Oracle® Argus Safety Japan

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Contents

Preface	v
Intended Audience	v
About This Book	v
The Oracle Health Sciences Safety Suite	v
Documentation Accessibility	vii
Related Documents	vii
Conventions	vii

1 Introduction

2 **Business Configuration**

2.1	Configuring Product Family	2-1
2.2	Configuring Licenses	2-1
2.2.1	License Configuration - Argus J Specific Parameters	2-1
2.2.2	Literature Intake Updates	2-3
2.3	Configuring Studies	2-5
2.4	Configuring Expedited Reporting Rules	2-6

3 System Configuration

3.1	Configuring Common Profile Switches	3-1
3.1.1	Common Profile Switches	3-1
3.1.1.1	Profile Switch for Incomplete Report Submission - Auto Action item	3-11
3.2	Configuring Field Level Validations	3-12
3.2.1	Field Label Configuration (J Specific)	3-12
3.2.1.1	PMDA Downgrade/nullification Report Scenario when All Events are Non-Reportable 3-13	
3.3	Configuring Field Labels	3-14
3.3.1	User Defined Fields Updates	3-14
3.4	Configuring Local Reports - Local Reporting Rule and Local Reports	3-14

4 Code List Configuration

Code Lists	4-1
General Functionality Changes	4-1
Device Reporting Category	4-2
Emperor	4-2
	Code Lists General Functionality Changes Device Reporting Category Emperor

4.1.4	J Reportable Product Keyword	4-3
4.1.5	License Category	4-4
4.1.6	Literature Type	4-5
4.1.7	Reporting Category	4-6
4.1.8	Literary Citation	4-7
4.1.9	Reporting Destination	4-8
4.1.10	Manufacturers	4-9
4.1.11	Reporter Information	4-10
4.1.12	Flexible Data Re-Categorization	4-13
4.1.12.1	Reporting Category (LM_RPT_CATEGORY)	4-13
4.1.12.2	License Category (LM_LIC_CATEGORY)	4-13
4.1.12.3	Dev Phase (LM_DEV_PHASE)	4-14
4.1.12.4	Risk Category of OTC Drug (LM_RISK_CATEGORY_OTC)	4-14
4.1.12.5	Route for Acquiring OTC Drug (LM_ROUTE_ACQUIRE_OTC)	4-15

Preface

This document describes the steps for installing and configuring the components of the Argus Console (Japanese) application.

Intended Audience

This document is intended for administrators of the Oracle Argus Safety Japan (Argus J) Safety system for configuring Argus Safety.

About This Book

This guide contains the following chapters:

Chapter 1, "Introduction"

Chapter 2, "Business Configuration"

Chapter 3, "System Configuration"

Chapter 4, "Code List Configuration"

The Oracle Health Sciences Safety Suite

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

Oracle Health Sciences Safety Suite

Integrated Solution for End-to-End Vigilance Through the Entire Product Lifecycle



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

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

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

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

Documentation Accessibility

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

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hearing impaired.

Related Documents

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

Oracle Argus Documentation

The *documentation set* includes:

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

Conventions

The following text conventions are used in this document:

Convention	Meaning
boldface	Boldface type indicates graphical user interface elements associated with an action such as Buttons, Dialog boxes, Check boxes, Combo boxes, Drop-down lists, Labels, Option (Radio) buttons, Tabs, Text boxes, etc.

Convention	Meaning
"between quotation marks"	Information that may appear as-is on screen, or information provided by the user.
Note	Information that should be noted before proceeding with the instructions.
Important	Important information that must be noted to ensure accurate, reliable, or safe behavior of the system.
Tip	Information that enables easier completion of the current task or helps in completing other tasks.
Bold Underline	Link indicating that additional "pop-down" information is available.
ALL CAPITALS	Keyboard keys
Initial Capitals	Names of user interface elements, modules, applications, proper nouns, etc.

Introduction

1

This guide lists the Japanese-specific (J-specific) features in Argus Console.

These features have been covered as per the modules where they are displayed, in the following chapters:

- Business Configuration
- System Configuration
- Code List Configuration

Business Configuration

This chapter lists the Japanese-specific (J-specific) features in the Business Configuration module of Argus Console.

2.1 Configuring Product Family

The following list indicates the changes in Product Family Configuration:

- Comments (J) has been added below the English Comments area.
- This field is displayed only to an Oracle Argus Safety Japan (Argus J) user when the Japanese module is enabled.
- It is printed in the Product Family Configuration print PDF right after the English Comments field.
- It is covered by the back-end PL/SQL APIs for Product Family Configuration data table updates and audit-logging.

2.2 Configuring Licenses

The following section describes the changes in License Configuration:

2.2.1 License Configuration - Argus J Specific Parameters

The following changes have been made for PMDA Device Reporting Support in Console:

- The following drop-down lists have been added to Console > Business Configuration > Products and Licenses. These drop-down lists have the following options in the same order.
 - PMDA Device Classification 1:

High Level Controlled Medical Device (Class IV)

High Level Controlled Medical Device (Class III)

Controlled Medical Device

Generic Medical Device

Combination products (Drugs)

Combination products (Tissue-Engineered Medical Products)

Stand-alone software (Class IV)

Stand-alone software (Class III)

Stand-alone software (Class II)
PMDA Device Classification 2:
Biogenous
Specific Biogenous
Other
PMDA Device Classification 3:
Single Use Medical Device
Reiteration Use Medical Device

Figure 2–1 Console License Configuration - PMDA Device Classifications

Browser							
Organized By Countries / License Type / Licen V	Y Trade Name		Award Date		Withdrawn Date		
			00-MMM-000		00-MMM-0000	9	
Contains V	Trade Name(J)		PMDA Re-examin	ation Date			
Displaying Rows 1-12 (12)					Exclude from	Report Candidates	
at 😂	Water of the design of the day			19.000	-	The second second second second	
🚊 🚞 ALGERIA (6)	 Market Authonization Holder 		Biologic / Vac	cine	Not in Traden:	ame Lookup / Not Auto-Scheduled	
- CANADA (6)			Labeled For 5	lingle Use	OTC Product		
FRANCE (6)	Datasheet URL		Countries List			Modity.	
g GERMANY (6)	1						
📋 🥅 INDIA (6)							
IRELAND (6)	* Authorization Country	✓ License Type					
👔 - 🧰 ITALY (6)		¥ l	~				
👜 - 🚞 JAPAN (6)	Datasheet Name		Application Type	License #	C	ompany Item Number	
SWEDEN (6)			V				
UNITED KINGDOM (6)	PMA/510(k)#	Nomenclature Code	Medical Device In	formation			
UNITED STATES (6)	1 m 1 m					~	
ZAMBIA (6)	Clipical Compound Number						
			200				
	DUD I Dudu Olav Barkan I	IIKEN	Blind J.10 In I	PMDA AE Paper Report			
	PMDA Device Classification 1	PMDA Device Classification 2	PMDA Device Cla	semcation 5			
		~1	~		~		
	Status Category of new drugs		Risk Category of	OTC drugs			
	1.		~			~	
	Product Name / Dosage Form / Strength						Add Delete
	Product Name						Product Name(J)
	Lange and the second						
							~
							~
	0700 0000 0000		Davidas Osmanas	and a state of the set	Device Ideality of		
	CTPR Group Name		Device Company	Identification#	Device Identificati	ious.	
	1 N		-77-8				
	Commenta						
	An and a second second						
	Comments(J)						
	12 C						
							PW

- These drop-down lists have <Blank> as the default value.
- These fields are displayed to only an Argus J user when Japanese module is enabled.
- These fields are editable only when Authorization Country is selected as Japan and License Type is selected as either Marketed Device or Investigational Device.
- The list options are displayed in English even to the Argus J user as this is an English base screen. The Japanese value specified for these options is used to populate them in PMDA Device Expedited Form 8 and 10.
- **Medical Device Information** and **Clinical Compound Number** have been adjusted in the user interface of the application.
- These three fields are printed in License Print PDF in three different rows, right below Clinical Compound Number field in alternate-colored rows thereafter.
- These fields are audit-logged.
- These fields are covered by the back-end PL/SQL APIs for License Configuration data table updates and audit-logging.

- A new checkbox TIKEN is available. Any changes to this checkbox value are audit logged.
- **Blind J.10 in PMDA AE Paper Report**: This checkbox is disabled by default and shall be enabled only when the License country is Japan.
- Status Category of new drugs: This list captures the Status category of new drugs. The data in this list is populated based on the data in the License Category code list.
- Risk Category of OTC drugs: This list captures the Risk Category of over-the-counter (OTC) drugs. The data in this list is populated based on the data in the Risk Category of OTC Drug code list.

These new fields available in License Configuration print for both **Print** and **Print All** options. They also support the License/Product with Licenses copy functionality. Any changes to these fields value is logged for audit.

- A separate Japanese Comments field is supported for the following in Console ' Business Configuration.
 - Comments (J) field has been added right below the English Comments area.

This field is displayed only to Argus J users when Japanese module is enabled.

It is printed in the License Configuration print PDF right after the English Comments field.

It is audit-logged and is also covered by the back-end PL/SQL APIs for License Configuration data table updates and audit-logging.

2.2.2 Literature Intake Updates

Following is the list of Literature Intake Updates:

- A new option Exclude from Report Candidates has been added to Console > Business Configuration > License Configuration as shown below.
 - This checkbox is displayed to only an Argus J user and when Japanese module is enabled.
 - By default, this field is unchecked.
 - This checkbox is enabled only when the Authorization Country is Japan.
 - This field value is printed in License Configuration print PDF.
 - Updates to this field value are audit-logged.

Trade Name	Award Date	Withdrawn Date
Algoheal_NV	01-JAN-1980	00-MMM-0000
Trade Name(J)	PMDA Re-examination Date	
		Exclude from Report Candidates
Market Authorization Holder	Diologic / Vaccine	Not in Tradename Lookup / Not Auto-Scheduled
Relays International - Germany	Labeled For Single Use	COTC Product (US MedWatch)
Datasheet URL	Countries List	Modify

- When the product is populated in the case created through J Literature Intake module, it populates only one record in the Case Form Products tab for each Product in the matching Product Family. If there are multiple Japanese licenses for a product, then the correct license is picked up based on the following logic:
 - License Authorization Country = Japan
 - Withdrawn date is blank or >= current system date

- Hide checkbox is not selected for that product license combination
- Not in Tradename lookup/Not Autoscheduled checkbox is not selected
- Exclude from Report Candidates checkbox is not selected
- If multiple licenses exist matching this criteria, then the Earliest awarded date license is considered
- If multiple licenses still exist matching this criteria, then the license with the lowest internal sequence number is considered.
- Following is the change in logic that is used to populate Japanese licenses on Event Assessment and PMDA tabs. There is no change in logic for other country licenses. Manually Added Products through Bookin or Case Form or Case Intake or Affiliate Event Acceptance:
 - If the user selects a Japanese license during product selection in Bookin / Case Form / Affiliate Event, then only that license is considered for Event Assessment and PMDA tabs irrespective of the value of Exclude from Report Candidates checkbox.
 - If the user selects a non-Japanese license during product selection in Bookin / Case Form / Affiliate Event, then only the Japanese licenses for which Exclude from Report Candidates checkbox is not selected is considered for populating Japanese licenses in Event Assessment and PMDA tabs.
- Products Added through Literature Intake:
 - Only the Japanese licenses for which Exclude from Report Candidates checkbox is not selected are considered for populating Japanese licenses in Event Assessment and PMDA tabs.
- Products Added through E2B Import:
 - Only the Japanese licenses for which Exclude from Report Candidates checkbox is not selected are considered for populating Japanese licenses in Event Assessment and PMDA tabs.
 - While identifying the product license to be used to populate the Products tab, only those Japanese licenses are used for which Exclude from Report Candidates checkbox is not selected.
 - This is applicable to all the E2B factory profile logic ICH, FDA, EMEA and PMDA.
- PMDA Event Assessment section on PMDA General tab:
 - Only the Japanese licenses for which **Exclude from Report Candidates** checkbox is not selected are considered for populating Japanese licenses in Event Assessment and PMDA tabs.
- Manual Report Scheduling dialog > License # drop-down displays only those Japanese licenses which are available on Event Assessment tab.
- The following change has been made while populating product licenses data in Case Form > Analysis tab > PMDA > General as well as Comment sub-tabs.
 - Marketed or Investigational Japanese Device Licenses is not populated, as PMDA General and Comments tab is not relevant for Device Reporting to PMDA.
 - Existing customer case data where Marketed or Investigational Japanese Device Licenses are already populated in PMDA General and Comments tab, has also been removed.

 Removal of Marketed or Investigational Japanese Device Licenses from PMDA tab for existing customer data is audit logged with the "System" user.

2.3 Configuring Studies

The user can now select a particular license that is then used to fetch the CCN and other related data.

The following changes have been made in Argus Console > Business Configuration > Study Configuration.

The application has been enhanced such that when user adds a J Drug to the Argus Console > Business Configuration > Study Configuration (J pop-up), the corresponding English Drug name is populated in the English Product name.

Note: The same English product name is populated in the Case form English Product name (as explained below) when the corresponding study drug is added in the case.

- The application lists the above added J drugs in the study for which the English product name is not blank (or not default text J DRUG in DB) in the corresponding English Study configuration screen. These products are listed in the existing Products grid of the corresponding English Study configuration screen.
- The functionality of associating the J Drug in the study configuration with WHO drug remains intact. When the user tries to associate the WHO drug with the J Drug, by clicking the WHO Drug association button such that English Drug Name is not blank (or default text *J DRUG*) then the WHO Drug Browser opens with pre-populated English Drug Name (Populated from the English sub file) in the Trade Name (text box) of WHO Browser for user to perform a quick search .Also, when the user associates the J Drug to the WHO, the English product name is updated with the Product name returned from the WHO dictionary.

When the user adds a JDrug from J Drug Browser for with English Drug Name is blank, the existing behavior of populating *J DRUG* in the English Product Name has been retained.

The Product Grid in both the English and J Study Configuration pop-up screens has been updated as follows:

 Product, Dosage, Unit, and Formulation have been merged into one column called Product Name (Dosage Form / Strength / Unit), as shown below:

🔊 Study Webpage Dia	log				×
MP STUDY1					
MP_STUDY1	MP_CSPSR	OTH1		•	
-	開発相				
└┘ テンプレートのみ	第I相	•			
治験成分記号	対象疾患 (使用理由)	投薬中の症例の有無			
C_P1-Lic 1	C_P1-Lic 1		-		
7-1. (1)					
♥試験名	♥ 試験の種	類製品のラ	イセンス		
MP_STUDY1	単純盲検	•			•
♥製品 (2)			JFE	ラッグを追加 自社製品を追加	肖除
# 製品名(剤型 /強度,	/単位)	WHOエンコー 盲検 ド	Product Type	License	-
1. Product 1		Π	Investigat	(JPN 1) DH_Prod2	
					_
					a
MP_STUDY1 (単)					
[MP_STUDY1]					

- A new license selection drop-down list, **License**, has been added in the J pop-up Product Selection grid. This list contains all the J Licenses that are present for the respective product.
- This license is used as the primary selected license when you select the product as the study drug in the Case Form, in the following format:

Trade name<space>(License Type)<space>Clinical compound Number or License Number

The License Type is printed as "MKT" for Marketed Drug/Device/Vaccine and "INV" for Investigational Drug/Device/Vaccine.

This license should be used as Primary license if the case is accepted as Initial/Follow-up from E2B, Literature Intake or Case Intake.

A new study configuration field, Notification number, has been added in the J
pop-up Product Selection grid to capture the notification number. The notification
number is the unique number allocated by PMDA to each study for a particular
Clinical compound number.

教育研究の	♥ プロジェクトロ	その他のD	観察された試験の)種類(E2B)		
	2	Begin other ID isEND	臨床試験	×		
	開発相	26.2	_	20	200	
ローテノリレードのみ 台線成分記号	? 対象疾患(使用理由)	投産中の症例の有無	ゴ 「届出回数 」			
7'1A (1) Residence	♥ 計算会び通道者	15/2	10-541207			
F INFI PARA INTE	- 1741X - 12XX					
1 100210	単純盲検					
▼ 果品 (0)	単純盲検		10	Holiラッジを追加 自社論	製品透度加	自诩余。

Arms		
届出回数	23	
投業中の症例の有無		
対象疾患(使用理由)		
治験成分記号		
コメント		
試験に特定したエンコードを可 能にする		

You must enter numeric data in this field.

This new field is available in Study Configuration print for both **Print** and **Print All** options. It also supports the Study copy functionality. Any change to this field value is logged for audit.

2.4 Configuring Expedited Reporting Rules

Following is the list of changes in Expedited Reporting Rules Configuration:

 A new drop-down list Device Reporting Category has been added to Console > Business Configuration > Expedited Reporting Rules screen as follows:

Report name		Report Destination	
F EXP Rule 1		ABC	
Active Auto Distribution	ute Reports 🛛 🗖 Blind Study Pro	oducts Protect Reporter and Patient Confidentiality	HCP Car
Domestic 🗌 Foreign	🕈 Timeframe 7 day	s 🗖 Active Molety 🗖 No Followup Downgra	de
Force Distribute da	ys before due	Listedness (Event)	
Form		Ignore	
US FDA MedWatch 3500A Dru	Pu Pu		
Local Comment Type	Clinical Reference Type	Seriousness	
	Ignore 👻	Fatal/Life Threatening Serious (Event) Serious	(Case)
Language		Ignore Ignore Yes	-
English	-	Severity (Event)	200
	_	Ignore	-
Product Specific			
Product Group		Family Name	
		-All-	
^aue alifu			
Most Conservative D Incl	ude Non-Clinical Trial Cases		
As Reported (Event)	As Determined (Event)	As Reported (Case) As Determined (Case	=)
Ignore	Ignore	Ignore Ignore	-
dvanced Condition		Responsible Group Cover Letter	
All cases	AC State		
eporting Category	License Category	Device Reporting Category	
		Super Rule - Cease	evaluation
		of normal rules upor	n match

Figure 2–2 Console Expedited Reporting Rules Configuration - Device Reporting Category

- This field is displayed to English as well as Japanese users only when Japanese module is enabled.
- This drop-down displays the English values as specified in the Device Reporting Category Code List and are marked as Display.
- It contains <Blank> as the first option and it is also the default value.
- This field is printed in Expedited Report Rules Print PDF right below License Category field in alternating colored row.
- This field is audit-logged.
- It is covered by the back-end PL/SQL APIs for Expedited Reporting Rules data table updates and audit-logging.

Figure 2–3 Console Expedited Reporting Rules Configuration - Print PDF

Reporting Category	
License Category	
Device Reporting Category	
Super Rule - Cease evaluation of normal rules upon match	

 A new option Urgent Report is available in the Reporting Rule Print. Selecting this checkbox will mark a report as urgent. The new option supports the copy functionality and changes to it will be logged for audit.

Expedited Domestic		
🕈 Report Name		* Report Destination
Expected Domestic		KDER
Active Acto Distribute Reports Origin of events to instude:	Bind Study Products	Protect Reporter and Partent Consider that y Property on Drug Not Administered Virgent Report
Domestic E Foreign	♥ Timetrame 15 days	C Active Malety
Adjust due date for Group 2 Countries by days		
Force Distribute days before	due	Listednese (Event)
₩Form		Unisted
US FDA Med/Addch 3500A Drug		Continuence
Local Comment Type Cl	inical Reference Type	Fatal/Life Threatening Serious (Event) Serious (Case)
Language		lignore I lignore I Ves Sevenity (Evenit)
inglish 🔄		Ignore
Product Specific		
Product Group		Family Name

System Configuration

This chapter lists the Japanese-specific (J-specific) features in the System Configuration module of Argus Console.

3.1 Configuring Common Profile Switches

This section describes the functionality for the J-specific Common Profile switches.

3.1.1 Common Profile Switches

This section explains the Common Profile Switches for Argus J.

The following figure is displayed when you navigate to **Common Profile** > **Argus J**:

COMMON PROFILE - Argus J	
Browser	Modify Argus J
Organized by Common Profile	Default viewing format of the PMDA E2B R3 report (used with interchange-J)
🖃 🚰 Common Profile	XML View
Advanced Conditions	O Decode View
Argus Lossier	
🛓 📷 Argus J	
Argus Mart	Datauit viewing format of the DMDA E28 82 report /used with Interchanne. II
Case Form Configuration	
Case Processing	
Local Labeling	
- Carlo Network Settings	O LECODE VIEW
🚔 🧰 Reporting	O J DECODE VIEW
Single Si	PMDA Paper Form
User Interface	
- Contraction -	Default Report type to be selected when Literature intake item is booked-in
	Shared Dath for the Liferature Infase
	ciuliniake
	P = 0.01 (2014)
	Enable half-width Alphanumeric characters forced input for Alphanumeric only fields
	Default name of Regulatory Agency for Draft Expedited PMDA Reports
	PMDA_R2 V
	Japan License to be available in case for Assessment and Reporting
COMMON PROFILE - Argus J Common Profile Comm	All valid Japan Licenses
OFILE - Argue J	O User Selected License only
PROFILE - Argus J	
	On Adding/Updating the Case form > Events > Description as Reported by English user, Auto populate the Description as Reported on the Japanese side with:
H PROFILE - Argus J soy Common Profile Anamae Contitions Angus Coester Coester Angus Coester Coester Angus Coester Coester Angus Coester Angus Coester Angus Social Status Social Status Coester Angus Coester Coeste	English Verbatim
	O Japanese PT (From Meddra J)
	Allow user to update the 'Reason for Downgrade/Nullification report' and 'Comments for start date of reporting timeframe' after the case is locked (globally and locally locked)
	• Yes
	O N0
Help Text	

Field Name	Description	Field Options
Enable half-width Alphanumeric characters forced input for Alphanumeric only fields	In the Argus J application, if this Profile Switch is on, the system automatically forces the input method to fixed half-width English when you enter data in the Alphanumeric only fields.	
	For example, J user sets Japanese as input method on the client system, and without changing the input method, they can work through Argus J.	
	Case Form:	
	The following items are always alphanumeric input only regardless of the profile switch:	
	All the fields in English UI are forced to enter half-width alphanumeric characters.	
	Login fields are forced to enter half-width alphanumeric characters.	
	All non-Japanese fields in the multi-language pop- up.	
	The following items are forced to input Alphanumeric characters by profile switch:	
	All global fields	
	PMDA tab General > Japan first information received date General > Japan follow-up received date	
Default viewing format of	This field represents the	I SGML
the PMDA E2B report (used with Electronic Submission	default viewing format of the PMDA E2B report (used	J SGML
Module (Interchange-J))	with Electronic Submission	I Decoded View
	Module (ESM)).	J Decoded View
	When PMDA Paper Form is selected, the system determines the correct paper format from the Reporting Category E2B item and creates paper draft image.	PMDA Paper Form
	Default Value: 1	
Shared Path for the Literature Intake	This field represents the shared path for the Literature Intake.	Maximum Length: 255
	Default Value is blank.	

The following table explains the fields used in the screen:

Field Name	Description	Field Options
	PSR configuration UI	
	Subject of Report/Report Number	
	Investigation Timeframe/Assigned Date	
	Investigation Timeframe/International Birthdate	
	Investigation Timeframe/Japanese Aware Date	
	Investigation Timeframe/Report is due _days after specified end date	
	Investigation Timeframe/Start Date	
	Investigation Timeframe/End Date	
	Report Batch Printing popup / Run at	
	Report Batch Printing popup / Due Date	
	Console J:	
	The following items are forced to input Alphanumeric characters by profile switch:	
	All the J pop-up fields marked as S (Share same value as English one. So there is same database field for both) in Console J SRS Population Rule section.	
	All the regular fields that have A (Alphanumeric only) in Input Lang Type classification of Console J SRS.	
	Default Value is checked.	
Default Report type to be selected when Literature Intake item is booked-in	This field represents the default report type value for Book-in screen for cases booked-in through Literature Cases.	Report Type configured in Console J
	Default Value is blank.	
Default name of the Regulatory Agency for New Draft Expedited PMDA Reports from Analysis Tab of the Case Form	This field represents the default name of the regulatory agency for new draft expedited PMDA reports.	Reporting Destinations configured in the Console

Field Name	Description	Field Options
Japan License to be available in case for Assessment and reporting	The field represents the selection for Japan licenses to be available for Assessment and reporting.	All valid Japan Licenses User Selected License only
On Adding/Updating the Case form > Events > Description as Reported by English user, Auto populate the Description as Reported on the Japanese side with:	The field represents the auto-population options for Description as Reported on the Japanese side on adding or updating the case form. Default Value is English Verbatim.	English Verbatim Japanese PT (From Meddra J)
Allow user to update the "Reason for Downgrade/Nullification report" and "Comments for start date of reporting timeframe" after the case is locked (globally and locally locked).	The field represents the options available after the case is globally locked. Default Value is Yes.	Yes No
Default viewing format of the PMDA E2B R3 report (used with Interchange-J)	The field represents the formats for viewing the PMDA E2B R3 report (used with Interchange-J) Default Value is Decoded.	XML Decoded HL7

The following screen is displayed when you navigate to **Common Profile** > **Argus J** > **E2B**:

💋 System Configuration : System Management - A	rgus J - E2B - Windows Inte	ernet Explorer					
ORACLE		Welcome Vipin Kumar B	haradwaj ‼, T	uesday, May 24, 2011 (A S602 S)	Home	Help	Close
Code Lists Business Configuration	Access Management	System Configuration	Tools				
Code Lists Business Configuration COMMON PROFILE - Argus J[E2B Browser Organized by Common Profile Common Profi	Access Management Modify Argus JIE28 E28 filename extension f SGM Drug assessment sourc 第一次情報源 Drug assessment sourc 報告企業 Drug assessment metho	System Configuration	I by E2B/Inter	change-J module)			
Cocal Labeling MedVatc Configuration Metwork Settings B-G Reporting B-G Security Morkflow	ダローバルイントロス・ Perform Japanese chara Additional invalid charact ** Characters to be allowed ABCDEFGHJKLMNOF	ペクション acter validation at E28 Check and i ter to be checked in Japanese d to use in All (Alphanumeric) 2QRSTUVWXYZabcdefghijkl	E2B Report Ge e character va E2B items mnopqrstuw	neration. Ildation xyyz0123456789.E+.I'#\$%*+	;=?@[\]^	<u></u>	
Holp Text	Seriousness criteria in E C Case Level Seriousness © Event Level Seriousness	vent Reportability Matrix					
						Save	

The following table explains the fields used in the screen:

Field Name	Description	Field Options
E2B filename extension for Interchange -J	This field represents the E2B filename extension for ESM-J	SGM
	Default Value: SGM	
Perform Japanese character validation at E2B Check and E2B Report Generation.	If this is checked, the Japanese language check is performed during E2B Report Generation. Default value is checked.	This option is in the same section as Additional invalid characters to be checked in Japanese character validation.
Additional invalid characters to be checked in Japanese character validation	This field allows you to add invalid Japanese characters to be checked in Japanese Language check in the profile switch.	This option is in the same section as Perform Japanese character validation at E2B Check and E2B Report Generation
		When the Perform Japanese character validation at E2B Check and E2B Report Generation checkbox is unchecked, this field is disabled.

Field Name	Description	Field Options
Characters to be allowed to use in AN (Alphanumeric) E2B items	In this field, you can enter English characters allowed in Argus J. When this is entered, the English characters E2B check validates if AN fields (Allow Japanese Characters=No) has undefined characters in the Profile Switch.	
	The E2B check displays following error message when invalid character(s) (characters not configured in the Profile switch) are found in the E2B item:	
	Value of element [element tag] has invalid English character(s).	
	Default Value:	
	ABCDEFGHIJKLMNOPQR STUVWXYZabcdefghijklmn opqrstuvwxyz0123456789.E +- !"#\$%'()*+,-:;;=?@[\]^_ /{ }~	
Drug assessment source for reported causality (used by E2B/Interchange-J module)	This function for the B.4.k.18.2 is different from EMEA rule, as in EMEA these values are hardcoded in the application while in PMDA they come from the CMN_Profile switch.	Field Length: 120J Audit Log: Yes
Drug assessment source for determined causality (used by E2B/Interchange-J module)	This function for the B.4.k.18.2 is different from EMEA rule, as in EMEA these values are hardcoded in the application while in PMDA they come from the CMN_Profile switch.	Field Length: 120J Audit Log: Yes
Drug assessment method (used by E2B/Interchange-J module)	The field value chosen in the Case Form > Event Assessment tab is populated for B.4.k.18.3 DRUGASSESSMENTMET HOD field for the Product Event combination selection for E2B report mapping. If you have the Drug Assessment Method field hidden for the Case Form, the value for B.4.k.18.3 DRUGASSESSMENTMET HOD is set to the value in this field by default.	Field Length: 70J Audit Log: Yes

Field Name	Description	Field Options
Seriousness criteria in Event	The Event Reportability	Case Level Seriousness
Reportability Matrix	algorithm used by the PMDA E2B and Paper Reports considers seriousness criteria value as Case Level or Event Level seriousness based on the value set for this common profile switch.	Event Level Seriousness
	Default Value: Event Level Seriousness	
File attachments allowed for PMDA E2B R3 Profile	This Common Profile Switch checks the allowed files that can be attached in the E2B (R3) report generated using PMDA profile.	Pdf, jpeg, jpg, bmp, png, gif, tif, tiff, rtf, txt, xls, xlsx, doc, docx, xml, html, and dicom
Compression algorithm for file attachments in PMDA E2B R3	This Common Profile Switch specifies the compression algorithm for the attachments in E2B (R3) report generated using PMDA profile.	DF (default selected) GZIP

The following screen is displayed when you navigate to **Common Profile** > **Argus J** > **Reporting:**

Code Liste	Pusiness Configuration	Access Hansacment	Sustem Configuration	Taola				
Code Lists	business computation	Access management	system configuration	TOOIS				
OMMON PROF	ILE - Argus JiReporting							
rowser	ing as chickening	Modify Argus JiReporting						
rganized by Con	nmon Profile 🔹 👻	Follow Up Action Item for	noompletion Deport Submissi	-				
🥁 Common Profi	le	v voidw-op Action item for i	ncompletion Report Submiss	ion -				
Advanced	Conditions							
Argus Dos	Isier	Due in days						
Argus J								
- 🚞 E28		Follow-Up Action Item for I	rcompletion Report Submiss	ion Group As	signment			
Repor	rting							
Case Porm	essing	Auto Distribution Submiss	ion Comments (J)					_
Document	Management]	
- C28								
Local Labe	ting Confouration	Text to display as commen	nt when a downgraded report	is scheduled	l)		1	
Network S	ettings	***************************************	***				1	
Reporting	6	Auto Distribution Transmi	ssion Comments (1)					
Security	face		(0)					
🔁 Workflow	8	Event counting logic for PS	R Form 3, 4 and ReSD Form 4,	5				
		Count each event as report	ted in that timeframe					
		Count each event from a c	ase with the timeframe where the	case was rep	orted first.			
		Listedness Assessment :	Source for PSR and ReSD					
		Configured Datasheets						
lo Text		Case Event Assessment						
		Offset from GMT used to a	alculate Japanese date/time fi	elds (in hour	s)			
			•			10		_

The following table explains the fields used in the screen:

Field Name	Description	Field Options
Auto Distribution Transmission Comments (J)	This field allows you to enter the Japanese Transmission comments used for Expedited Reports Transmission, which are auto-distributed by the system based on Expedited Reporting Rules or Reporting Destinations.	Field Length: 1000 Audit Log: Yes
	These comments are used in the same way as Auto Distribution Comments , but when J user is on the system.	
Auto Distribution Submission Comments (J)	This field allows you to enter the Japanese Submission comments used for Expedited Reports Transmission, which are auto-distributed by the system based on Expedited Reporting Rules or Reporting Destinations.	Field Length: 1000 Audit Log: Yes
	These comments are used in the same way as Auto Submission Comments , but when J user is on the system.	
Offset from GMT used to calculate Japanese date/time fields for Interchange-J (in hours)	This field represents the offset from GMT that is used to calculate Japanese date/time fields. ESM-J	
	Default Value: 7	
Text to display as comment when a downgrade report is	The field length is 2000 J.	
scheduled	The text appears in the Report Detail > Comment tab.	
"Follow-Up Action Item for Incompletion Report Submission"		Populated based on Action Type Code list values (not deleted and not hidden)
"Due In days"		
Major Developed Countries for Approval Status in J-DSUR	This field lists the countries to be considered as major developed countries for	Text box with 1000 characters limit, without any default value.
	J-DSURs.	Users can also configure comma-separated A2 country codes.
Follow-up Action Item for Incompletion Report Submission Group Assignment	This field represents the user group to which the Incompletion Report Submission Action Item is assigned.	User Groups from Console
	Default value is blank.	

		1
Field Name	Description	Field Options
Count each event as reported in that timeframe	Enables you to count each event as reported in the specified timeframe.	
Count each event from a case with the timeframe where the case was reported first	Enables you to count each event from a case with the timeframe where the case was reported first.	
Configured Datasheets	Enables you to configure datasheets as per your requirements.	
Case Event Assessment	Enables you to assess the case event.	

PIP PMDA Profile Integration for No Reportable Events

The existing Argus Safety application checks for reportable events for PMDA E2B generation for transmission and import process. Due to this check, cases with un-encoded events or missing causality cannot be accepted successfully during follow up import process as reportable events scenario is not met for such follow ups. The Inform-Argus PIP profile has removed the check of reportable events from their profile SQLs. However, because of the 'No reportable' events check during E2B generation for follow up import, it is not possible to accept any follow-up report.

This scenario is encountered during Inform when other system sends un-encoded events to Argus.

This problem has been fixed only for custom PMDA profile. Argus Safety now has an option of excluding 'No Reportable' events check during PMDA E2B generation for transmission and import process based on a common profile switch 'PIP PMDA PROFILE'':

- 1. Argus Safety now excludes the 'No Reportable' events check for a PMDA E2B report for custom PMDA profile configured in the 'PIP PMDA PROFILE' switch. This will allow a follow up report for a configured custom profile to be imported even though there are no reportable events in the case.
- **2.** No Reportable events check is excluded for E2B generation both for transmission and import scenarios.

Device Report Responsible Officer

A new tree-node, **Device Report Responsible Officer**, has been added under Console > System Configuration > System Management (Common Profile Switches) > Argus J > Reporting. It has the following new switches in the same order as specified below:

- Responsible Officer Company Name: Textbox, Maxlength = 100
- Responsible Officer Department: Textbox, Maxlength = 100
- Responsible Officer Address: Textbox, Maxlength = 60
- Responsible Officer Telephone: Textbox, Maxlength = 50
- Responsible Officer Fax: Textbox, Maxlength = 50
- Responsible Officer Email: Textbox, Maxlength = 255

The existing common profile switch, **Offset from GMT used to calculate Japanese date/time fields for Interchange-J (in hours)**, under Console > System Configuration > System Management (Common Profile Switches) > Argus J > Reporting has been renamed to **Offset from GMT used to calculate Japanese date/time fields (in hours)** to remove the reference of Interchange-J and use it for device reports and E2B.

The following common profile switches are available under Common Profile > Argus J > Reporting > Device Report:

- SQL used to populate the Listedness field on the PMDA Device report form 8 (parameters: P_CASE_ID, P_PRODUCT_ID, P_LICENSE_ID, P_AGENCY_ID, P_ PROD_SEQ_NUM)
- SQL used to identify Events to be printed under Status of Patient's health damage field on the PMDA Device report form 8 and 10 (Parameters: P_CASE_ID, P_ PRODUCT_ID, P_LICENSE_ID, P_AGENCY_ID, P_PROD_SEQ_NUM)

The following table explains the fields used in the screen **Common Profile** > **Argus J** > **Reporting** > **Device Report**:

Field Name	Description	Field Options
Event counting logic for PSR Form 3, 4 and ReSD Form 4, 5	Default option is radio button option #1. If this	Count each event as reported in that timeframe
Form 4, 5	form 3,4 and ReSD Form 4,5 shall count all events from the timeframe reported.	Count each event from a case with the timeframe where the case was reported first.
	If radio option # 2 is selected, then the PSR Form 3, 4 and ReSD Form 4, 5 shall be updated to count / print all the events from case only under the timeframe where that case was reported first. Even if a new event (new event_seq_ num) from a case has been reported in an E2B / Paper Report to PMDA in the current reporting period, still it shall be counted / printed under the original timeframe.	
Event counting logic for PSR Form 3, 4 and ReSD Form 4, 5	If this common profile switch is set to "Yes", then when the case is locked from any point in Argus Safety application, it shall trigger the fresh calculation of the PMDA Event Reportability data.	Yes, No (Default).

Field Name	Description	Field Options
Listedness Assessment Source for PSR and ReSD	When switch is set to "Configured Datasheet", the listedness shall be determined based on the configured Datasheets.	Configured Datasheets, Case Event Assessment (Default).
	When the switch is set to "Case Event Assessment", the listedness is considered from the Case Event Assessment data in the following sections of the report:	
	a.PSR Form 3 (and ReSD Form 4)	
	b.PSR Form 4 (and ReSD Form 5)	
	c.ReSD Tabulations	
	i.Tabulation for UnListed Events	
	ii.Tabulation for Listed Events.	
Blinded text for PMDA AE Paper reports	Enables you to enter blinded text for PMDA AE Paper reports.	

3.1.1.1 Profile Switch for Incomplete Report Submission - Auto Action item

- When this action item is configured, the system creates an action item automatically when Incompletion report is submitted.
 (Mhlwadmicsrcompleteclass, 1=Incomplete, 2=Complete, Case Form/Analysis/PMDA/PMDA General/Incompletion checkbox)
- Blank (Default): if this option is present in the Action Item drop-down, the system does not create any Action Items for the Incompletion Report Submission (current functionality).
- Action Item drop-down (Codelist):
 - This option displays all the Action Items configured within the Code List Action type which are not deleted or allowed to be viewed.
 - If there is a value selected, the system creates an Action Item which would be Due in, as defined by you.
 - The **Due in** field allows you to enter up to 99 days.
 - The group assigned to the Action Item is Unassigned.
 - The Action Item is created as soon as the status of the Incompletion Report is changed to **Submitted**.
- The Audit Log tracks the updates made to this field.
- Once the Follow-up Completion Report is submitted, the Action Item associated to the report is **Closed** with the Close Date as the System Date (Server date).
- If the Follow-up report is still an incompletion report, the Action Item remains open.

- If the report is nullified (Nullification Report is sent), the Action Item is closed.
- When there are multiple incompletion reports from one case, the system creates the action items, which are same in number as that of the reports generated.
- The system appends a default text in front of description (J): Incompletion Report:
 XXX where XXX refers to the text entered in the Description (J) field.
- The Group can be assigned using the Follow-up Action Item for Incompletion Report Submission Group Assignment profile switch.

3.2 Configuring Field Level Validations

This section lists the configuration of fields in Argus Console.

3.2.1 Field Label Configuration (J Specific)

In order to change the field labels, to hide and unhide fields in Case Form, navigate to **System Configuration** > **Field Validation**. This displays the following screen:

DRACLE'				Welc	ome Pradeep Ra	aj Arusia (J), Mo	nday, March 8, 2	010 (ARMOD60)	Home Help
Code Lists Business Configur	ation	Access Management	System Configuration	Tools					
SE FORM FIELD CONFIGURATI	DN	Research Indonesia Rese							
owser		General Information	Contraction and an	C. M. C. State State State	500 C				
ganized by Pield Label		Field Name A	Field Form Label	field Form Label (J)	E28 Field	hidden	brug	Device	vaccine
<u> </u>	-	Case Central Safety Date	Central Hecept Date	センドラル油和人子日	No	NO			
AROUS SAFETY		Case Classification	Classification	万根 ボーカカリーンアッゴ	NO	NO			
GENERAL		Case Followup Data Clean up	bata Clean up	4493.60	No	No			
-Case Followup		Case Initial Receipt Date	Initial Heceipt Date	11111111111111111111111111111111111111	NO	NO			
Case Information		Case Report Type	Report Type	報告の種類	NO	NO			
- Case Study		Case Requires Follow-up	Case Requires Follow-up	道加戦省か必要な証例	No	No			
General information		Case Status	Case Status	証例ステータス	No	No			
Lterature		CLOSE DATE	Closure Date	症例終了日	No	No			
Reporter		Country of Incidence	Country	発現回	No	No			
PATENT		Date for Reports	Aware Date:	相告起算日	No	No			
Case Neonates		Date for Reports (J)	Aware Date:	報告起算日	No	No			
inedical status		Follow up Justification	Follow up Justification	追加情報の理由	No	No			
Parent information		Global ID	Global D	グローバルID	No	No			
Patient History		Master Priority Level	Case Priority	症例の優先順位	No	No			
Patient information		User Defined Date 1	UD Date 1	ユーザー定義日付 1	No	Yes			
Patient Lab Data		User Defined Date 10	UD Date 10	ユーザー定義日付 10	No	Yes			
Pregnancy		User Defined Date 11	UD Date 11	ユーザー定義日付 11	No	Yes			
Relevant Tests		User Defined Date 12	UD Date 12	ユーザー定義日付 12	No	Yes			
Braduet Vaccines		User Defined Date 2	UD Date 2	ユーザー定義日付 2	No	Yes			
Product Vaccries		User Defined Date 3	UD Date 3	ユーザー定義日付 3	No	Yes			
Ellico Device		User Defined Date 4	UD Date 4	ユーザー定義日付 4	No	Yes			
Product Device		User Defined Date 5	Date	ユーザー定義日付 5	No	Yes			
Product Device		User Defined Date 6	UD Date 6	ユーザー定義日付 6	No	Yes			
Product Drug / accine		User Defined Date 7	UD Date 7	ユーザー定義日付 7	No	Ves			
Product brog vacche		Liser Defined Date A	UD Date A	フーザー定義日付月	No	Ves			
Draduct information		Liner Defined Date 9	UD Date 9	フーザー定義日付り	No	Ves			
Draduct Vaccine									
Quality Control		Modify General Information							
Vaccine History		Field Name		Field Form Label					
Vaccine Prior AE		Case Central Safety Date		Central Receipt Date					
B C EVENTS		Help Text		Hidden	Read Only				
Event Assessment		Enter the date this case was init	ally received at your central sa	fety @ No	E prug				
Event Death		headquarters.		C Yes	Device				
Event Death Details			E E28 Field	E Vaccine					
Event Hospitalization		Selp Text (J)		Field Form Label (J)					
		安全管理本部が庭例の報	告を最初に受理した日付	を入 セントラル情報入	(手目				
Nature of Event		カしてください。							
Product Event Details									

Note: The Field Form Label (J) and Help Text (J) are visible on this screen (grid, data entry, and print) only to Argus J user, when Argus J module/license is enabled.

The following table explains the J specific labels on the screen mentioned above:

Field Name	Description
Field Form Label (J)	This field allows you to edit the field labels. It is valid only for the labels where label change is allowed. This is an optional field.
Help Text (J)	You can enter the help text here for a selected field. This is an optional field.

3.2.1.1 PMDA Downgrade/nullification Report Scenario when All Events are Non-Reportable

When reportable event is deleted from a Case Form by significant follow-up change, downgrade report against E2B to PMDA cannot be sent. Also, user is not able to send the nullification report when all the reportable events are deleted.

As per MHLW notification for investigational drugs, if reportable events disappears (becomes invalid events) by follow-up information and if there are no "reportable event" as result, it is necessary to report as nullification report. If reportable event(s) become non-reportable by follow-up information then a downgrade report is sent.

For Marketed drugs, when events in the case are updated in such a manner that none of the events in the case is valid then only nullification report is sent. If the reportable event becomes non-reportable by the follow-up information then a downgrade report shall be sent.

- Definition of "Non-Reportable" and "Invalid" events:
 - Non-Reportable events same as it exists today.
 - Invalid events are:
 - Deleted events and
 - Those events for which the "Not include for the report in Japan" (available in the Case Form | Japan Event tab) checkbox is checked
- The PMDA E2B follow-up Downgrade report is generated when all the valid events in the case became "non-reportable". A downgrade report shall:
 - Include all the latest valid events that exist in the case.
 - Ignore non-coded events as it has already been implemented in the current functionality.
 - Not reference previously submitted report's data.
- For Marketed reports (reporting categories (1, 2, 3 and 4), In a scenario when events in the case are updated in such a manner that none of the events in the case remains valid (as described in the point # 1b above) then the PMDA E2B Nullification report is generated.
- For investigational reports (reporting categories (8, 9, 10, and 11), if all the reportable events w.r.t. previously submitted report becomes invalid (as described in the point # 1b above) by the follow-up information then the PMDA E2B Nullification report is generated.
- As per the existing implementation, the nullification E2B report will get its data (including the REACTION section) from the previous submitted E2B XML.
- When the nullification E2b reports is auto-scheduled for the above mentioned scenarios:

- A new common profile switch "PMDA E2B Nullification Reason Text for No Valid Event Scenario" is created in console under Argus J > Reporting with default value in Japanese - (There is no valid event available in the case). The profile switch is a text box having a maxlength of 200 characters. It support English as well as Japanese data entry.
- The value specified in the common profile switch "PMDA E2B Nullification Reason Text for No Valid Event Scenario" is used for the value of E2B element A.1.13.1 NULLIFICATIONREASON in PMDA E2B.

This enhancement is applicable for PMDA E2B Downgrade/nullification reports.

3.3 Configuring Field Labels

This section displays the updates made to the user-defined fields.

3.3.1 User Defined Fields Updates

The Argus J system has the following:

Field Name	Field Form Label					
User Defined Number 1	UD Number 1					
lelp Text	Hidden	Read Only		Selectable	Add	
User defined field for entering numbers.	C No	Drug	#	English	Japanese	
	· Yes	Device	1	%	X	
	E2B Field	Vaccine	2	% (V/V)	(V/V)X	
lelp Text (J)	Field Form Label	(J)	22			
飯値を入力するためのユーザー定義されたフィールド	ユーザー定義番号 1					
टे न े						
					0.000	

- Argus J allows you to enter Japanese drop-down items as well as English.
- Only the English drop-down is a mandatory field. When the English drop-down value is not present, an error message, User Defined Dropdown English values can not be blank is displayed.

3.4 Configuring Local Reports - Local Reporting Rule and Local Reports

In order to control which reports need to be generated only after Local data entry is done, the application maintains a list of Report forms that are considered as Local Reports, by storing the following data fields:

- Country This is typically the country of license of the suspect product in a case for which there is a local reporting obligation. This could also be the local country expecting an active moiety reporting.
- Reporting Destination This is the reporting destination receiving the local report. This shall be populated based on user input during post upgrade script.
- Report Forms This is the local report. This is stored with the following reports for this release, as displayed in the image below:

- i. 医薬品 症例報告書 別紙様式1・2(Mktd 1,2)
- ii. 医薬品 研究報告調查報告書 別紙様式 3 · 4 (Mktd 3, 4)
- iii. 医薬品 外国での措置報告 別紙様式5・6 (Mktd 5, 6)
- iv. 治験薬 症例報告書 別紙様式1・2(Inv 1, 2)
- v. 治験薬 研究報告調査報告書 別紙様式3・4 (Inv 3, 4)
- vi. 治験薬 外国での措置報告 別紙様式5・6 (Inv 5, 6)
- vii. 報告様式8:医療機器不具合·感染症症例報告書
- viii. 報告様式10: 医療機器の研究報告調査報告書/外国措置調査報告書
 - ix. E2B

A reporting rule that is for the Country + Reporting Destination + Report Form is the Local Reporting Rule.

Any reporting rule that is for the country + reporting destination + report form configured in the above table and in addition satisfies the Truly Local Case system criteria for the case from which these rules are triggered (i.e., the SQL or PL/SQL block or the database function configured in the 2.3.0 returns a value > 0) is referred to as **Local reporting rules**.

Any report that is scheduled by a Local reporting rule is considered a Local report (note that this would have already satisfied the Truly Local case switch as described above).

For the purpose of this release, this configuration data is maintained via backend procedures and no maintenance facility needs to be provided via UI.

Note that to utilize the local locking feature, the customer is expected to maintain the proper **Reporting Destination** value in this table.

Expedited Reports generated as part of Periodic Reports are not considered local reports for this release.

Code List Configuration

This chapter lists the Japanese-specific (J-specific) features in the Code List Configuration module of Argus Console.

4.1 Code Lists

This section describes the functionality for the J specific Code List features.

4.1.1 General Functionality Changes

This section lists the Argus J general functionality Code List changes:

- **Sort Order**: The sort order for display of the elements in the Code Listing is based upon English element as default. For Japanese-only elements, the priority sort language is Japanese.
- **Print**: The PRINT functionality is modified to display all the Japanese fields also.
- If Japanese translation is not available for any drop-down (Code list/Factory Data), corresponding J values are shown on the UI in the drop-down but database values remain blank.
- J Fields Display:
 - All the J translation fields end with (J).
 - All the J specific fields are available only if J license is enabled.
 - All the J specific fields are available only for Argus J users. For English users, it is hidden.
- The following functionality is provided when the **Copy** function is used. Unless it is mentioned in each **CodeList** section, the following are the general rules for the copy function of Code List items:
 - When Argus Safety user copies the data, the equivalent Japanese data is not copied.
 - When Argus J user copies the data:
 - Copy of is appended in front of the data in the English field (First mandatory textbox field) which is same as current Argus Safety.
 - "TBD" is appended in front of the data in the (J) field (First mandatory J textbox field).
 - If the either English name (first mandatory English field unless specified) or Japanese name (first mandatory Japanese field unless specified) is not unique in the existing data table, and you click the Save button, the pop-up with a

message **A duplicate <field name> already exists**! is displayed to change the duplicate field value.

4.1.2 Device Reporting Category

A new Japan specific code list has been added under Console ' Code Lists ' Argus J menu option as "Device Reporting Category".

 Screen Mockup: The help text for this code list is - "The values entered here and marked as "Display" will appear in the - Product Device tab - PMDA Device -Medical Device Reporting Category drop-down list."

ORACLE				Vielcome Aditi a	Aggarwal Jap, Tuesday, A	ugust 6, 2013 (PR	703CER-DEFAUL	.T) Horne	i Help Clo
Code Lists Business Configuration	on Access Management System	n Configuration T	ools						
••••••••••••••••••••••••••••••••••••••			a fair						
CODE LIST MAINTENANCE									
CODE LIST MAINTENANCE	Device Develop Colores Eller								
Browser	Device Reporting Category Fater			Vature					
Organized by Code List	- I Held	-	adalaa 🖉	value	- Fritan				
🕞 🥁 Code List	1	-100	noens 🔄		THE ACCOUNTS				
Device Reporting Category	Total Number of Rows (5)								
- Car Emperor	Desire Reporting Category		5	Revice Reporting Category ()			1	lisolar	
J Reportable Product Keyword License Category Literature Type Reporting Category	Infection Report			感染症報告			X	(es.	
	Malfunction with health damage	Malfunction with health damage					Y	/es	
	Malfunction without health damage			不具合報告			Y	/es	
	Measures in Foreign Country Report			外国措置報告			٧	/es	
	Research Report			研究報告			Y	'es	
		13							
						Add New	Coss]]	Dalete.	Print
	Add New Device Reporting Category								
	Plevice Reporting Category								
				Display					
	* Device Reporting Category (J)								
The values entered here and marked as Display	-		1010						
will appear in the Case Form - Product Device	Note: "Add New" and "Copy" are not alle	wed for this Code List it	tem.						
tab - HNUA Device - Medical Device Reporting	-								

Field Name	Description
Device Reporting Category	Allows user to enter Device Reporting Category value in English.
Display	Allows user to display/hide a device reporting category in Argus Safety .
Device Reporting Category (J)	Allows user to enter Device Reporting Category value in Japanese.

- This code list now opens up by default in place of Emperor code list, when user selects Console > Code Lists > Argus J menu option.
- It is covered by the back-end PL/SQL APIs for Device Reporting Category data table updates and audit-logging.

4.1.3 Emperor

This dialog box allows you to add and configure various Japanese Emperor Data/Era. This is a J specific LM.

ORACLE						vielcome Adati Aggarwai Jap, Toesday	/, August 6, 2013 (PK/03CER-DE		
Code Lists	Business Configuration	Access Management	System Configuration	Tools					
DE LIST MAINTE	NANCE	<i></i>							
		Emperor Filter							
panized by Code Lin	t (•	Field			Value				
Code List		-	2	Contains	•	a.EziBet.a			
Code List Device Reporting Category		Total House of Doors (D							
J Cense Category		Total Hulfiber of Powes (4)							
		tmperor Name (J)		Emperor Name	2	Date in Office	Date Entry Abbr	Intry Abbreviation Display	
				Maina		00. JAN 1999		Ver	
Literature Type		明治		Meil		01-JAN.1968	M	Yes	
Benorting Category	873 ¥0		Syowa		25-DEC-1926	s	Yes		
							Add Num	I Destr. J. Pa	
		Add New Engers					Add Nes	H Dente H Par	
		Add Herry Engeror ¥ Engeror Hame ()				₹ Bate in Office	Add Nem	I Deste J. Pa	
p Test		Add Herry Engance Temporar Name (J)				T Bate in Office	Add Yess	I Prete Par	
Y Test	to configure The value of	Add New Traperor * Emperor Name () * Emperor Name				T Bate in Office	Add New Corre	1 - Director - 11 - Para	

The following table lists the fields used in the dialog box and their description:

Field Name	Description
Emperor Name (J)	This represents the label for the column of text boxes for entering the names of the Japanese Emperors.
Date in Office	This represents the label for column of text boxes for entering dates when the Japanese Emperors assumed their offices
	Date format DD-MON-YYYY
Display	You can select to display the record in Administrator route in the Products screen
Emperor Name	This represents the label for column of text boxes for entering the names of the Japanese Emperors.
Date Entry Abbreviation	This abbreviation is used as shortcut in Argus Safety and Console Date field to Japanese UI screens while entering year value.
	This Abbreviation is unique, and duplicate characters are not saved. When you try to enter a character that is already in use and save, a pop-up error message : A duplicate Date Entry Abbreviation already exists! is displayed, and the save operation is canceled.
PROTECTED	Internal Only - Protected Field

4.1.4 J Reportable Product Keyword

This code list allows you to associate keywords to Product Families. This is a J specific code list.

Help text: The keyword entered here and marked **Active** is matched with foreign, non-company suspected Product Name, and Generic Name. The associated Product Family's product is used for assessment in the **PMDA** tab.

ORACLE				Vielcome Ad	iti Aggarwal Jap, Tuesday, August 6, 2013 (PR703CI	R-DEFAULT) Home Help Clos
Code Lists Business Configuration	Access Management	System Configuration	Tools			
ODE LIST MAINTENANCE	12.5					
rowser	J Reportable Product Keywe	ord Filter				
rganized by Code List	Field			Value		
Code List		4	Contains	-	afebta.	
Device Reporting Category	Total Number of Rows (1)					
Enperor	Keyword 📥			Product Family (J)		Activate
J Reportable Product Keyword	J Reportable Key 1			WHO-		Ves
Calegory Calegory Calegory						
Reporting Category						
			20			
			13			
					Add New Cr	a Defete Print
	Add New Reportable Produc	t Keyword				
	* Keyword					
tip Text	Product Family (J)			M Activate		
is field allows the user to configure the value of J portable Product Keyword				Select		
						240

The following lists the fields used in the dialog box and their description:

Field Name	Description
Keyword	This field is used to enter keywords to search related company Product Family from foreign non-company suspected drugs.
Activate	By clicking this, you can decide if you want to include the keyword in the search.
Product Family (J)	If the keyword matches the foreign non-company suspected drug Trade Name or generic name, this Product Family is the target for assessment in Japan (in PMDA tab).
Select	When you click the Select button next to the Product Family, the Argus Product Browser is displayed to select the Product Family.
	If you type any text in the Product Family textbox, and click Select , the entered text is transferred to the Product Brower when you navigate away from the Product Family textbox.
	Once a Product Family is selected in the Product Browser, the Product Family name is transferred to the Product family textbox.

4.1.5 License Category

This dialog box allows you to add and configure various Japanese License categories. This is a J specific code list.

DRACLE		Welcome	e Pradeep Ra	j Arusia (J), Fr	iday, April 16, 2010 (ARMOD60)	Home Help
Code Lists Business Configuration	Access Management	System Con	figuration	Tools			
DE LIST MAINTENANCE							
wser	License Category Filter						
anized by Code List 💌	Field	Containe	Valu	ie	Filter		
🧉 Code List		Contains			[addressing	A	
🛅 Emperor	Total Number of Rows (6)						
J Reportable Product Keyword	License Category (J) 🔺		License C	ategory		E2B Code	Display
License Category Literature Type Depending Category	 一変治験中 (新有効成分、 型、配合剤など) 	投与経路、剤	Under clinic e ingredient c.)	al trial for partia s, admin, formul	I change (New activ ation, modification, et	4	Yes
Kepotang Calegory	一変治験中(用法・用量/ 変更/削除)	/効能・効果の	Under clinic y for chang	al trial for partia e on indication/li	l change (clinical stud stedness)	4	Yes
	承認2年以内		Within 2 yea	r of approval		2	Yes
	未承認		Not approve	d		3	Yes
	第一市販直後調査中		Under surve	aillance immedia	tely after put on mark	1	Yes
	該当なし		Does not ap	ply		5	Yes
	Add New Lisense Catagony			Ac	d New Copy	Dele	te Print
	License Category (1)				E2B Code		
a Taut	Listinge energy (J)				LED CODE	1.6	Display
field allows the user to configure the value of	V License Category						an 18 S.
POSE Category							

The following table lists the fields used in the dialog box and their description:

Field Name	Description
License Category (J)	This represents the label for entering PMDA License Category in Japanese.
E2B Code	This represents the label to enter the E2B value corresponding to the License Category Name.
Display	You can select to display the record in Administrator route in Products screen.
License Category	This represents the label for column of text boxes for entering the License Category in English.
PROTECTED	Internal Field - Protected

4.1.6 Literature Type

Use the following procedure to configure action taken:

- 1. From the Argus Console, select Code Lists -> Argus J -> Literature Type.
- **2.** When the system opens the Code List Maintenance screen, click Literature Type 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 Aggarwal Jap, Tuesday, August 6, 2013 (PR76	CER-DEFAULT) Home Help (
Code Lists	Business Configuration	Access Management	System Configuration	Tools			
CODE LIST MAIN	TENANCE						
Browser		Literature Type Filter			Mahar		
Organized by Code	ist 🔄	(ridu		Contains	*	Lafattera .	
Code List		1. Internet in the second seco	-			a to have a	
Device Re	porting Category	Total Humber of Rows (2)					
J Reported	e Product Keyword	Literature Type 📥			Literature Type (J)		Display
License C	ategory	VMDIS			准外医掌情報研究	7 4	Yes
- Cterature	Type						
- Cal Reporting	Category						
	6	l l					
	ា						
						Add New	env I profe I Paul
		Add New Literature Type					
		* Literature Type					
Help Test					P	Display	
The values entered wi	I be used for categorizing the	T Literature Type (J)					
Literature imported for	the Literature make.						

- **4.** This screen enables you to view the English and Japanese names of the configured categories. You can also set the display preferences for these code lists.
- **5.** Click Add to add a entry in the code list after filling the required information in the mandatory fields.
- **6.** Click Save to save any changes.

4.1.7 Reporting Category

Use the following procedure to configure action taken:

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

DE LIST MAINTENANCE						
weer	Reporting Citegory Filter					
anized by Code List	Field	- 10	Value	10000		
😼 Code List	1	210	ztens 🔄 🔄	1 Internet		
Device Reporting Category	Total Number of Power (15)					
Enperor	Descent Colonson	Description (D		Benedettee	TOD Code	Disalar
J Reportable Product Keyword	A A A A A A A A A A A A A A A A A A A	The set option (1)	ト (市飯谷)	Description Description report (Marketed down)	Eze Code	Ver
License Category	â	間の副体田庁の取る		Contestic/ADR second (Markedod drug)	1	Ves
Literature Type	0	外国威达在在例解:	5 (minista)	(harreast finite report (Marketer and))	-	Vet
Reporting Category	ň	外国副作用症例解释	(ingeta)	Overseas(ADR report (Marketed drun)	4	Ves
57	E	感染症研究報告 (古	5版(油)	Research/Infection report (Marketed drug)	s	Yes
0	r.	副作用研究報告 (計	5版(4)	Research(ADR report (Marketed drug)	6	Yes
	0	外国における製造中 (市販価)	P止、回収、廃棄等の措置報告	Measures in foreign countries including discontinuation of ma ure, recall and withdrawn (Marketed drug)	nufact 7	Yes
	н	国内感染症報告 G	h 教会)	Domestic/Infection report (Investigational drug)	8	Yes
	I.	国内副作用症例報告	5(治験)	Domestic/ADR report (Investigational drug)	9	Yes
	J	外国感染症症例報告	5(治療剤)	Overseas/Infection report (investigational drug)	10	Yes
	к	外国副作用症例報告	5(治験)	Overseas/ADR report (Investigational drug)	11	Yes
	L	感染症研究報告(治	50)	Research/Infection report (Investigational drug)	12	Yes
	M	副作用研究報告()	台懸矣)	Research/ADR report (Investigational drug)	13	Yes
	N	外国における製造中 (治験)	P止、回収、廃棄等の措置報告	Measures in foreign countries including discontinuation of ma ure, recall and withdrawn (Investigational drug)	nufact 14	Yes
	0	医革部外品研究解剖	5	Research report (Quasi drug)	15	Yes
	P	化粧品研究報告		Research report (Cosmetics)	16	Yes
					Add New Garry	Callela B
	A 14 Marshow Contraction Contraction				4	
	Add New Reporting Category					annome i emis
	Add New Reporting Category		Description (J)	E28 (Code	
	Add New Reporting Category 약 Reporting Category		Description (J)	E28 (Code	F Display
	Add New Reporting Category		Description (J)	E28.0	Code	C Display
	Add How Reporting Category Reporting Category		Description (J) Description	628 0	Code	Display

- **4.** This screen enables you to view the English and Japanese names of the configured categories. You can also set the display preferences for these code lists.
- 5. Click Save to save any changes.

Note:

When the nullification E2b reports is auto-scheduled for the No valid event scenarios, a new common profile switch called **PMDA E2B Nullification Reason Text for No Valid Event Scenario** has now been made available in Argus Console under the Argus J > Reporting menu.

The default value of this switch in Japanese is 'There is no valid event available in the case'. This switch can contain up to 200 characters and it supports English as well as Japanese data entry.

The value entered in this switch is used as the value of the E2B element A.1.13.1 NULLIFICATIONREASON in PMDA E2B.

The reason for nullification is populated when a nullification report is generated.

4.1.8 Literary Citation

The following is the list of the J Specific Literary Citation functionality changes:

- There is a note (only for J users) right at the end before the user action buttons displaying Note: Clicking the SAVE button will reflect the changes made on this English screen to the Japanese pop-up.
- The main English screen has a J Data Entry button, which is available only to J users.
- Clicking on the J Data Entry button displays a message to enter the data in the mandatory fields (Name) in English screen before opening the Japanese Translation Window.
- Clicking on the J Data Entry button displays a pop-up window as a resizable modal dialog with Japanese equivalent content where you are able to enter Japanese equivalent text for the corresponding field. The Japanese screen looks like this:

文献の変更 Webpage Dialog 本社の本本		
× mm// x 史 ♥ 雑誌名	標題	巻
著者名		発行年
		頁
注: この日本語ポップアップスクリーン上で行われた変更	」 目は"保存" ボタンを選択することにより英語のメインスクリー	一、二反映されます
	保存 キャンセル	

- The mandatory fields need to be filled in before displaying the Japanese pop-up, else the **J Data Entry** button displays a warning message: **Enter data in all the mandatory fields!**.
- The Japanese pop-up contains all the fields and all of them are editable.
- There is a note above the **Save and Cancel** button

The following functionality is provided while navigating from English screen to J pop-up for Existing Literature:

 On clicking of the J Data Entry button, you are prompted to save the data on the English screen before opening the J screen. The following is the Prompt message:

Do you want to save the changes before opening the Japanese screen?

- If you choose to save the data, the data is saved and the changes are reflected on the J Screen.
- If you choose not to save the data, the changes made on the English screen are not reflected on the J Screen .

The following functionality is provided while navigating from English screen to J pop-up for New Literature:

 On clicking of the J Data Entry button, you are prompted to save the data on the English screen before opening the J screen. The following is the Prompt message:

Data must be saved before opening the Japanese screen. Do you want to save?

- If you choose to save the data, the data is saved and the changes are reflected on the J Screen.
- If you choose not to save the data, the J screen does not open.

The following functionality is provided when the **Copy** function is used:

- When the Argus Safety user copies the data, the equivalent Japanese data is not copied.
- When Argus J user copies the data:
 - **Copy of** is appended in front of the data in the **Journal** field of English UI.
 - TBD is appended in front of the data in the **Journal** field of Japanese UI.
- If the English Literary Citation (all fields in the English section) is not unique in the existing data table, and you click the Save button or J Data Entry button, the pop-up with a message A duplicate Literary Citation already exists! is displayed to change the duplicate name.
- If the Japanese Literary Citation (all fields on **Japanese** section) is not unique in the existing data table, and you click the **Save** button in the J data entry pop-up, the pop-up with a message **A duplicate Literary Citation (J) already exists!** is displayed to change the duplicate name in the **J Data Entry** field.

The following is the Print template of the Literature Citations:

PELSVS				Co	ode List Ma	intenance
I KELSIS					09-May-2007	16;49 GMT+
Literature Citations						
As of 09 May 2007	0. dian	Title		Vor	Dogoo	
Mut 4	***	A S S			rayca	
4244-10	1818-0	Der ditt	8	3114	Ą	
Journal	Will Smith	Title	Vol-2	2007	999	
1 5 5 5 5 5 5	6 × 10 - 2 ≥ 2	与之际出	101-2	2001	000	

4.1.9 Reporting Destination

The following is the list of the J Specific Reporting Destination functionality changes:

The *Argus Console -> Code list -> Reporting Destination-> EDI* (tab) has been enhanced:

- In the Message Profile drop-down list, the PMDA E2B R3 profile (*ICH-ICSR V3.0 MESSAGE TEMPLATE PMDA*) is available to users for configuration.
- In the ACK profile, users can select the PMDA E2B R2 Ack Profile.
- The following fields in Reporting destination are populated with default values and displayed in the read-only for the PMDA E2B R3 profile (similar to the ICH E2B (R3) profile):
 - Encoding UTF-8
 - XML Version 1.0
 - Maximum # of reports to include in the msg-1
 - SGML (Disabled) / XML (Selected)
 - Identification Code (Agency Information and Local company contact Information)
 - Code Qualifier (Agency Information and Local company contact Information)
 - EDI header Required
 - URL for Message Schema and URL for Ack Schema
- The EDI -> Message Profile 2 drop-down list has been blanked and disabled for all the R3 Profiles including PMDA E2B R3 profile.(This drop-down list is only visible to a J user).

4.1.10 Manufacturers

The following is the list of the J Specific Manufacturers functionality changes:

- There is a note (only for J users) right at the end before the user action buttons displaying Note: Clicking the SAVE button will reflect the changes made on this English screen to the Japanese pop-up.
- The main English screen has a J Data Entry button, which is available only to J users.
- Clicking on the J Data Entry button displays a message to enter the data in mandatory fields (Name) in the English screen before opening the Japanese Translation Window.
- Clicking on the J Data Entry button displays a pop-up window as a resizable modal dialog with Japanese equivalent content where you are able to enter Japanese equivalent text for the corresponding field. The Japanese screen looks like this:

♥ 会社名	担当者	登録番号		
レルシスインターナ・ 住所	ショナルロー市	都道府県	郵便番号	
	围	電話番号	Fax	
注: この日本語ポップア・	ップスクリーン上で行われた変更は"	▲ 保存"ボタンを選択することにより英語の:	メインスクリーンに反映されます	

• The mandatory fields need to be filled in before opening the Japanese pop-up, else the **J Data Entry** button displays a warning message:

Enter data in all the mandatory fields!

- The Japanese pop-up contains all the fields and all of them are editable.
- There is a note above **Save and Cancel** button.

The following functionality is provided while navigating from English screen to J pop-up for Existing Manufacture:

• On clicking the **J Data Entry** button, you are prompted to save the data on English screen before opening the J screen. The following is the prompt message:

Do you want to save the changes before opening the Japanese screen?

- If you choose to save the data, the data is saved and the changes are reflected on the J Screen.
- If you choose not to save the data, the changes made on the English screen are not reflected on the J screen .

The following functionality is provided while navigating from English screen to J pop-up for New Manufacture:

 On clicking the J Data Entry button, you are prompted to save the data on the English screen before opening the J screen. The following is the Prompt message:

Data must be saved before opening the Japanese screen. Do you want to save?

- If you choose to save the data, the data is saved and the changes are reflected on the J Screen.
- If you choose not to save the data, the J screen does not open.

The following functionality is provided when the **Copy** function is used:

- When the Argus Safety user copies the data, the equivalent Japanese data is not copied.
- When the Argus J user copies the data:
 - Copy of is appended in front of the data in the Name field of the English UI.
 - "TBD" is appended in front of the data in the **Name** field of Japanese UI.
- If the English name is not unique in the existing data table, and you click the Save button or J Data Entry button, the pop-up with a message A duplicate Name already exists! is displayed to change the duplicate name.
- If the Japanese name is not unique in the existing data table, and you click the Save button in the J Data Entry pop-up, the pop-up with a message A duplicate Name (J) already exists! is displayed to change the duplicate name in the J Data Entry field.

4.1.11 Reporter Information

The following is the list of the J Specific Reporter Information functionality changes:

- There is a note (only for J users) right at the end before the user action buttons displaying Note: Clicking the SAVE button will reflect the changes made on this English screen to the Japanese pop-up.
- The upper grid does not have Phone, Alt.Phone, Fax column (for Both English and Japanese users), and has a new 2nd column for First Name (J), Last Name (J), and ID (J) for Japanese user only.

- The main English screen has a J Data Entry button, which is available only to J users.
- Clicking on the J Data Entry button displays a message to enter the data in mandatory fields (Name) in English screen before opening the Japanese Translation Window.
- Clicking on the J Data Entry button displays a pop-up window as a resizable modal dialog with Japanese equivalent content where you are able to enter Japanese equivalent text for the corresponding field. The Japanese screen looks like this:

收称 名	₹ 9±	サフィックス	ID	職種
久仁	杵村	先生	004	医師 💊
服告者の種類		部署		
病院	💌 🗹 医療専門家			
主所	市	都道府県		郵便番号
-2-3美味町	世田谷区	東京都		233
	E	電話番号		その他の電話番号
	日本	03-333-9999		
AX	Eメール	優先する連絡方法	£	
			🛛 電子	「伝送の受取人
MLER.				

• The mandatory fields need to be filled in before opening up the Japanese pop-up else the **J Data Entry** button displays a warning message:

Enter data in all the mandatory fields!

- The Japanese pop-up contains all the fields and all of them are editable.
- There is a note above **Save and Cancel** button.

The following functionality is provided while navigating from English screen to the J pop-up for Existing Reporter:

• On clicking the **J Data Entry** button, you are prompted to save the data on English screen before opening the J screen. The following is the prompt message:

Do you want to save the changes before opening the Japanese screen?

- If you choose to save the data, the data is saved and the changes are reflected on the J Screen.
- If you choose not to save the data, the changes made on the English screen are not reflected on the J Screen .

The following functionality is provided while navigating from English screen to the J pop-up for New Reporter:

• On clicking the **J Data Entry** button, you are prompted to save the data on the English screen before opening the J screen. The following is the prompt message:

Data must be saved before opening the Japanese screen. Do you want to save?

- If you choose to save the data, the data is saved and the changes are reflected on the J screen.
- If you choose not to save the data, the J screen does not open.

The following functionality is provided when the **Copy** function is used:

- When the Argus Safety user copies the data, the equivalent Japanese data is not copied.
- When the Argus J user copies the data:
 - Copy of is appended in front of the data in the Name field of the English UI.
 - "TBD" is appended in front of the data in the **Name** field of the Japanese UI.
- The Duplicate last name can be saved. If the English ID is not unique in the existing data table, and you click the **Save** button or the **J Data Entry** button, the pop-up with a message **A duplicate ID already exists!** is displayed to change the duplicate value.
- If the Japanese ID is not unique in the existing data table, and you click the Save button in the J Data Entry pop-up, the pop-up with a message A duplicate ID already exists! is displayed to change the Duplicate ID in the J Data Entry field.

The following is the Print template of the Reporter Information:

REL	SYS				09-May-2007 16:49 GMT+7
Penorters					
As of 09 May 200	7 Health Prof			Phone	Email
Reporter ID Occupation	Reporter Type Department	Institution	Address City, State, Postal Code Country	Alt. Phone Fax	Electronic Transmission Receipt Preferred Method
名前 報告者 D 職種	医麦専門家 報告者の種類 夢客	施設	回 住所	電話番号 その他の電話番号 Fax	Eメール 電子伝道の受取人 優先する連絡方法
Dr First Last 121 Investigator Dr.野村 義男 121	No Company Representative Safe ty Division いいえ 会社代表	Kaiser Hospital Tokyo University Hospital Yokohama University Hospital カイザーホスピタル 増益(度学士学病院	123.Main.Street City, CA 8976 UNITED STATES 米国 8976 カリフォルニア州メイン市	341-908-9087 453-908-9087 564-786-9087	abc@yahoo.com
PLA	X & LT BYI J		X4 7XF0=F123		

- The Japanese print out of **Name** section consists of:
 - Title
 - Last Name
 - First Name
 - Suffix
- The Japanese print out of **Address** section consists of:
 - ZipCode
 - State
 - City
 - Street Address
- The Institutions are printed with line feed.

4.1.12 Flexible Data Re-Categorization

The flexible data re-categorization feature allows Argus Safety and its associated applications, such as Argus Mart and Argus Insight, to handle the code list values with more flexibility.

This feature allows applications and customers to store and maintain all types of code list values in a single flat database table structure which is easier to maintain. This code list data storage design can be leveraged to easily add new and custom code lists or values without adding new database tables and columns.

The Flexible Data Re-Categorization feature allows administrators to manage and display the existing and new code list items. You can edit the custom language attribute E2B_R3 and its values.

The following code lists are available under Console > Code List > Flex Data Re-Categorization.

For more information on Flexible Data Re-Categorization, see the *Oracle Argus Safety Administrator's Guide*.

4.1.12.1 Reporting Category (LM_RPT_CATEGORY)

Code listed data in the following table has been added and is synchronized with the Reporting Category flex bucketing code list as indicated in the following table. New language attribute E2B_R3 has been added to flex bucketing code list ID, REPORTING_CATEGORY.

Description	E2B_R3	
Domestic/Infection report (Marketed drug)	AA	
Domestic/ADR report (Marketed drug)	AB	
Overseas/Infection report (Marketed drug)	AC	
Overseas/ADR report (Marketed drug)	AD	
Research/Infection report (Marketed drug)	AE	
Research/ADR report (Marketed drug)	AF	
Measures in foreign countries including discontinuation of manufacture, recall and withdrawn (Marketed drug)	AG	
Domestic/Infection report (Investigational drug)	DA	
Domestic/ADR report (Investigational drug)	DB	
Overseas/Infection report (Investigational drug)	DC	
Overseas/ADR report (Investigational drug)	DD	
Research/Infection report (Investigational drug)	DE	
Research/ADR report (Investigational drug)	DF	
Measures in foreign countries including discontinuation of manufacture, recall and withdrawn (Investigational drug)	DG	
Research report (Quasi drug)	BC	
Research report (Cosmetics)	BD	

4.1.12.2 License Category (LM_LIC_CATEGORY)

Code listed data in the following table has been added and is synchronized with the License Category flex bucketing code list as indicated in the following table. New language attribute E2B_R3 has been added to flex bucketing code list ID, LICENSE_CATEGORY.

Category	E2B_R3
Under surveillance immediately after put on market	1
Within 2 year of approval	2
Not approved	3
Under clinical trial for partial change (clinical study for change on indication/listedness)	4
Under clinical trial for partial change (New active ingredients, admin, formulation, modification and so on)	4
Partial change during clinical trial	4
Does not apply	5
During the re-review period (Medicines that Require Pharmacist Intervention)	6
During the PMS period (Medicines that Require Pharmacist Intervention)	7

4.1.12.3 Dev Phase (LM_DEV_PHASE)

Code listed data in the following table has been added and is synchronized with the Dev Phase flex bucketing code list as indicated in the following table. New language attribute E2B_R3 has been added to flex bucketing code list ID, DEV_PHASE.

DEV_PHASE	E2B_R3
Microdose tests and so on	0
Phase I	1
Phase II	2
Phase III	3
Phase I/II Trial)	4
Phase II/III Trial	5
Biological equivalence study	8
Clinical pharmacology study	8
Preparation NDA submission	8
NDA submitted	7
Other	8

4.1.12.4 Risk Category of OTC Drug (LM_RISK_CATEGORY_OTC)

Code listed data in the following table has been added and is synchronized with the Dev Phase flex bucketing code list as indicated in the following table. New language attribute E2B_R3 has been added to flex bucketing code list ID, DEV_PHASE.

RISK_CATEGORY	E2B_R3
Class I OTC drugs	01
Class II OTC drugs	02
Designated Class II OTC drugs	2S
Class III OTC drugs	03
Medications manufactured and marketed by pharmacies	04
Medicines that Require Pharmacist Intervention	05

4.1.12.5 Route for Acquiring OTC Drug (LM_ROUTE_ACQUIRE_OTC)

A new list Route for acquiring OTC Drug has been added and is available for editing only through the Flexible Data Re-categorization. The language attribute E2B_R3 has been added to flex bucketing code list ID, ROUTE_ACQUIRE_OTC.

Route	E2B_R3
Sold over the counter at pharmacies, and so on	S
Household distribution	Н
Mail order via the internet	Ι
Other mail order (telephone, and so on)	Т
Checked but unable to obtain information	ASKU
	This denotes a Null flavor value.
Unable to confirm for unavoidable reasons, unknown	UNK
	This denotes a Null flavor value.