Welcome Aditi Agga	rwal Jap, Tuesday	August 6, 2013 (PR)	03CER-DEFAULT)	Home Help Close
Code Lists	Business Configuration	Access Management	System Configuration	Tools						
CODE LIST MAIN	TENANCE									
Browser		Action Taken Filter								
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- 🔁 Anatomical	Locations	Dose Decreased			減量			2	Yes	
— Attachmeni	t Classification	Dose Increased			增量			3	Yes	
- Cal Attachment	Keywords	No Change			変更無し			4	Yes	
- 🔁 Autosignal		Non-Drug Therapy			非業物療法			5	Yes	
- Datch Repr	orts	Unknown			不明			5	Yes	
- 🗀 Birth Type		Withdrawn			投与停止			1	Yes	
- Case Class	ification									
- Causality C	ategory									
- Causality S	ource									
- Clinical Ref	erence Type									
- Condition T	ype									
Contact Ty	pe									
_ Countries										
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- Delivery Ty	pes									
- Device Pre	iminary Comments									
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appear in the Action Ta	ken drop-down list, in the				13					
Case Form > Product to	ib > Product Details									Save

- **4.** Click Add New and enter the E2B code for the new action in the Add New Action Taken section.
- 5. Click Save.

Configuring Age Groups

Use the following procedure to configure age groups:

- 1. From the Argus Console, select Code Lists -> Argus -> Age Groups.
- **2.** When the system opens the Code List Maintenance screen, locate and click Age Groups in the Code List in the left pane.
- **3.** The system places the corresponding data for the selected item in the right pane.

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- 🗀 Autosigns	is 👘	Child	小児	2	13	3	Yes
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- 🧀 Birth Type		Neceste	40.76	1	2	2	Yes
- Case Clas	sification	Puberty	WILL PG	12	17	·	Ves
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- Ca Electronic	Transmission Recipient	🔻 Group	😤 Range(years)	A Che	ars) E2B Code		
Help Text				through		Display	
The values entered he	re and marked as "display" will	T Group (J)					
appear in the Patient In	formation Screen, Age Group	L					
drop-down list.							Save.

- **4.** Click Add New and enter the E2B Code for the new age group in the Add New Age Groups section.
- **5.** Click Save.

Configuring Age Units

Use the following procedure to configure age units.

- 1. From the Argus Console, select Code Lists -> Argus -> Age Units.
- **2.** When the system opens the Code List Maintenance screen, click Age Units in the Code List in the left pane.
- **3.** The system places the data for the selected item in the right pane.

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- Attachme	nt Keywords	Decades	年代	0.1	800	Yes
- Autosigne	NS	Hours	8時間	8760	805	Yes
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- 🔁 Birth Type	,	Months	7月	12	802	Yes
- Case Clas	ssification	Second	17	31536000		Yes
- Causality	Category	Trinester	二十期	3		Yes
— Causality	Source	Vieeks	28	52	803	Yes
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- **4.** Click Add New and enter the E2B Code for the new age unit in the Add New Age Units section.
- **5.** Click Save.

Configuring Attachment Classifications

Use the following procedure to configure attachment classifications:

1. From the Argus Console, select Code Lists -> Argus -> Attachment Classification.

- **2.** When the system opens the Code List Maintenance screen, click Attachment Classification in the Code List in the left pane.
- 3. The system places the data for the selected item in the right pane.

								Home Hole Close
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Care Classification			BEJ.	Att cla2独立行政法人	医苯品医度横器総合横	横		
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Causality Source								
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The values entered here and marked as "display" will								
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- **4.** Click Add New and click the E2B Additional Doc check box in the Add New Attachment Classification section.
- 5. Click Save.

Configuring Dosage Units

Use the following procedure to configure dosage units:

- 1. From Argus Console, Code Lists -> Argus -> Dosage Units.
- **2.** When the system opens the Code List Maintenance screen, click Dosage Units in the Code List in the left pane.
- **3.** The system places the data for the selected item in the right pane.

Number Description Access management System Configuration Loss UST MAINTENANCE UST MAINTENANCE Value									
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Use Decision Strategiment Terms ppl us//ill Ves No No Use Test Assessment Terms upls us//ill Ves No No Use Test Assessment Terms upls us//ill Ves	Justifications		bà	μ g	004	Yes	Yes	Yes	
Lace for tops Lace for top Lace for	Lab Result A	ssessment Terms 📃	hight	ug/ul		Yes	No	No	
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Monufacturers V that Name E20 Code v that Name V th	Local Evaluat	tor Comment Type	Add New Dosage Units						
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erfered here and marked as "display" will theme (J)		<u> </u>	7 Unix Harrie		E28 Code	H. a	E	E an an an	
entered here and marked as "display" will			V Holt Margar (B		(r≠ Dosage Unit	💌 Lab Test Unit	™ uisplay	
	entered here	and marked as "display" will	(one name (3)						

- **4.** Select an existing Dosage Unit and enter the new E2B code in the Modify Dosage Units section.
- **5.** Click Save.

Configuring an Event Outcome

Use the following procedure to configure an Event Outcome:

- 1. From the Argus Console, select Code Lists -> Argus -> Event Outcome.
- **2.** When the system opens the Code List Maintenance screen, click Event Outcome in the Code List in the left pane.

ode Liete	Rusiones Configuration	Access Management	System Configuration	Toole				
Jour Lieva	business conligation	Access management	ayatem connguration	Tuois				
E LIST MAIN	ITENANCE							
ser		Event Outcome Filter					((
nized by Code	e List 💌 🗸	Field			Value			
EVEN COU	urrea as consequence or	1	<u>∎</u> c	ontains		_11194/_		
Event Out	tcone	Total Nurobar of Down (15)						
- Etal Outc	one	Total Hamber of Rows (10)						Planta a
— Difference Formulation	n	Event Outcome			Event Outcome (J)		128 Code	Utsplay
		Abortion due to AEAntection			「「青季原/窓米による半宅」	***		Yes
- 📴 Holiday Ca	alendar	Begin Event Outcome Event Outc	ome Event Outcom END		機器に関する情報提供を行っています。端	LINE DE OCCUELTRE	3	Yes
— ingredient:	s	Congenital Anomaly			先天性異常			Yes
— institution		Death due to AEAnfection			有害事象/感染による死亡			Yes
— 🤁 Intermedia	ry	Death not due to AE/Infection			有害事象/感染によらない死亡			Yes
- Cartification	255.	Fatal			死亡		5	Yes
- 🗀 Lab Resu	Assessment Terms	Improved			☆子●云		2	Yes
	Group	Lasting Damage			持続性の損傷		4	Yes
— 🧀 Lab Test 1	Type	Not Reported			未報告		6	Yes
	nfiguration	Recovered			回復		1	Yes
	tation	Recovered with Treatment			治療による回復		1	Yes
- Cal Eval	luator Comment Type	Resolved			回復		1	Yes
🚞 Manufactu	arers .	Resolved/Recovered					1	Yes
- i Medical St	tatus	Unchanged			変化なし		3	Yes
Message	Type	Unknown			不明		6	Yes
Nature of	Event	Worsened			悲化		3	Yes
C Occupatio	ns							
Package L	Inits							
Product G	quor					Add New	Сору	Delete Pr
Project ID		Add New Event Outcome						
Reference	Туре	Aug new Event Outcome						
Con Downed Man	uda 🔍	V Event Outcome				2B Code		_
								Display
alues entered he	re and marked as "display" will	* Event Outcome (J)						

- 3. The system places the data for the selected item in the right pane.
- **4.** Enter the E2B Code for the new event outcome in the Add New Event Outcome section.
- 5. Click Save.

Configuring Gender

Use the following procedure to configure Gender.

- 1. From Argus Console, select Code Lists -> Argus -> Gender.
- **2.** When the system opens the Code List Maintenance screen, click Gender in the Code List in the left pane.

ORACLE			Welcome Aditi Aggarwal Jap,	Tuesday, August 6, 2013 (PR703CER-DE	FAULT) Home Help Close
Code Lists Business Configuration	n Access Management	System Configuration Tools			
CODE LIST MAINTENANCE					
Browser	Gender Filter				
Organized by Code List	Field		Value		
Concent		▼ Contains ▼		Filter	
Gender	·	;			
Calendar	Total Number of Rows (5)				
- Calingredients	Gender A	Gender (J)		E2B Code	Display
🦳 Institution	B gder end	開a1あいうえ	にえお端	2	Yes
🦳 Intermediary	Female	女性		2	Yes
🚞 Justifications	Male	男任		1	Yes
	Other	てい地			Yes
🚞 Lab Test Group	OW	1-41			165
🚞 Lab Test Type					
Letter Configuration					
- Docal Evaluator Comment Type					
- Medical Status					
Cal Message Type					
Nature of Event					
Cocupations					
- Product Group					
Reference Tune					
Report Meria				Add New Copy	Delete
Benort Type					
Reporter Information	Add New Gender				
Page Reporter Tune	• Gender		E2B Code		
Help Text				i⊽ Di	splay
This dialog shall allow the user to enter a new	r Gender (J)				
Gender term					
					Carra

- **3.** The system places the data for the selected item in the right pane.
- 4. Enter the E2B Code for the gender in the Add New Gender section.

5. Click Save.

Configuring Report Type

Use the following procedure to configure Report Type:

- 1. From the Argus Console, select Code Lists -> Argus -> Report Type.
- **2.** When the system opens the Code List Maintenance screen, click Report Type in the Code List in the left pane.

DRACLE				Welco	me Aditi Aggarwal	Jap, Tuesday, August 6, 2013 (PR78	SCER-DEFAULT)	me Help
Code Lists Business Configuration	Access Management	System Configuration T	ools					
E LIST MAINTENANCE								
vser	Report Type Filter							
pined by Code List	Field		٧	alue				
		▼ Contains						
Lab Result Assessment Terms	1.							
Lab Test Group	Totel Humber of Rows (11)							
Lab Test Type				Includes	Includes	Includes Research		
Letter Configuration	Report Type A	Report Type (J)	Abbreviation	Clinical	Literature	Reporting Cases	E2B Code	Display
				Cases	Cases			
Local Evaluator Comment Type	begin Report Type Report END	品医療機器総合機構等	RPT	Yes	Yes	No	3	Yes
Manufacturers	Compassionate Use	例外的使用	Com	Yes	No	No	2	Yes
	Epidemiological Study	Epidemiological Study	EPS	No	No	No	1	Yes
i Message Type	Literature	文獻	LR	No	Yes	No	1	Yes
Nature of Event	Literature Clinical Trial		Lct	Yes	Yes	No		Yes
— Que Constituires	Not Available to Sender	送信者に情報が得られず	NAS	No	No	No	4	Yes
Package Units	Other	その他	Oth	Yes	No	No	3	Yes
Product Group	Post Marketing Surv.	市販後調査	Pos	Yes	No	No	2	Yes
Project ID	Regulatory Authority	規制当局	Reg	No	No	No	3	Yes
Reference Type	Sponsored Trial	支援されている治験	Spo	Yes	No	No	2	Yes
Peport Media	Spontaneous	自発報告	Spo	No	No	No	1	Yes
Report Type								
Reporter Information								
Reporter Type								
a Reporting Destination						Add New	Copy Delete	Pritri
Reporting Destination Type	Add New Report Type							
a Routes of Administration	ная керот турс							
Carl Study Center	P Report Type		bbrewation	E2B Code				
Study Development Phase	-					Display		
User Sites 👻	This type includes cases from I	terature	This type includes cases	from clinical trials		This type includes cases for Rese	earch Reporting	
Text						Considered cases for report type		
the entered here and marked as "Nector" will	Y Report Type (J)					Marketed 💌		
ar in General Screen, Report Type drop down								

- **3.** The system places the data for the selected item in the right pane.
- 4. Enter the E2B code for the new report type in the Add New Report Type section.
- 5. Click Save.

Configuring Reporter Type

Use the following procedure to configure Reporter Type:

- 1. From the Argus Console, select Code Lists -> Argus -> Reporter Type.
- **2.** When the system opens the Code List Maintenance screen, click Reporter Type in the Code List in the left pane.
- **3.** The system places the data for the selected item in the right pane.

Cade List Business Configuration Access Management System Configuration Total DDE List MainTexance		
De LIST MAINTENANCE Verifier Section 2010 Content Type (1) Value Value <th col<="" th=""><th></th></th>	<th></th>	
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Instage Type Non-Media Protessional // #P# & Z(Z = COUED PLB,DB @PT1& 5 Instage Type Nata 4000 0000 0000 0000 0000 0000 0000 0000 0000 0000 0000 0000 0000 0000 0000 0000 0000 00000 0000	Yes	
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Ander Service Ander S	Yes	
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Import Modia Percentari Import Modia Percentaria Import Modia<	Yes	
forgoter from forma in a figure forma in a	Yes	
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Ver Stes		
Text Reporter Type (J)		
values entered here will appear in the General Provide Company Com	av	
Toward of Net own read with a physical strate of the second second second second second second second second se	-	
en. Reporter type's drop-down list.		

- **4.** Enter the E2B Code for the new reporter type in the Add New Reporter Type section.
- **5.** Click Save.

Configuring Routes of Administration

Use the following procedure to configure Routes of Administration:

- 1. From the Argus Console, select Code Lists -> Argus -> Routes of Administration.
- **2.** When the system opens the Code List Maintenance screen, click Routes of Administration in the Code List in the left pane.

ORACLE				Welcome	Aditi Aggarwal Jap, Tuesday, Augus	t 6, 2013 (PR703CER-DEFAULT)	Home Holp C
Code Lists	Business Configuration	Access Management	System Configuration Tools				
DE LIST MAIN	TENANCE						
war		Boutes of Administration Filter					
and have been	114	Field		Value			
anized by Cook	i Litt		▼ Contains	•	mEilterm		
🔁 Lab Resul	t Assessment Terms	<u></u>		_			
🚞 Lab Test 🤇	Group	Total Number of Rows (84)		Displaying Rows 1-5	0 💌 Page Siz	e 50 💌 🔜 🔉	
Lab Test T	lype	Administration Route	Description	Administration Route (.)	Description (.)	F2B Code	Display
- Con	figuration	Auricular	Auricular	耳介	耳介	001	Yes
Cline Literary Cl	tation	hands a deal and	Begin Administration Route Desc				100
Local Eval	luator Comment Type	begin Admik end	ripti END	Mint autrop いうえんの Smi		3	res
🦳 Manufactu	rers	Buccal	Buccal	頬側	頬側	002	Yes
🦳 Medical St	atus	Cerebral	Cerebral	脳	脳		Yes
- Cal Message 1	Type	Conjunctival	Conjunctival	結膜	結膜		Yes
— Description - Description	Event	Costel	Costal	肋骨	助骨		Yes
- Cccupatio	ns	Cutaneous	Cutaneous	皮膚	皮膚	003	Yes
- Deckage U	Inits	Dental	Dental	İ	1	004	Yes
Product G	roup	Drop	Drop For Injection	注射用ドロップ	注射用ドロップ		Yes
Project ID		Endocervical	Endocervical	預管内	預管内	005	Yes
Reference	Type	Endosinusial	Endosinusial	洞内(副鼻腔内)	洞内(副鼻腔内)	006	Yes
Report Me	dia	Endotracheal	Endotracheal	気管内	気管内 (Endo-)	007	Yes
Report Typ	De la	Epidural	Epidural	硬膜外	硬膜外	008	Yes
Beporter I	nformation	Extra-amniotic	Extra-amniotic	羊膜外	羊順外	009	Yes
Reporter 1	lvpe				Ad	Id New Copy I	Print Print
Reporting	Destination	Add New Poutes of Administra	tion				
Reporting	Destination Type		(III)			540.0.4.	
Routes of	AdminEtration	Administration Route		Sh	ort Name	E28 Code	
Carl Shuth Carl	tar. 0						🛛 Display
Study Con	alonment Phase	Description					
Calleer Stee		* Administration Pourte (D					
- Josef Skes	· <u> </u>	Commence addit Robite (J)					
plext		Description (J)					
values entered he	re and marked "Display" will						
ser in the in the Ko sucts tab	ute or warministration list in the	P					
000 0001							

- 3. The system places the data for the selected item in the right pane.
- **4.** Enter the E2B Code for the new route of administration in the Add New Routes of Administration section.
- 5. Click Save.

Configuring a Message Type

Use the following procedure to configure a Message Type:

- 1. From the Argus Console, select Code Lists -> Argus -> Message Type.
- **2.** When the system opens the Code List Maintenance screen, click Message Type in the Code List in the left pane.

JIEACLE						Welcome Aditi Aggarwal Jap, Tuesday, August 6	3, 2013 (PR703CER-DEFAULT)	Home Help
Code Lists Business Configur	ition	Access Management	System Configuratio	n Tools				
DE LIST MAINTENANCE								
		Message Type Filter						
anized by Code List		Field			Value			
Coll als David Association of Taxing]	•	Contains	•	Filter		
Lab Result Assessment Terms								
Lab Test Group		Total Number of Rows (7)						
Lab rest type	- 11	Message Type 📥	De	scription		Expedited / Periodic	Auto Submit	Display
Letter Configuration		backlog				Periodic	No	Yes
Literary Ctation		backlogct				Periodic	No	Yes
 Local Evaluator Comment Type 		begin mes tp end	be	gin MT descrip END		Expedited	Yes	Yes
- Manufacturers	9	ctasr				Periodic	No	Yes
- Cal Medical Status		ichicsr				Expedited	No	Yes
Message Type		mhiwadminitemsicsr				Periodic	No	Yes
— Disture of Event	1	psur				Periodic	No	Yes
— Cocupations								
— Deckage Units								
🔁 Product Group								
- Droject ID								
Reference Type								
— Providence -	- 10 H							
- Carl Report Type								
— Diagnostic Content Information								
- Carl Reporter Type								
Reporter Type Reporting Destination								
Reporter Type Reporting Destination Reporting Destination								
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Reporter Type Reporting Destination Reporting Destination Reporting Destination Type Routes of Administration Study Center Study Destinement Phase						Add	New Copy	Peleter Print
Reporter Type Reporting Destination Reporting Destination Reporting Destination Type Routes of Administration Study Center Study Development Phase Lines State						Add	New Copy 1	Delete:][Print
Reporter Type Reporting Destination Reporting Destination Reporting Destination Study Center Study Center Study Development Phase User Sites	-	Add New Message Type				AM	New Copy 1	Doleto.
Reporter Type Reporting Destination Reporting Destination Routes of Administration Study Development Phase User Sites	-	Add New Message Type Y Message Type		Description		Expedited	New [Copy]]C	ooleto

- **3.** The system places the data for the selected item in the right pane.
- **4.** Enter the new message type and other relevant data in the Modify Message Type section.
- 5. Click Save.

E2B Length Check

When you select E2B Length Check, the system generates a report that prints the code list item length check and M2 validation warnings. This menu item has been added under Argus Console -> Tools -> E2B Length Check.

1.	Maintenance ICH-ICSR V2.1 MESSAGE TEMPLATE
2.	ICH-ICSR V2.1 MESSAGE TEMPLATE - EMEA
3.	ICH-ICSR V2.1 MESSAGE TEMPLATE - EMEA EXTEND
4.	ICH-ICSR V2.1 MESSAGE TEMPLATE - FDA
_	Data I I I I
Vall	dation Type Element DTD Element Case Form Field Actual Error Message Profiles LM Data

The following table lists the Code List items the length check is run on.

Data Element	LM Field	Argus Field Length	DTD Allowed Length
A.2.1.1d	LM / Clinical Studies / Study Information / Study Description.	2000	100
	The application needs to consider the EUDRA-CT length (35) while displaying the message.		
A.3.1.3b	LM / Regulatory Authorities / Local Company Contact / Title	40	10
A.3.1.4a	LM / Regulatory Authorities / Local Company Contact / Address	120	100
A.3.1.4f	LM / Regulatory Authorities / Local Company Contact / Phone	20	10
A.3.1.4g	LM / Regulatory Authorities / Local Company Contact / Phone / Ext.	10	5
A.3.1.4i	LM / Regulatory Authorities / Local Company Contact / Fax	50	10
A.3.1.4j	LM / Regulatory Authorities / Local Company Contact / Fax / Ext.	10	5
A.3.2.2c	LM / Regulatory Authorities / Agency Information / Contact Information / Title	40	10
A.3.2.2f	LM / Regulatory Authorities / Agency Information / Contact Information / Last Name	40	35
A.3.2.3a	LM / Regulatory Authorities / Agency Information / Contact Information / Address	120	100
A.3.2.3f	LM / Regulatory Authorities / Agency Information / Contact Information / Phone	20	10
A.3.2.3g	LM / Regulatory Authorities / Agency Information / Contact Information / Phone / Ext.	10	5
A.3.2.3i	LM / Regulatory Authorities / Agency Information / Contact Information / Fax	50	10
A.3.2.3j	LM / Regulatory Authorities / Agency Information / Contact Information / Fax / Ext.	10	5
A.2.1.2c	LM / Reporter Information / Address	120	100
B.4.k.2.2	LM / Products / Key Ingredient	120	100
B.4.k.4.1	LM / Licenses / License Information / Number	40	35

E2B Code Validation

The following table lists the E2B Code Validation items.

Tag Name	DTD Element	Case Form Field	LM Field
primarysourcecountry	A.1.1	Case Form / General / Reporter Information / Country	LM / Countries / Code (A2)
occurcountry	A.1.2	Case Form / General / General Information / Country	LM / Countries / Code (A2)

Tag Name	DTD Element	Case Form Field	LM Field
reporttype	A.1.4	Case Form / General Information / Report Type	LM / Report Type / E2B Code
reportercountry	A.2.1.3	Case Form / General / Reporter Information / Country	LM / Countries / Code (A2)
qualification	A.2.1.4	Case Form / General / Reporter Information / Reporter Type	LM / Reporter Type / E2B Code
observestudytype	A.2.3.3	Case Form / General / Study Information / Observe Study Type	LM / Case Classification / E2B Code
sendertype	A.3.1.1	LM / Regulatory Authorities / Local Company Contact / Sender Type	LM / Regulatory Authorities / Local Company Contact / Sender Type
sendercountrycode	A.3.1.4e	LM / Regulatory Authorities / Local Company Contact / Country	LM / Countries / Code (A2)
receivertype	A.3.2.1	LM / Regulatory Authorities / Agency Information / Agency Type	LM / Regulatory Authorities / Agency Information / Agency Type
receivercountrycode	A.3.2.3e	LM / Regulatory Authorities / Agency Information / Contact Information / Country	LM / Countries / Code (A2)
patientonsetageunit	B.1.2.2b	Case Form / Patient / Patient Information / Age Units	LM / Age Units / E2B Code
patientagegroup	B.1.2.3	Case Form / Patient / Patient Information / Age Group	LM / Age Group / E2B Code
patientsex	B.1.5	Case Form / Patient / Patient Information / Gender	LM / Gender / E2B Code
parentageunit	B.1.10.2.2b	Case Form / Patient / Parent / Age Unit	LM / Age Units / E2B Code
parentsex	B.1.10.6	Case Form / Patient / Parent / Gender	LM / Gender / E2B Code
reactionoutcome	B.2.i.8	Case Form / Events / Event Information / Outcome of Event	LM / Event Outcome / E2B Code
testunit	B.3.1e	Case Form / Patient / Lab Data / Lab Data / Units	LM / Dossage Units / E2B Code
obtaindrugcountry	B.4.k.2.3	Case Form / Products / Product Information / Obtain Drug Country	LM / Countries / Code (A2)
drugauthorizationcount ry	B.4.k.4.2	LM / Licenses / License Information / Country	LM / Countries / Code (A2)

Tag Name	DTD Element	Case Form Field	LM Field
drugstructuredosageuni t	B.4.k.5.2	Case Form / Products / Dosage Regimens / Dose Units	LM / Dosage Unit / E2B Code
drugcumulativedosage unit	B.4.k.5.7	Case Form / Products / Total Dose to Primary Event	LM / Dosage Unit / E2B Code
drugadministrationrout e	B.4.k.8	Case Form / Products / Dosage Regimens / Patient Route of Administration	LM / Routes of Administration / E2B Code
drugparadministration	B.4.k.9	Case Form / Products / Dosage Regimens / Parent Route of Administration	LM / Routes of Administration / E2B Code
drugintervaldosagedefi nition	B.4.k.5.5	LM / Dosage Frequency / Unit	LM / Dosage Frequency / Unit
actiondrug	B.4.k.16	Case Form / Products / Product Details / Action Taken	LM / Action Taken / E2B Code
mhlwadmicsrcasenumcl ass	J.4a	Case Form / Analysis / PMDA / General / Report Category	LM / Reporting Category / E2B Code
mhlwadmicsrnewdrugc lass	J.8	Case Form / Analysis / PMDA / Comments / Category of the new drug	LM / License Category / E2B Code
mhlwphaseofstudies	J.12.i.2	Business Configuration / Studies / Study Development Phase	LM / Study Development Phase / E2B Code

3 E2B Check

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

Why perform an E2B Check

You can run an E2b check by clicking the E2B icon from the Quick Launch menu shown below.



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

Running an E2b check validates if the E2b report has all these mandatory elements present that is required for its successful processing.

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

The following illustration shows a sample E2b check report that is generated in PDF format:

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	10440581011	ARCINGE TEN	ADLATE FAREA				
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	POHICOR V2.11	ACCORDENCE TEN					
· •.	ICHICOR V2.11	ACCOVER LEN	APDATE - PAQUA - I				
Va	lidation Type	Data	DTD Element	Case Form Field	Actual Error Message	Profiles	LM Data
0	her Validation	A.1.2	OCCURCOUNTRY	10円フォーム/一般/一般情 数/発展図	Invalid E28 Code - GG	4	GUERNISEY
		A.1.2	OCCURCOUNTRY	北例フォーム/一般/一般情 報/発報図	Invalid E2B Code - RS	4	SERDIA
		A12	OCCURCOUNTRY	12例フォーム/一般/一般情 報/発税図	Invalid E2B Code - JE	4	JERSEY
		A12	OCCURCOUNTRY	応用フォーム/一般/一般情 報/発用図	Invalid E28 Code - TL	4	TIMOR-LESTE
		A.1.2	OCCURCOUNTRY	応用フォーム/一般/一般情 報/発用図	Invalid E2B Code - MF	4	SAINT MARTIN
		A.1.2	OCCURCOUNTRY	症例フォーム/一般/一般情 教/発展調	Invalid E2B Code - EU	4	EUROPEAN UNION
			OCCURCOUNTRY	1	Invalid E2B Code - EU	1, 2, 3	EUROPEAN UNION
		A.1.2	22220000000000000000000000000000000000	shifters and a second second			SAINT BARTHE-
		A.1.2	OCCURCOUNTRY	N/RNN	Invalid E28 Code - BL	•	LEMD.
		A12 A12 A12	OCCURCOUNTRY	10月27-5/一枚/一枚日 税/発用因 10月21-5/一枚/一枚日 税/発用因	Invalid E28 Code - BL Invalid E28 Code - ME	4	MONTENEGRO

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

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

The validation checks are profile-dependent but every E2b check report tests for Mandatory Elements check and Mandatory Optional Elements check.

ICSR Validation

This report has 5 main sections:

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

Transmitting and Monitoring E2B Reports

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

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

Logging In and Out of Argus Safety

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

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

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

- The Date/Time format is DD-MMM-YYYY HH:MM:SS to reflect the 24-hour format used by the Web server.
- When you click the name of an enabled/disabled module, the system opens the an Oracle Web site page in a new Internet Explorer window to enable you to access product information:

http://www.oracle.com/us/industries/health-sciences/resources
/overview/index.htm#Datasheets

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: Available modules appear in bold text on the log-in screen. Once the system authenticates your log-in information, you will be able to access these modules. 3. Select the appropriate database from the Database drop-down list and click Login.

Note: If you get an error message such "Unable to connect to the database," you may not have permission to access the database. Please contact your database administrator for assistance.

	Argus	Safety
	Username	
10/0393		
	Password	
14 1 Y 1 1		
E 1	Database	
all the	PR703CER	
2.0	30-JUL-2013 04:26:1]本語。 Login 。
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- Argus Safety	- Argus Analytics	- Empirica Topics
- Argus Safety Japan	- Argus Insight	 Empirica Signal Empirica Shudu
- Argus Interchange	- Argus Dossier	- WebSDM
- Argus Unblinding	- Argus Reconciliation	- Siebel AECM

4. Once the system authenticates your log in, you can access the modules whose names are in Bold text.

To Log Out of the Argus Application

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

Scheduling an E2B Report

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

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

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.

	RACLE	E'	Argus Sat	fety Web					Welcome ayesh	a, Tuesday, Apr	i 20, 2010 (F	PRSTD60) Home	Help Logout
Ac	ctive Case	s	Worklist	Case Actions	Reports	Local Affiliate	Utilities Das	hboards	Argus Console	Argus Insi	ght Ar	gus Perceptive	
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3. When the system opens the New Expedited Report dialog box, enter the relevant information and click OK.

🖉 Schedule New Expedited Re	eport Webpage Dialog	X
New Expedited Report		
Report Information		
Product	Somborin(Somobrin) Tablet 200 mg - Headache	*
License #	UNITED STATES (Investigational Drug) 2001	~
Destination	FRANCE (Marketed Drug) 2005	
Report Form	GERMANY (Marketed Drug) 2004 IRELAND (Investigational Drug) 2006	
Aware Date	JAPAN (Marketed Drug) 2002 UNITED STATES (Investigational Drug) 2001	
	Protect Confidentiality of Reporter and Patient	
	Blind Study Product	
Group	Administrators	*
Notes	Manual: Somborin(Somobrin) Tablet 200 mg - Headache (UNITED ST	ATE
Cover Letter		*
Due Date		
	In 5 Days C In Days Days C In Days C On OO-MMM-0000 In 30 Days	
	OK Cancel	

New Expedited Report Dialog Fields

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

Report Information		New Report	2
Product	AF Licence mkt(AF Product) Tablet	New Report Non-Reportable Follow	uo Ri
License #	JAPAN (Marketed Drug)		
Destination	ESM FOA 1		
Report Form	US FDA MedWatch 3500A Drug		
Aware Date	23-APR-2010		
	 Protect Confidentiality of Rep Blind Study Product 	orter and Patient	
Group	US REPORTING		
Notes	Manual: AF Licence mid(AF Product) 1	Fablet (JAPAN (Marketed D	rug)
Cover Letter	JCTest		
Due Date			
	C in 15 Days C in 15 Days C in 20 Days	Days	

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

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

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

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."

Viewing a Scheduled E2B Report

Use the following procedure to view a scheduled E2B report.

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

The report is generated and can be viewed in the E2B Viewer.

If a validation error occurs during E2B report generation, the validation details are stored in the Report Details dialog.

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

Transmitting E2B Reports

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

Transmitting Bulk Reports by Form

Use the following procedure to transmit Bulk Reports by Form:

1. Click Reports ->Bulk Reporting.

Active Cases Worklist Case Actions Reports Local Attiliate Utilities Dashboards Argus Ensight Argus Perceptive Reports bulk Reporting BULK REPORTING Bulk Reporting Filer Destination Filter Report Form Filter Report Status Print Regulatory Report as Final Image: Status Final Final Final Image: Status Final	ORACLE Argus Safety Web Welcome ayesha, Tuesday, April 20, 2010 (PRSTDB0) Home Helip Logout												
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Total Humber of Rows (5) Displaying Rows 1.5 Page Size 100 Selected I Case Number Suspect Product SURR Report Form Days Past Due Lock State Country of Incidence Diagnosis F / LT Destination Days Past Due Status Report Type (Event Verbatim) 7 15 Initial / Followup (4) Downgrade JaPAI Pain No Estination 0 0 Generated Spontaneous (Pain) 7 1 Initial / Followup (4) 0 JAPAII Pain No Estination 0 0 Generated Spontaneous (Pain) 7 Initial / Followup (3) 0 JAPAII Pain YVY E28 07-EEE300 0 Generated Spontaneous (Pain) 7 Inital / Followup (3) 0 JAPAII Pain YVY E28 21-APAI 7 Abground Spontaneous (Pain) 7 Inital / Followup 7 JAPAII Pain YVY E28 23-UH-2009 Generated Spontaneous (rash) 7 Inital / Followup 24-UH-2009 Generated Generated Generated Spontaneous						(ALL)							*
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- **2.** When the system opens the Bulk Reporting dialog box, enter the appropriate data in the fields.
- **3.** In the Report Form list, select E2B.
- 4. Under Printing Options, select Transmit.
- **5.** Select the Mark as Submitted check box if it is required to mark the report as "submitted" after the transmission is successful.
- **6.** Click OK after all the required items in the dialog have been entered. Use the table at the end of this topic to understand the function of each item in the dialog.
- **7.** When the system opens the Transmission Comments dialog box, enter the notes for transmission.

Transmission Comment Webpage Dialog	X
Transmission Comment	
Comment	
This is a transmission comment.	
OK Cancel	

8. Click OK to transmit the report(s)

OR

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

🙆 Mark as s		
Date	19-APR-2010 12:00	Select
Notes		
	E2B transmission	
	OK Cancel	

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

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

Note:

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

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

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

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

Monitoring E2B Transmit Statuses

Use the following procedure to monitor E2B Transmit Statuses:

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

ORACL	ORACLE: Argus Safety Web Welcome ayesha. Tuesday, April 20, 2010 (PRSTD69) Home Help Legoul																	
Active Ca	ses	Worklist	Cas	se Actions		Reports	Local Affili	ate	Utilities Da	shboards		Argus Console	Argus Insi	ight	Argu	s Perceptive		
Utilities > E2B	illites > E2B > E2B Transmit Status 📃 🗎 📔 🗉																	
E2B Trans	28 Transmit Status																	
Search Repo	Search Reports																	
Agency/Tradi	ing Par	toer		ALL														
Agencymaa	ing rai				_		1 -				0							
• Transmit	t Date I	Range From		01-APR-2010			10 2	0-A	PR-2010	Range		ustom Date Range		×				
C Message	e # Ran	ge From					То			Туре	(4	Any)		*	Seard	h		
Total Numbe	r of Ro	ws (7)										Displaying Rows	1-7 💌		Page Size	. 100 🔽		>>
Туре 📥	Tradi	ng Partner			Lo	ocal Msg #		Fi	le Name			EDI Tracking ID				Transmissio	on Status	
Reports	Cont	rol #			Re	emote Msg #		T	ansmit to EDI			EDI Transmit Date				EDI Receive I	Receipt	
ACK	EMEA	- XML-EXTEND			24	4_007		C	LESM_EXT\OUT\RELSYS00	24_PRSTD60	_20					Failure		~
MSG	DECE	N/FD			15	5_007 8_007		1.	-APR-2010 17.56		סוס					Success		
1	112.02				2	_123		1	3-APR-2010 12:54	10011021021						0000000		
MSG	RECE	IVER			25	5_007		W	10.178.90.198\ESM_IN_OUT		R\R					Success		
🕙 1					6_	_123		1	3-APR-2010 18:06									
MSG	RECE	IVER			20	0_007 123		16	10.178.90.198\ESM_IN_OUT	NOUT\SENDER	R\R					Success		
MSG	RECE	IVER			22	2_007		W	10.178.90.198\ESM_IN_OUT		R\R					Transmit		
🕘 1								1	6-APR-2010 18:26									
MSG	EMEA	- XML-EXTEND			23	3_007		С	ESM_EXT\OUT\RELSYS00	23_PRSTD60	_20					Transmit		
21	DEOF	1 (50)				0.007		1	-APR-2010 16:19							0		
MSG ∰T₄	RECE	IVER			15	9_007 123		1	10.178.90.198\ESM_IN_OUT S-APR-2010 17:11	NOUTISENDER	-					Success		
						-												
																		~
																		Print

E2B Transmit Status Fields

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

Item	Description
Column Headers	Clicking the column header sort the data by that column alternately in a ascending and descending order.
Agency / Trading Partner	Enables you to filter data by selecting the Agency / Trading Partner from the list.
Transmit Date Range From	The search start date.
Transmit Date Range To	The search end date

Item	Description
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.
Туре	Enables you to filter data by selecting the pre-defined Type of Message (MSG, ACK) from the list.
Print	Enables you to print the current view.
Search	Enables you to perform the search.

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

- **1.** Select the appropriate agency or trading partner from the Agency/Trading Partner list.
- **2.** Select the appropriate option, Transmit Date or Message # to search by transmit date or by message number.
- 3. Enter the appropriate search criteria beside the selected option and click Search.
- 4. In the search results, click the appropriate report.
- 5. The Message Acknowledgement Status dialog appears.

🖉 Message Acknowledge	ment Status Webpag	e Dialog					×
Message Acknowledgeme	ent Status						
ICSR Message Number	18_007		Sender Acknowledgement Me	ssage #	2_123		
ICSR Message Date	16-APR-2010 12:24		Acknowledgement Message Ir	itiated	16-APR-20	010 12:16:15	
ICSR Message Sender ID	SENDER						
ICSR Message Receiver ID	RECEIVER						
Transmission ACK Code	All reports loaded into o	database.					
Case Number	Authority Number	Local C	ase Number Other Number	Report	Status	E2B Report Type	
Message							
JP-SENDER-1004-006AA		JP-SEND	DER-1004-006/	Report k	aded	Initial	~
; Multiple values in List Maintena [LM_REPORTER_TYPE] , DTD El	Ince for table [LM_REPORT_T ement: QUALIFICATION, E2b	YPE], DTD E Code: 5	lement: REPORITYPE , E2b Code: 1	; Multiple va	lues in List I	Maintenance for table	
							~
		-	Print Close				

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

Message Acknowledgement Status Dialog Fields

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

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

PMDA ACK Import Logic

E2B (R2) Reports

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

The following scenario is being used to explain the requirement,

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

PMDA E2B (R2) ACK:

• A.1.6 (TRANSMISSIONACKNOWLEDGMENTCODE)

Possible Values as per ICH:

01= All Reports loaded into database

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

03= SGML parsing error, no data extracted

B.1.8 (REPORT ACKNOWLEDGMENTCODE)

Possible Values as per ICH:

01=Report Loaded Successfully

02=Report Not Loaded

B.1.9(ERRORMESSAGECOMMENT)

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

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

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

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

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

E2B (R3) Reports

As per PMDA E2B R3 guidance, the structure for PMDA E2B R3 ACK is similar to that of the ICH E2B R3 ACK. The PMDA E2B R3 Ack is converted to E2B R2 ACK and then imported in application. Hence the same PMDA E2B R2 ACK profile is used for improving the ACK.

The ACK import logic of the PMDA E2B R3 ACK (after downgrade) is similar to that of the PMDA E2B R2 except for the following:

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

XX-YYYYYYYYZZZ

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

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

ZZ: represents the count of successfully loaded initial and follow-up reports for that case and reporting category. This is sent by PMDA to the company for information purposes only.

- **c.** Application logic for ACK import has been enhanced such that application identifies the ACK that is getting imported is against the PMDA E2B R3 report, the import logic has been enhanced to handle the newly added ZZ component in the such a way that it is loaded in the ESM schema and is available for user to view in the Report Details Dialogue *View ACK* Acknowledgment Report Tracking # and Bulk E2B Transmit *Messages* (tab) View Acknowledgment (context menu).
- **d.** The Case Form > PMDA Tab > PMDA Number displays only the 8 digit YYYYYYY number as it does for the PMDA E2B R2 report.
- **2.** Transmission Acknowledgement Code (A.4) and Acknowledgement Code for a ICSR Message (B.r.6)

The above elements in the PMDA E2B R3 ACK indicate the status of the PMDA E2B R3 report, and the values for the code are in line with that of ICH. For ready reference, below are the values for these elements:

Allowed Values for A.4

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

Allowed Values for B.r.6

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

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

Allowed Values for A.1.6

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

Allowed Values for B.1.8

- 01=Report Loaded Successfully
- 02=Report Not Loaded
- Currently while importing the ACK for PMDA E2B R2 if the ACK File is received such that the value of A.1.6 = 01 and B.1.8 = 02 the application interpret it to ACK with a warning i.e. the PMDA has loaded the report in there system but are some warnings for which a follow-up report is required.

- **2.** As per the PMDA E2B R3 guideline the same warning situation is indicated with A.4 = AE and B.r.6 = CA, and application logic shall be enhanced to handle the warning ACK similar to that of PMDA E2B R2
- **3.** The warming ACK shall be handled across the application not limited to the following locations:
 - ACK Import
 - -Worklist ' Bulk E2B Transmit (Reports & Messages Tab)
 - Report Details Dialogue

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

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

Monitoring E2B Receive Statuses

Use the following procedure to monitor E2B Receive Statuses:

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

E2B Receive Status Dialog Fields

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

Item	Description
Agency / Trading Partner	Enables you to filter data by selecting the Agency / Trading Partner from the list.
Receive Date Range From	The search start date.
Receive Date Range To	The search end date.
Range	Enables you to select a pre-defined date range
Message # Range From	The beginning message number for the search.
Message # Range To	The ending message number for the search.
Туре	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.

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

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

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

Message Acknowledgement Status Dialog Fields

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

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

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

Validation Check of Incoming Message

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

The recipient of the E2b message acknowledges receipt of message and notifies the sender about the validity and usability of the data in the reports. The acknowledgment message is called as ICSR Acknowledgment Message. When a message is acknowledged, workflow status of the E2b report is updated with one of the following three status:

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

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

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

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

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

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

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

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

Process	Error message	Possible Reason of error
Read the Incoming message from the folder	XML File not in path.	File is removed.
Identification of the incoming message type	< <file name="">> not a valid XML File</file>	File format is not as per ICH guidelines.
Identification of the incoming message type	Not valid ICH ICSR message Tag ' <ichicsrmessageheader>' not found</ichicsrmessageheader>	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</messagetype>	The incoming file is identified as a message or acknowledgment. The identification value is wrong.
Identification of the incoming message type	Record not found in CFG_PROFILE table for DTD version '2.1', DTD release '1.1', Active profile = 'Y' and profile type starts 'ACK%'	Profile does not exist in cfg_ profile table.
Validation of the incoming message type	M2 Validation failed for incoming message. The following are the elements and values:< <element, value>></element, 	M2 validation failed on the message header.
Identification of the incoming acknowledgement type	Not valid ICH ICSR message Tag ' <messageacknowledgment>' not found</messageacknowledgment>	File does not contain the valid ICH Acknowledgment Header.
Processing acknowledgment	Record not found in MESSAGES table for the ICSRMESSAGE number < <messagenum>> ICSRMESSAGE receiver identifier <<receiver info="">> for the received acknowledgment</receiver></messagenum>	Record is deleted from the database.
Processing acknowledgment	Duplicate acknowledgment received for ICSRMESSAGE number < <message number="">> and ICSRMESSAGE RECEIVER IDENTIFIER <<receiver info="">></receiver></message>	Acknowledgment already exists for this message number.
Processing acknowledgment	<reportacknowledgment> section is missing from the received acknowledgment, MESSAGE number <<message number="">></message></reportacknowledgment>	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="">></message></company>	Record is deleted from SAFETYREPORT table from database.

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

In case of invalid XML format:

From: E2b service user

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

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

Error has occurred on Line: <kerror Text>>, Source Text <<Error Text>>, Error Code <<Parsing Error Code>>, Error Reason <<Error Reason>>

Thanks,

<< E2b service user >>

In case the application fails to identify the incoming message:

From: E2b service user

Subject: Failure to Identify the Type of Incoming Message.

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

Thanks,

<< E2b service user >>

In case of validation failure of the incoming acknowledgement:

From: E2b service user

Subject: Validation Failure of the Incoming Acknowledgement.

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

The following are the reasons for this failure:

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

Thanks,

<< E2b service user >>

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

The status of the each E2b report is updated based on the information extracted from the ICSR acknowledgment, irrespective of the transmission status (Success or Failure). Refer to the section "Viewing Acknowledgement Information" on page 4-19 for viewing the acknowledgement information.

Nullification Reports

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

 When a case is deleted and an E2B Report is submitted to a reporting destination based on the Profile switch for sending E2B nullifications.

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

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

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

xxx is the value entered in the Notes field.

- By default, the system assigns the action item to the user group in the User Group field.
 - There can be a maximum of 25 user groups in the drop-down list.
 - The system performs a like search when you select a value in the User Group field.
 - If the User Group field is blank, the system does not assign the action item.
 - This is enabled after you select an action item.
- If you do not select an action item, the system does not create an action item for the case.
- If you accept multiple cases, the system creates action items for all accepted cases.
- The system skips open, locked, or archived cases or cases you don't have permission to access.
- If the system archives a case while you are accepting the nullification report, the system displays the Archived Case dialog to enable you to open the archived case.
- After you reopen the case, the system displays the Accept Nullification E2B dialog.
- If you do not have permission to reopen an archived case, the system displays the following message:

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

Viewing Statuses

Argus Safety provides the feature to monitor the transmission status of E2B reports. Use the following procedure to check the status of transmitted E2B reports.

1. Select Worklist -> Bulk E2B Transmit.

ORACL	€' Argus Sa	fety Web					Welcom	e ayesha, T	uesday, Apr	il 20, 2010 (P	RSTD60)	Home He	lp Logout
Active Cas	es Worklist	Case Actions	Reports	Local Affiliate	Utilities	Dashboards	Argus Cor	nsole	Argus Insi	ight Ar	gus Percept	ive	
Vorklist > Bulk	E2B Transmit											🖻 💽) 🚅 🔳
BULK E2B	TRANSMIT												
Reports	Messages												
Search Criter	ia												_
Case #		Message Type	•	Periodic Report		Range		Star	t Date	End D	ate		_
		All	\sim			This Month		✓ 01-4	APR-2010	01-JA	N-2999	🔎 Sea	rch
Only show	transmissions that	have reached a failure	state							N	/iew 💿 Indi	vidual 🔘 G	roup 🔘 All
Total Numb	er of Rows (1)					Di	splaying Rov	vs 1-1 💌		Page Size	100 💌	- 44	
	Case Number 📥 Case Status	Date Created Date Transmitted	Due Date	Reporting Desti Local Company	ination Name	Status Message Type		Transmit	EDI In	EDI Out	MDN Rec.	Ack Rec.	V
		??-???-0000											
		??-???-0000		·									
🗆 👶	1004-046 US Non Exp Data Entry	17-Apr-2010	21-Apr-2010	ESM_PMDA Oracle Japan		Submission to Local ichicsr	EDI Failure	•	•	•	•	-	
							Stage Legen	d 🔷	Dendina				Collect
tatus Details							Suge Legen	- J	Pending	- warni	ing 😈 S	uccess	- ralled
											Print	Print L	.ist

2. Click the Bulk E2B Transmit tab to view the status of transmitted reports.

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

Viewing Acknowledgement Information

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

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

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

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

Argus Safety			12	근근! Aditi Aggarwal Ja	p.2013年7月30日、火曜日 (PR703CER-DEFAULT)	1 N/0 077
アクティブ症例 ワークリスト 症例アクション 報告 Local Affiliate ユーティ	リティ ダッシュボード Argus Conse	de .				
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				(B)		
Case Form - JP010100000016 "BBb"			Ca	se Status : US N	Ion Exp Data Entry	
General Patient Products Events Analysis Activities Additional Information	Regulatory Reports					
Regulatory Reports Organized by Report Type / Subm	t Category / Reporting Destination 🔹					-
Reports (1)						
Total Number of Rows (1)	Lincole Trees	Constant	Calman	Dee	Occupation in the second se	-
Status Destination	License Type	Local Comment	Submitted	Due	Nesponsible	
And Ital Apple	United .	26. III. 2013 12:01	notes	28,558,2011		
View Report Details	and the second s		15 64 7 MIL		belast a a first station manual st	
Init PRDA ICSK Valdation Report	Mikt Degi Jie		手取入りシュール	with bright US 3(Product 1-3)	())))())()) = 3 (())(4. (())(0)()())()(0)()()())())	
Remove Report						

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

When the Acknowledgement Information dialog opens:

Click Print to print the acknowledgement details

OR

Click OK to close the dialog box.

Using the E2B Viewer

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

You can print these files from the E2B viewer. This chapter includes discussions on the following:

- Opening the E2B Viewer
- Exporting an SGML File

Opening the E2B Viewer

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

View	Description
SGML	Displays the E2B report in the SGML format. This view is applicable for non-Japanese E2B reports.
Decoded View	Displays all the E2B elements in groups and subgroups. Elements eligible for decoding with their decoded values in parentheses.
	Decoded View supports the following Argus J specific views for Japanese E2B reports:
	 I - Decoded View
	 J - Decoded View
	I and J Decoded Views display following information on the screen in Japanese language:
	Field Labels on the screen
	Folder Tree Values
	 Decoded description values wherever there is a text.
	In this view, the application lists the ICH and PMDA element in the decoded formats as per the applicable decoded value based on the allowed values set for the element against the profile. Besides, the element number and decoded element description (both English and J) are based on the "Data Additional Information Tab Case Form 1-28 Element R3" and Title/J Title respectively as per PMDA E2B R3 Mapping.
CIOMS	For details on the CIOMS view, refer to the "E2BCIOMSMapping" document. This view is applicable for non-Japanese E2B reports.

View	Description
HL 7 View	In this view, the application opens the report within the HL7 message format as per the PMDA Guidance (as explained in the report generation section).
MedWatch	For details on the MedWatch view, refer to the "E2BMedWMapping" document. This view is applicable for non-Japanese E2B reports.
I-SGML	Displays ICSR I data items in SGML format.
J-SGML	Displays ICSR J data items in SGML format.
I-Decoded	Displays the Decoded view for all the I elements of a PMDA E2B report.
J-Decoded	Displays the Decoded view for all the J elements of a PMDA E2B report.
PMDA Report Form	Displays the appropriate PMDA form, as per the reporting category.
Native XML View	In native XML view, the application lists all the ICH and PMDA specific elements as per the PMDA E2B R3 Mapping.

You can also view the E2B Report from the Argus Safety application.

Click the Draft or Final status for a report in the Regulatory Reports tab of Case Form.

PMDA E2B Report Mapping

Companies often send the expedited case reports to PMDA through E2B XML transmission over a specified gateway. The E2B Report adheres to the guidelines provided by the PMDA in conjunction with the ICH, which the Argus Safety Applications need to follow.

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

- 1. SERIOUSNESSDEATH
- **2.** SERIOUSNESSLIFETHREATENING
- 3. SERIOUSNESSHOSPITALIZATION
- 4. SERIOUSNESSCONGENITALANOMALI
- **5.** SERIOUSNESSDISABLING
- **6.** SERIOUSNESSOTHER

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

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

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

- 1. SERIOUS
- 2. SERIOUSNESSDEATH
- **3.** REACTIONOUTCOME

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

Note: For additional details, refer to the PMDA E2B Report Mapping Guide that is part of the Technical Reference Manual, as part of this release.

Exporting an SGML File

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

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

(皆の種類)	送信者の症例番号	表示フォーマット	
nitial	JP01010000017	I-SGML	
R告わ 16号	DTDバージョン		
P-ORACLE ARGUS-JP010100000017AA	2.1		
- <safetyreport></safetyreport>			G
<safetyreportversion>1</safetyreportversion>			
<pre><pre>saletylepoildessp oracle and sp or /pre></pre>			
<occurcountry>JP</occurcountry>			
<transmissiondateformat>102</transmissiondateformat>			
<transmissiondate>20130731</transmissiondate>			
<reportcype>1</reportcype>			
<pre>serioussesdeath>l</pre> /seriousnessdeath>			
<pre><seriousnesslifethreatening>2</seriousnesslifethreatening></pre>			
<pre><seriousnesshospitalization>2</seriousnesshospitalization></pre>			
<seriousnessdisabling>2</seriousnessdisabling>			
<seriousnesscongenitalanomali>2</seriousnesscongenitalanomali>			
<seriousnessother>1</seriousnessother>			
<receivedateformat>102</receivedateformat>			
<receivedate>20110315</receivedate>			
<receiptdaterormat>102</receiptdaterormat>			
<additionaldocument>1</additionaldocument>			
<documentlist>開JAtt da2独立行政法人 医薬品医療機器総合機構端</documentlist>			
<fulfillexpeditecriteria>1</fulfillexpeditecriteria>			
<companynumb>IP-ORACLE ARGUS-IP010100000017AA</companynumb>			
<companynumb>IP-ORACLF ARGUS-IP010100000017AA</companynumb>			

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

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

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Importing E2B Reports

Incoming E2B Reports

Incoming E2B Reports can be viewed from the Incoming E2B Report screen. This section includes discussions on the following:

- Searching for Duplicate Cases
- Using the View Differences Report
- Viewing the E2B Report
- Accepting Single/Multiple E2B Reports

Searching for Duplicate Cases

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

Use the following procedure to perform a duplicate search.

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

Duplicate Search Dialog Box Fields

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

Field	Description
Agency	The name of the primary agency.
Original Case Number	The submitter's original case number.
Message Number	The case message number.
Product Name	The name of any product on XML.
Generic Name	The active substance on XML.

Field	Description
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.
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.

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

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

Using the View Differences Report

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

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

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

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

Field	Description
Trading Partner	Enables you to view the name of the Trading Partner sending the E2B report.
	Note: The Lock/Archive icon displayed with this field indicates the status of the case.
DTD Version	Enables you to view the DTD version of the follow-up E2B report.
Case Number	Displays the sender's original case number for the E2B report.
Follow Up #	Displays the sequence number of the follow-up for the E2B report.

Field	Description						
Total Number of	Allows you to select the type of E2B Difference to view from:						
Rows	Current E2B vs. Current Case in Database						
	Current E2B vs. Last Imported E2B						
	Current Case in Database vs. Last Imported E2B						
Import	This check box highlights import differences.						
E2B Element	Refers to the data elements in the incoming E2B report or in the existing report.						
Current E2B	Refers to the data in the incoming XML that has not yet been accepted in the current E2B.						
Current Case in Database	Refers to the data in the current case in the database.						
Last Imported E2B	Refers to the data showing the last imported E2B.						
Accept Follow-up	Allows you to accept follow-up reports with the corresponding fields selected for import.						
Reject Follow-up	Enables you to reject follow-up reports for import.						
Print List	Provides the difference report in a PDF format.						
Close	Enables you to close the window.						

Displaying Differences

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

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

Viewing the E2B Report

Use the following procedure to view the E2B Report:

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

Accepting Single/Multiple E2B Reports

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

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

Select Accept ICSR to accept a single report

OR

Select the check boxes for each report and click Accept ICSRs to accept multiple reports.

- **3.** When the system opens the Acceptance of Initial Report Confirmation dialog box, enter the password and any relevant notes.
- 4. Click OK to accept the case.

Note: Accept ICSRs can be performed only when the system numbering is set to Automatic.

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

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

E2B Initial/Follow-up Intake

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

- The Selective Acceptance feature is enabled only for single initial ICSRs and is a right-click option.
- If you select multiple ICSRs, the system disables this button.
- If you select a single follow-up or nullification ICSR, the system disables this button.
- When the system displays the E2B Difference Report dialog, you can select the elements required to create or update a case without the system displaying the Case Number and Follow-up Number in the difference report dialog for initial reports.
- The following changes have been made to the Initial Intake and the Follow-up Difference Report dialogs:
 - The system displays the decoded view to enable you to select the elements (e.g., US [United States]).
 - The system prints the check box options for the Initial Intake and Follow-up Difference Report dialogs.
 - The label is updated to Select when selecting elements for the Initial Intake and the Follow-up Difference report dialog.
- You must select the following fields before the system will permit you to accept the Initial case. By default, all the fields are selected.
 - Country of Incidence (default and grayed out)
 - Report Type (default and grayed out)
 - Initial Receipt Date (default and grayed out)
 - Any one Product
 - Any one Event Term
- If you fail to select these fields, the system displays the following message:

E2B cannot be imported as it does not meet minimum Argus requirements.

The system permits you to print the Initial ICSR report.

- When you click Accept Initial, the system displays the Accept E2B Case dialog. When you complete the data elements and click OK, the system displays the Error/Warning message dialog for any elements you have selected.
- Once you accepts the case as an initial or follow-up case, the system attaches the Source XML (ICSR) and the Initial Selection PDF to the case in the Additional Info tab.
- Initial/Follow-up Source XML
 - Attachment Classification. As specified in the Reporting Destination for the XML source classification.
 - Date. The system date when the case you accepted XML for the case.
 - Description. The acceptance notes you entered for XML.
 - When you click the Source ICSR, you can see the ICSR when opening the ICSR View (E2B Viewer).
- Initial Selection PDF
 - Attachment Classification: As specified in the Reporting Destination for the Selection Source Classification.
 - Date: The system date when you accepted XML for the case.
 - Description: The date you entered acceptance notes for XML.
- Follow-up Source XML
 - When you click the Source ICSR PDF or the E2B Difference Report, you can view the Initial Selection PDF or the E2B Difference Report in a different IE window.
- Once you accept a case as an initial or a follow-up ICSR, the system prefixes the Business Level Acknowledgement Notes with the case number in the following format:

Imported Case #: XXXXXX

where:

XXXXXX is the case number

- The system attaches the current notes sent in the Business Level Acknowledgement.
- If the system receives the ICSR via the physical gateway (configured at the reporting destination level), the system sends a low level ACK to indicate the file was received by the Argus Interchange Service.
- For Auto Accepted ICSRs, the system does not attach the source PDF in the case because the source XML is attached.
- The system places this file in the Physical Out folders as configured for the reporting destination in the E2B Mapping Configuration.
- For EDI received files, the system continues to let the EDI Gateway send the low level ACK as it does currently.
- The 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 system archives a case while you are accepting the report, the system displays the Case Re-open dialog to enable you to open the case.
- If the system locks a case while you are accepting a report, the system displays the Case Unlock dialog to enable you to unlock the case.
- After the you reopen the case, the system accepts all updates as defined in the follow-up information you selected.
- If the you do not have permission to reopen an archived or locked case, the system displays the following message:
- You do not have permission to Re-open an Archived/Closed case or Locked Case.
- If you select multiple open, locked, or archived cases or if you do not have permission to open the case, the system skips the cases.
- The system does not create follow-up actions for cases that it accepts automatically.

Source XML Received for the Case

Once Argus accepts a case as an initial or follow-up case, the system attaches the source XML (ICSR) and the Initial Selection PDF to the case in the Additional Info tab as follows:

- Initial/Follow-up Source XML
 - Attachment Classification & endash; As specified in the Reporting Destination for XML Source Classification.
 - Date &endash; The system date when the user accepted the case for XML.
 - Description &endash; The acceptance notes entered by the user for XML.
 - When the user clicks the Source ICSR, the system permits the user to view the ICSR by opening the ICSR Viewer (E2B Viewer).
- Initial Selection PDF
 - Attachment Classification. As specified in the Reporting Destination for Selection Source Classification.
 - Date. The system date when you accepted the case for XML.
 - Description. The acceptance notes you entered for XML.
- Follow-up Source XML
 - When you click the Source ICSR PDF or the E2B Difference Report, the system enables you to view the Initial Selection PDF or the E2B Difference Report in a different IE window.
- When you accept the case as an initial or follow-up ICSR, the system inserts the case number before Business Level Acknowledgement Notes in the following format: Imported Case #: xxxx
- If the system receives the ICSR via the physical gateway, it sends a low level ACK to indicate that the file was reviewed by Argus Interchange Services.

- The system places the file in the Physical Out folders as defined in the reporting destination configured in the E2B Mapping.
- When the system receives files from EDI, the system continues to let the EDI Gateway send the low level ACK.
- The Interchange Services does not process the Low Level ACK in the Physical In destination folder but enters any errors in the log file because the file will always be rejected by the Interchange Service.

Processed E2B Reports

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

ORACLE	Argus S	afety Web					Welcome ay	esha, Ti	Jesday, A	pril 20, 2010	(PRSTD60) Home	Help	Logout
Active Cases	Worklist	Case Actions	Report	s Local Affiliate	Utilities	Dashboards	Argus Conso	le	Argus In	sight	Argus Per	ceptive		
Reports > Processe	d E2B Reports											6	2 🛐	💕 🗉
PROCESSED E	2B REPOR	TS												
Search Criteria														
Trading Partner		Filter Rer	nove All Pr	oduct Name		In	nport Status Impor	Status	Report	Туре				
						• •	Successful	Y	AI					~
			D	ate Range	Start Range	E	nd Range		Range					
				Fransmission Date 🗸 🗸	19-APR-2005	0	1-JAN-2999		Last 5 \	'ears	~	Retrieve		
Pending Proce	essed													
Total Number of Ro	ws (4)						Displaying	Rows	-4 🗸	Pac	e Size 100	~	- 44	>>
Originated Case # Initial / F-U /Nullificat	tion	Trading Partner 📥 World Wide Unique #	# C	mport Status - Warnings / I Case # Imported As	Errors	Accepted / Notes	Rejected By		l	nterchange)ate Import	Date ed / Reject	ed	ACK GEN	EDI OUT
E2B CASE 3		EMEA - XML	5	Success / Warnings	ŵ	ayesha			1	3-JUL-2009	15:45		•	
TEST E2B 5 Initial		US-RELSYS-E28 CAS EMEA - XML US-RELSYS-TEST E28	5	UPORT CASE Success / Warnings UPORT 2	ê	astogasotta ayesha vadvagsd	ISC		1	13-JUL-2009 13-JUL-2009 13-JUL-2009	15:46 16:07 16:11		0-	-
TEST E2B SPONTAEO	US	EMEA - XML US-RELSYS-TEST E2E	SPONTAE	Success / Warnings 95-030101	¢	Administrato Test Admin	r		3	80-JUN-2009 10-AUG-2009	17:54 9 13:24		0	
EXT-092-050102 Initial		EMEA - XML-EXTEND US-RELSYS-EXT-092-	050102 g	Success / Warnings 201-062	¢	syeda testing for E	2b Extedn		1	17-APR-2010	16:27		0-	•
														2
Stage Legend	Pending	💛 Warnings	Success	Failed									-	Print List

The Processed E2B screen contains the following:

- Search Criteria
- Total Number of Rows

Total Number of Rows Fields

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

Field	Description
Originated Case#	Displays the Originated Case Number of the case.
Initial/F-U/Nullifica tion	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.

Field	Description
Case # Imported As	The Case Number used when importing the case.
Accepted / Rejected By	Identifies who accepted or rejected the case.
Notes	The case notes.
Interchange Date	The Interchange Date.
Date Imported/Rejected	The date the case was imported/rejected.
ACK Gen	Yellow indicates the case is still pending
	Orange indicates the case is accepted with warnings / errors
	Red indicates the user or system rejected the case.
	Green indicates the case has been successfully imported.
EDI Out	Yellow indicates the system is waiting to send the report out of the EDI / XML or PHY out folders
	Green indicates the report is already sent out of the EDI / XML or PHY out folders
	Red indicates that the EDI gateway failed to send the report out of the EDI / XML or PHY out folders.

Glossary

Electronic Format

A document stored on the computer, instead of printed on paper.

Encode

To convert data by the use of a code in such a manner that reconversion to the original form is possible.

Field Description

Information that describes the characteristics of data in a field.

Field Format

A format in which the output consists of structured field introducers and variable data rather than output in line format.

Filter

A device or program that separates data, signals, or material in accordance with specified criteria.

Home Page

The top-level Web page of a portal. Sometimes used as a synonym for default portal page.

Periodic Safety Update Report

The Periodic Safety Update Report (PSUR) is required as part of the FDA Post Marketing Drug Risk Assessment (PMDRA) program. The PSUR software is designed to track the submission of Periodic Safety Update Reports by marketed product and country.

Portable Document Format

Portable Document Format (PDF) is a file format proprietary to Adobe Systems for representing two-dimensional documents in a device independent and resolution independent fixed-layout document format.

Query

A request for information from the database based on specific conditions. For example, a request for a all reports related to a particular study.

Report

A formatted presentation of information relating to a model or to process simulation results. Reports can be viewed online, printed, or exported to a variety of file formats.

Report Type

A data source and how it is mapped.

Rich Text Format (RTF)

A document file format developed by Microsoft for cross-platform document interchange.

Spontaneous Report

A communication from an individual (e.g. health care professional, consumer) to a company or regulatory authority that describes a suspected adverse experience. It does not include cases identified from information solicited by the applicant such as individual cases or findings derived from a study.

Study

Any organized data collection system (such as adverse experience information derived from a clinical trial, patient registry, including pregnancy registries). Reports from company-sponsored patient support programs should be handled as if they were study reports and not as spontaneous reports.

Text

A broad term for something that contains words to express something.

Universal Resource Locator (URL)

In addition to identifying a resource, URLs provide a means of locating the resource by describing its primary access mechanism (e.g., its network 'location').

Web Browser

A client program that initiates requests to a Web server and displays the information that the server returns.

Web Page

Any document that can be accessed by a URL on the World Wide Web.

Web Server

A software program that is capable of servicing Hypertext Transfer Protocol (HTTP) requests.

Web Site (or Website)

A related collection of files available on the Web that is managed by a single entity (an organization or an individual) and contains information in hypertext for its users. A Web site often includes hypertext links to other Web sites.

Web-based Application

An application that is downloaded from the Web each time it is run. The advantage is that the application can be run from any computer, and the software is routinely upgraded and maintained by the hosting organization rather than by each individual user.

World Wide Web (WWW)

A network of servers that contain programs and files. Many of the files contain hypertext links to other documents available through the network.