# Oracle Argus Safety Japan Administration Guide



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ORACLE

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# Preface

This preface contains the following sections:

- Documentation accessibility
- Diversity and Inclusion
- Related resources
- Access to Oracle Support

# Documentation accessibility

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

# **Diversity and Inclusion**

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

# **Related resources**

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

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

# Access to Oracle Support

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- English interface of Oracle Life Sciences Support Cloud (https:// hsgbu.custhelp.com/)
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# 1 Business Configuration

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

For more information, see:

- Configuring Product Family
- Configuring Products
- Configuring Licenses
- Configuring Studies
- Configuring Expedited Reporting Rules

# **Configuring Product Family**

The following table displays the Japanese specific fields:

Field	Description
Product Family Name (J)	Enter a new product family name in Japanese.
Comments (J)	Enter the comments.

#### Note:

These fields are displayed only to an Oracle Argus Safety Japan (Argus J) user when the Japanese module is enabled.

The fields are printed in the Product Family Configuration print PDF and are covered by the back-end PL/SQL APIs for Product Family Configuration data table updates and audit-logging.

# **Configuring Products**

The following table lists the Japanese specific fields in the Product screen:



Field	Description				
J-DRUG ⊐∽ ⋡	Captures the J Drug Code for each ingredient of the product. This field is configured from Argus Console > Business Configuration > Product and Licenses > Product (J Data Entry) > Key Ingredients > J-Pop-up.				
	<ul> <li>This is a text field, and is audit logged.</li> <li>When the product is added to any case, the Ingredients are populated under Case Form &gt; Product &gt; Substance Information. The J Drug Code of the Ingredient is also populated as configured in Oracle Argus Safety Console.</li> </ul>				
医療機器の一般名 (Device Generic Name)	Provides the Device Generic Name from the JMDN glossary.				
JMDN コード (JMDN Code)	Provides the JMDN Code from the JMDN glossary.				
使用辞書コード (Terminology Code)	Provides the Terminology Code from the JMDN glossary.				
J-DRUG コード for Product (J Drug Code or OTC Code or Temp Code)	Provides the J Drug Code from the Drug Coding dialog box. You can manually configure the OTC Code or Temp Code if the J Drug Code is not available for the product.				

#### Note:

The other fields on this window, such as Product Name (J) or Ingredient Name (J) are equivalent Japanese values to the corresponding English fields.

# **Configuring Licenses**

The following section describes the changes in License Configuration:

- License Configuration
- Exclude from Report Candidates option

# License Configuration

The following table displays the Japanese specific fields on the License Configuration window:

Field	Description
PMDA Re-examination Date	The date of the next PMDA examination.



Field	Description
Clinical Compound Number	The number that identifies the specific chemical compound.
	<ul> <li>You can edit this field when the Authorization Country is Japan and the license type is either Investigational Drug or Investigational Vaccine.</li> </ul>
	<ul> <li>The Clinical Compound field is only available to users to Oracle Argus Safety Japan.</li> </ul>
TIKEN	Selecting the TIKEN check box indicates that the customer will not send the investigational report for the other license.
Blind J.10/J2.11 in PMDA AE Paper Report	This check box is disabled by default and shall be enabled only when the License country is Japan.
Medicinal Product Name	This field is to transmit the investigational products for the DC or DD reporting category in G.k.2.2. This configuration could be used in specific use cases as per the PMDA guidance if:
	<ul> <li>The drug has multiple CCNs (Clinical Compound Numbers).</li> </ul>
	<ul> <li>It is used for different studies due to a different route of administration.</li> </ul>
	<ul><li>The active ingredient is approved in JP.</li><li>It is a foreign CT report.</li></ul>
PMDA Device Classification 1	This field PMDA Device Classification 1 is for configuring Device Classification printed in PMDA Device report.
PMDA Device Classification 2	This field PMDA Device Classification 2 is for configuring Device Classification printed in PMDA Device report.
PMDA Device Classification 3	This field PMDA Device Classification 3 is for configuring Device Classification printed in PMDA Device report.
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 <b>Print</b> and <b>Print All</b> options. They also support the License/Product with Licenses copy functionality. Any changes to these fields value is logged for audit.

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.



The 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.

Note:

Other fields, such as Trade Name (J) or Comments (J), are for Japanese data entry equivalent to English fields.

## Exclude from Report Candidates option

- The option Exclude from Report Candidates has been added to Oracle Argus Safety Console > Business Configuration > License Configuration as shown below.
  - This check box is displayed to only an Oracle Argus Safety Japan user and when Japanese module is enabled.
  - By default, this field is unchecked.
  - This check box 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_RV	01-JAN-1980	00-MMM-0000
Trade Name(J)	PMDA Re-examination Date	
		Exclude from Report Candidates
Market Authorization Holder	Eiologic / Vaccine	Not in Tradename Lookup / Not Auto-Scheduler
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 check box is not selected for that product license combination
  - Not in Tradename lookup/Not Autoscheduled check box is not selected
  - Exclude from Report Candidates check box 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 check
   box.
- 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 check box 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 check box 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 check box 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 check box 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 check box 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.

# **Configuring Studies**

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

The following list displays the Japanese specific fields:

- 治験成分記号 (Clinical Compound Number)
- 対象疾患(使用理由) (Target disease)
- 投薬中の症例の有無 (Are any subjects given this investigational drug?)
- 届出回数 (Notification Number)
- Test Drug Type

#### Note:

This field can be used to configure the type of drug as required for the PMDA reporting by using this configuration in the advanced condition SQL queries for the reporting rules.



After selecting a J Drug, the user must add it to the product section of the J pop-up. The column called **WHO Encoded?** has been added to the product grid. If the J Drug

is not associated with a WHO drug, an  $\square \square \square \square \square \square \square \square$  ("Encode") button appears in the column. Clicking this button opens the WHO Drug Browser, so the user can associate the J Drug with the corresponding WHO drug, if it is available. This step is not mandatory. Once the J Drug has been associated with a WHO drug, the button is replaced with the letter **Y**, meaning "Yes".

Note: Clicking the ビンコード (Encode) button opens the English version of the WHO Drug Browser.

Before closing the J pop-up, the user is reminded to associate the J Drugs with WHO drugs if the association has not been made for all the J Drugs. This is not mandatory.

The application has been enhanced such that when you add 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 the corresponding WHO drug remains intact. When the user tries to associate the J Drug with the WHO drug, by clicking the WHO Drug association button such that English Drug name is not blank (or default text *J DRUG*), the WHO Drug Browser opens with the pre-populated English Drug Name (populated from the English sub file) in the Trade Name (text box) of the WHO Drug Browser, for the user to perform a quick search. Also, when the user associates the J Drug to the WHO drug, 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 which the 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).



- The 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.

 The 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.

当からす		
対象疾患(使用理由)		
投薬中の症例の有無		
届出回数	23	

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.

# **Configuring Expedited Reporting Rules**

When you configure a reporting rule report from Console > Business Configuration > Expedited Reporting Rules and if you select PMDA Device Report in the Form drop-down menu, then the application populates ichicsr in the Message Type drop-down field and disables it.

The following list displays the Japanese specific fields and information:

- Reporting Category
- License Category



Device Reporting Category

The drop-down list **Device Reporting Category** has been added to Oracle Argus Safety Console > **Business Configuration** > **Expedited Reporting Rules** screen as follows:

Code Lists	Business Configuration	Access Management	System Configuration	Tools							
EXPEDITED REP	ORTRULES										
Browser		AK PMDA Device XML 15 d	ays								
Organized By Con	untry / License Type / Reportin 🗸	Report Name					Preport Destination				
Containe V	Filter	AK PMDA Device XML 15 da	аув				PMDA Device				
Displaying Rows 1-11 (11)				Protect Reporter and Patient Confidentiality HCP Case							
		Y Origin of events to incluse	de:				Report on Drug No	t Administered	🗌 No Follo	w-up or Downgrade	
B- 🎽		🗹 Domestic 🗹 Foreign		🕈 Timeframe	15 days		Active Molety				
AUSTRIA (1	1)	Adjust due date for Group	2 Countries by	days							
EUROPEAN	N UNION (4)	Force Distribute	days before	e due		Lister	edness (Event)				
GERMANY	(5)	🖲 Form				lana	ore				
#- [] ITALY (3)		PMDA Device				1					
JAPAN (19	ə)	Local Comment Type	c	linical Reference Typ	e	Serio	ousness				
Investig	ational Device (0)		✓ 1	Ignore	~	Fatal	ULife Threatening	Serious	Event)	Serious (Case)	
E Investigational Drug (6) Language Message Type				Sever	Severity (Event)						
Danvestigational Vaccine (0)			<b>v</b>	V Ichicsr V			Ignore				~
🕀 🚰 Markel	ted Device (1)	Product Specific									
🗟 AK	PMDA Device XML 15 days	Product Group				Eamily	v Name				
🕸 🛄 Markete	ed Drug (11)	-All-				-All-	,				~
🗷 🚞 Marketi	ed Vaccine (1)	Caucality									
🕸 🚞 KOREA, RE	EPUBLIC OF (6)	Causanty	Include New Obstant Telef Oct								
🕸 🦳 SPAIN (5)		Most Conservative	include Non-Clinical That Cas	ses							
🕸 🛄 TURKEY (1	I)	As Reported (Event)		As Determined (Even	9	As Re	eported (Case)		As Determined (Car	86)	
🖶 🚞 UNITED KI	NGDOM (2)	Ignore	~	Ignore		<ul> <li>Ignore</li> </ul>	re	~	Ignore		~
🕸 🛄 UNITED ST	TATES (18)	Advanced Condition				Respo	onsible Group		Cover Letter		
🗄- 🚞 WORLD (1)		(None)						~			×
		Reporting Category	1	License Category		Devic	ce Reporting Category		Super Rule - Cel	ase evaluation of norm	ai rules upon
			~			✓ Dome	nestic defect case report	~	Evaluate Produc	t/License for Report Sc	heduling
		Comments									
		1									

- 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 1-1 Figure 1-3 Console Expedited Reporting Rules Configuration - Print PDF

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



# 2 System Configuration

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

- Configuring Common Profile Switches
- Configuring Field Level Validations
- Configuring Field Labels
- Configuring Local Reports Local Reporting Rule and Local Reports

# **Configuring Common Profile Switches**

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

- Common Profile Switches for Oracle Argus Safety Japan
- Common Profile Switches for Reporting
- Common Profile Switches for Device Report
- Common Profile Switches for E2B

## Common Profile Switches for Oracle Argus Safety Japan

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

Code Lists	Business Configuration	Access Management	System Configuration	Tools				
COMMON PROP	COMMON PROFILE - Argus J							
Browser		Modify Argus J						
Organized by Con	nmon Profile 🗸 🗸	Default viewing format of t	he PMDA E2B R2 report (used	with Interchange-J				
🖃 🚰 Common Profi	e							
Calanced C	onditions	O I SOM						
🖶 🧰 Argus Dossier								
🖶 🚰 🗛 Argus J								
Background	Services							
Case Form	Configuration	PMDA Paper Form						
Case Proce	essing	Default viewing format of t	he PMDA E2B D3 report (used	with Interchance, I				
Database				and interestingers,				
Document N	fanagement	Decode View						
Help		O LUI 716mm						
Local Label	ing	O Depart lifery						
Network Se	ttings	O Paper View						
Reporting		Default Report time to be selected when Literature lotake item is booked in						
Single Sign	00	×	Detext report type to be service when it is booked-in					
System Mai	ntenance							
- User Interfa	ce	Shared Path for the Literature Intake						
Workflow		C/softwareVLIT						
		Japan License to be quelle	ble in case for Assessment on	d Deporting				
		All valid Janan Licensee	one in cuse for Assessment un	arceporting				
		Ali valu Japan Licenses						
		C User Selected License of	ny					
		On Adding/Updating the C	ase form > Events > Descriptio	n as Reported by E	nolish user. Auto populate the Description as Reported on the Japanese side with:			
		English Verbatim						
		Japanese PT (From Med	dra J)					
		Allow user to update the 'F	eason for Downgrade/Nullifica	tion report' and 'Co	mments for start date of reporting timeframe' after the case is locked (globally and locally locked)			
		Yes						
		O No						
1								

The following table explains the fields used in the screen:



Field Name	Description	Field Options
Default viewing format of the	The field represents the formats for	XML
with Interchange-J)	with Interchange-J)	Decoded
	Default Value is Decoded.	HL7
PMDA F2B R2 report (used	I his field represents the default viewing format of the PMDA E2B R2 report	I SGML
with Electronic Submission	(used with Electronic Submission	
Module (Interchange-J))	Module (ESM)).	I Decoded View
	When <b>PMDA Paper Form</b> is selected, the system determines the correct paper format from the <b>Reporting Category</b> E2B item and creates paper draft image.	PMDA Paper Form
	Default Value: 1	
Default Report type to be selected when Literature Intake item is booked-in	This field represents the default report type value for <b>Book-in</b> screen for cases booked-in through Literature Cases.	Report Type configured in Oracle Argus Safety Japan
	Default Value is blank.	Console
Shared Path for the Literature Intake	This field represents the shared path for the Literature Intake.	Maximum Length: 255
	Default Value is blank.	
	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 duedays after specified end date	
	Investigation Timeframe/Start Date	
	Investigation Timeframe/End Date	
	Report Batch Printing popup / Run at	
	Report Batch Printing popup / Due Date	
	Oracle Argus Safety Japan Console:	
	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 Oracle Argus Safety Japan Console SRS <b>Population Rule</b> section.	
	All the regular fields that have A (Alphanumeric only) in Input Lang Type classification of Oracle Argus Safety Japan Console SRS.	
	Default Value is checked.	

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

# Common Profile Switches for Reporting

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

			Marrie Mater
ORACLE	Welcome Administrator, Thursday, July 16, 201	9 (A\$813)	nome nap
Code Lists Business Configuration	Access Management System Configuration Tools		
COMMON PROFILE - Argus J Reporting			
Browser	Modify Argus JReporting		
Organized by Common Prote  Common Prote Common Prote Anance Constance Anance Constance Anance Constance Anance Constance Anance Constance Common Constance Background Societs Common Configuration Common Com	Palor System for the transporterion Report Submission Date In  Falor System State Institute Transport Submission Group Assignment Auto StateMedian Submission Company Auto StateMedian Submission Company		
🗐 🛅 Case Processing			
Costasse	Teal & dealpars a comment when a dwanguided report is scheduled (本語音文)(金)(出版)語音+a		
Reporting     Security	Ardo Enterholmon Transmission Commerts (/)		
- Uning Composition	Event counting logic for 91% From 3, 44 and Red D Form 50, 11 Count each end on a scale with the limitation Recordsol in the Interfamily Recordsol in the Interfa		
	Luktores Assessment Source Jer FR and Te 50 (Deprecated) Condepared Statement @ Case Even Assessment		
	Offset free GMT seed to calculate Agamese data time fields (in hours) 9		
	Manked Form 12 下AI開告/安全部医風音安全課 前中1		
	Mananet Form 14 「作山間也」/規模学会部業業品安全課 前中」		
Help Text	Maratef zom 5.5	_	

The following table explains the fields used in the screen:



Field Name	Description	Field Options	
Follow-Up Action Item for Incompletion Report Submission"Due In days"		Populated based on Action Type Code list values (not deleted and not hidden)	
		For more information, see Profile Switch for Incomplete Report Submission - Auto Action item .	
Follow-up Action Item for Incompletion Report	This field represents the user group to which the Incompletion Report	User Groups from Console	
Submission Group	Submission Action Item is assigned.	For more information,	
, toolgriniont	Default value is blank.	See Profile Switch for Incomplete Report Submission - Auto Action item .	
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 <b>Auto Submission Comments</b> , but when J user is on the system.		
Text to display as comment	The field length is 2000 J.		
when a downgrade report is scheduled	The text appears in the <b>Report Detail</b> > <b>Comment</b> tab.		
Auto Distribution	This field allows you to enter the	Field Length: 1000	
Transmission Comments (J)	for Expedited Reports Transmission, which are auto-distributed by the system based on Expedited Reporting Rules or Reporting Destinations.	Audit Log: Yes	
	These comments are used in the same way as <b>Auto Distribution Comments</b> , but when J user is on the system.		

Field Name	Description	Field Options	
Event counting logic for PSR Form 3, 4 and ReSD Form 10, 11	Option 1 is deprecated. Option 2 - If this option is selected, then the PSR Form 3, 4 and ReSD Form 10, 11 is be updated to count or print all the events from the 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 or Paper Report to PMDA in the current reporting period, it must be counted or printed under the original timeframe.	<ol> <li>Count each event as reported in that timeframe (Deprecated))</li> <li>Count each event from a case with the timeframe where the case was reported first.</li> <li>Count each event from a case with the timeframe where the</li> </ol>	
	Option 3 - If this option is selected, then the PSR Form 3, 4 and ReSD Form 10,11 are updated to count or print the events from the latest submitted E2B or Paper Report in the latest timeframe where it was reported across all the timeframes for which the report is executed.	case was reported last.	
Listedness Assessment Source for PSR and ReSD (Deprecated)	The common profile switch "Listedness Assessment Source for PSR and ReSD" is marked as deprecated. Instead a new report level parameter is added "Listedness Assessed on" in PSR/ReSD configuration window.	Configured Datasheets Case Event Assessment	
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-JDefault Value: 7		
Blinded text for PMDA AE Paper reports	Enables you to enter blinded text for PMDA AE Paper reports.		
Major Developed Countries for Approval Status in J- DSUR	This field lists the countries to be considered as major developed countries for J-DSURs.	Text box with 1000 characters limit, without any default value.	
		Users can also configure comma- separated A2 country codes.	
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.	

Field Name	Description	Field Options	
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 <b>Perform Japanese</b> <b>character validation</b> <b>at E2B Check and</b> <b>E2B Report</b> <b>Generation</b> When the <b>Perform</b> <b>Japanese character</b> <b>validation at E2B</b> <b>Check and E2B</b> <b>Report Generation</b> checkbox is unchecked, this field is disabled.	
Characters to be allowed to use in AN (Alphanumeric) E2B items	In this field, you can enter English characters allowed in Oracle Argus Safety Japan. 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: ABCDEFGHIJKLMNOPQRSTUVWXYZ abcdefghijkImnopqrstuvwxyz012345678 9.E+- !"#\$%'()*+,:;=?@[\]^_/{[]~		
Perform PMDA Event Reportability calculation on each Case Lock	If this common profile switch is set to "Yes", then when the case is locked from any point in the Oracle Argus Safety application, it triggers fresh calculation of the PMDA Event Reportability data.	Yes, No (Default).	
PMDA E2B Nullification Reason Text for No Valid Event Scenario		No For more information, see PMDA Downgrade/ nullification Report Scenario when All Events are Non- Reportable	

Field Name	Description	Field Options
Product details printing format in PSR NUPR - Word format	When you select Option 1 ( <b>Print Trade</b> <b>Name, Formulation, Strength, Drug</b> <b>code as available</b> ), the application prints data in the format <trade name<br="">(J)&gt; (<formulation (j)="">space<strength> <unit (j)="">) (Drug Code (J)). If the Formulation or Strength fields (or both) do not contain value, then prescribed text is printed to indicate that they are unknown.</unit></strength></formulation></trade>	
	When you select Option 2 ( <b>Print Trade</b> <b>Name unknown when Formulation or</b> <b>Strength not available</b> ) the application prints data in the format: <trade name<br="">(J)&gt; (<formulation (j)="">space<strength> <unit (j)="">) (Drug Code (J)). If the Formulation or Strength fields (or both) do not contain value, then the application prints only the J Drug Code.</unit></strength></formulation></trade>	

For more information, see:

- Profile Switch for Incomplete Report Submission Auto Action item
- PMDA Downgrade/nullification Report Scenario when All Events are Non-Reportable

#### 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.

# 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.

## Common Profile Switches for Device Report

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

COMMON PROFILE - Argus J Reporting De	evice Report
Browser	Modify Argus J[Reporting]Device Report
Organized by Common Profile V	Responsible Officer – Address
E-P Common Profile	This is configurable
- Carous Dossier	Responsible Unicer – relepione This is configurable
🖃 🥁 Argus J	
- 🛱 Reporting	Responsible Officer – Fax
💕 Device Report	This is configurable
🚞 E2B	
🗀 Argus Mart	Responsible Officer – Email
Case Form Configuration	I nis is configurable
- Case Processing	FOL word to exercise the "Linkshows" End on the DMDA During count from 8 (Research to D.A. SAFE ID. D. DDDD)/CT. ID. D. LICENEE ID. D. ACENCY, ID. D. DDDD, ECO. NUMP (Research to D.
Document Management	SELECT DECODE(MAX(NVL(LISTEDRESS ID.3)),1.2) FROM CASE PROD MALFUNCTION WHERE CASE [ID +P_CASE ] D AND PROD SEQ NUM-P (PAD SEQ NUM-P) (SEPTEMBER 2000)
- 🔁 Local Labeling	REPORTABILITY_ID=1 AND DELETED IS NULL
- Detwork Settings	
Becutty	SQL used to identify Events to be printed under "Status of Patient's health damage" field on the PMDA Device report form 8 & 10 (Parameters: P_CASE_ID, P_PRODUCT_ID, P_UCENSE_ID, P_ARDD_SEQ_NUMI (Deprecated)
	SELECT PKG_PSR.F_COLLECTION_TO_STRING(CAST(COLLECT(CASE WHEN inc term_selection IS NULL OR inc term_selection = 1 THEN
Workflow	DECODE(CE.INC_IEMM_JNULL_DECODE(DESC_REPT0_JNULL_DESC_REPT0_DESC_REPT0_J).CE.INC_IEMM_J)   "   DECODE(Ce.Senousness,NULL_NS'(J, NS', 1, 'S)    "/ WHEN Inc.term_selection = 0 THEN DECODE(CE.PREF_TERM_JNULL_DECODE(DESC_REPT0_JNULL_DESC_REPT0_DESC_REPT0_J).CE.PREF_TERM_J)   "/
	File attachments allowed for PMDA Device Profile
	PDF_JPEG_JPG_BMC_IPNO,GIF_TF_TFF_RTF_TXT_XLS_XLS_XDOC,DOCX_XML_DICOM_HTML;
	Attachment encoding method in PMDA Device XML report
	Outple step encoding
	Single step encoding similar to PMDA E2B R3
Help Text	

#### **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 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) (Deprecated)
- 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) (Deprecated)



- File attachments allowed for PMDA Device Profile: it is populated by default with PDF;JPEG;JPG;BMP;PNG;GIF;TIF;TIFF;RTF;TXT;XLS;XLSX;DOC;DOCX;XML ;DICOM;HTML;
- Attachment encoding method in PMDA Device XML report: it has the Double step encoding and Single step encoding similar to PMDA E2B R3 options. For PMDA Device XML, the Double step encoding default value has to be set.

## Common Profile Switches for E2B

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

ORACLE					Welcome docuser, Tuesday, April 3, 2018 (AS82U_AS05-ORACLE)	Home	Help Close
Code Lists	Business Configuration	Access Management	System Configuration	Tools			
COMMON PRO	ILE - Argus J Reporting	E2B					
Browser		Modify Argus J Reportin	JE2B				
Organized by Co	mmon Profile 🗸 🗸	-					
Common Pr	ofile	SGM	for interchange-J (used in E2)	s (Rz) reports)			
Advance	d Conditions						
📄 🦳 Argus Do	ssier	Drug assessment source	for reported causality (used	by E2B/Interchange-I r	adule)		
Argus J		第一次情報源					
нер	levice Report						
	E28	Drug assessment sourc	of for determined causality (us	ed by E2B/Interchange-	J module)		
- Case For	m Configuration	報告企業					
📄 🦳 Case Pro	cessing	1000 00 00 00		10 NO 20			
Database		Drug assessment metho	d (used by E2B/Interchange-J	module)		-	
Help	t Management		ハワンヨン				
Local Lat	eling	File attachments allows	for PMDA E2D D2 Brofile				
Network	Settings	PDF;JPEG;JPG;BMP;PN	3;GIF;TIF;TIFF;RTF;TXT;XLS;>	LSX:DOC:DOCX-XML:D	ICOM;	7	
Reporting	12						
Security	00	Dummy Reaction for Re	search & Measure Report(R3)				
User Inte	face	有害事象なし					
Workflow							
		Compression algorithm	for file attachments in PMDA	E2B R3			
		• DF					
		O GZIP					
		Seriousness criteria in E	vent Reportability Matrix	N			
		Case Level Seriousne	5	~			
		Event Level Seriousne	55				
Male Tool							
theip text							
							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	
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 <b>CMN_Profile</b> switch.	Field Length: 120JAudit 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 <b>CMN_Profile</b> switch.	Field Length: 120JAudit Log: Yes



Field Name	Description	Field Options	
Drug assessment method (used by E2B/Interchange-J module)	The field value chosen in the <b>Case</b> Form > Event Assessment tab is populated for B.4.k.18.3 DRUGASSESSMENTMETHOD 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 DRUGASSESSMENTMETHOD is set to the value in this field by default.	Field Length: 70JAudit Log: Yes	
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	
Dummy Reaction for Research & Measure Report (R3)	New Enterprise level profile switch is added in the Oracle Argus Safety Console to configure the Dummy Reaction.	Text: 255(max length) Default value: 有害事象なし	
	A dummy event is created in the case. If the event exits in the report use that event. Else if no event exists then use this dummy event of a PMDA R3 report of research and measure category ('E', 'F', 'G', 'L', 'M', 'N', 'O', 'P'). Also the exclusions for the same are done in the Minimum case validation for these reporting categories.		
	<b>Note:</b> If E.i.1.2 is available and E.i.2.1b is not available in the E2B element then encode the Reaction using E.i.1.2 Tag value (Primary Source Path). Refer to the Mapping Document for details.		
	This dummy event is visible in the Pending screen and also listed in the Difference Report Viewer.		
	<b>Note:</b> PMDA E2B R3 import logic is implemented based on the Import framework to support EMA R3 import. Hence all the framework level concepts applies to PMDA E2B R3 import as well. Refer <i>Oracle Argus Interchange User's</i> <i>Guide</i> for details of the framework.		
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	
Seriousness criteria in Event Reportability Matrix	The Event Reportability 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. Default Value: Event Level Seriousness	Case Level Seriousness Event Level Seriousness	



# **Configuring Field Level Validations**

This section lists the configuration of fields in Oracle Argus Safety Console:

• Field Label Configuration (J Specific)

# 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:

de Lists Business Configuration	Access Management System C	onfiguration Tools							
FORM FIELD CONFIGURATION								_	
er (	General Information								
red by Field Label	Field Name	Field Form Label	Field Form Label (J)	ICSR Field	Research Field	Hidden	Drug	Device	Vaccine
	Case Central Safety Date	Central Receipt Date	セントラル情報入手日	No	No	No			
	Case Classification	Classification	分詞	No	No	No			
ARGUS SAFETY	Case Followup Data Clean up	Data Clean Up	データ・クリーン・アップ	No	No	No			
GENERAL	Case Initial Receipt Date	Initial Receipt Date	情報入手日	No	No	No			
Case Followup	Case Report Type	Report Type	報告の種類	No	No	No			
Case Information	Case Requires Follow-up	Case Requires Follow-up	追加報告が必要な症例	No	No	No			
Case Shutu	Case Status	Case Status	症例ステータス	No	No	No			
Case addy	Country of Incidence	Country	発現国	No	No	No			
General Information	Date for Reports	Aware Date	報告起算日:	No	No	No			
Literature	Date for Reports (J)	Aware Date	報告起第日:	No	No	No			
Reporter	Follow up Justification	Follow up Justification	追加権限の理由	No	No	No			
ATIENT	Global ID	Global ID	グローバル10	No	No	No			
Case Neonates	Master Priority Level	Case Priority	(定例の)優先順位	No	No	No			
Medical Status	Medically Confirm	Medically Confirm	医型的1.5確認	No	No	No			
Parant Information	User Defined Date 1	UD Date 1	ユーザー定義日付」	No	No	Yes			
Defect line	User Defined Date 10	UD Date 10	7 ーザー定義日付10	No	No	Yes			
Papent History	User Defined Date 11	UD Date 11	フーザー完善日付け	No	No	Yes			
- Calent Information	User Defined Date 12	UD Date 12	ユーザー定義日付12	No	No	Yes			
- Datient Lab Data	User Defined Date 2	UD Date 2	フーザー定義日付2	No	No	Yes			
- Dia Pregnancy	User Defined Date 3	UD Date 3	フーザー定義日付3	No	No	Yes			
Product Name Part Info	Liter Defined Date 4	UD Date 4	フレゼレ空美ロ付付	No	No	Ver			
Race Information	User Defined Date 5	UD Date 5	7 - 11 - 空義日付5	No	No	Yes		-	
Bolowant Tests	Lieer Defined Date 6	UD Date 6	ユージー 定義日付8	No	No	Yee			
- Nelevant reata	User Defined Date 7	UD Date 7	2 / 2420150	No	No	Voc		-	
Substance into	User Defined Date 7	UD Date 7	ユージール(秋日内)	No	No	Ves		-	
PRODUCTS	User Defined Date 6	UD Date 0	ユーリール(秋日110	No	No.	Vez	_	-	
— Dosage Regimen	User Defined Number 1	UD Number 1	ユーリー定義日刊8	No	NO	Voc			
Drug or Device or Vaccine	User Defined Number 1	UD Number 1	ユーリー正教留与	NO	NO	Tes		-	
EU/CA Device	oser Denned Komber To	op Number To	12-9-2466610	NO	ing.	Tes			
PMDA Device									
Directure Device	Modify General Information								
Product Device	Field Name		Field Form Labor						_
Product Drug	Field Name		Field Form Label						
Product Drug/Vaccine									
- Product Indication	Help Text		Hidden Read Only	Max Length	Null Flavors				
- Product Information			No Drug			~			
Product Vaccine			Yes Device	Safe Length					
Product Vaccines			LOOD Field						
Cuality Cantral			CSR Field Vaccine						
Cutality Control			Research Report Field						
Vaccine History	Help Text (J)		Field Form Label (J)						
Vaccine Prior AE									
🖶 🚰 EVENTS									
Event Assessment	4								

#### Note:

The Field Form Label (J) and Help Text (J) are visible on this screen (grid, data entry, and print) only to Oracle Argus Safety Japan user, when Oracle Argus Safety Japan 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.

# **Configuring Field Labels**

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



• User Defined Fields Updates

## User Defined Fields Updates

The Oracle Argus Safety Japan system has the following:

ield Name	Field Form Label				
Jser Defined Number 1	UD Number 1				
lelp Text	Hidden	Read Only	V 5	Selectable	Add Dele
Jser defined field for entering numbers.	C No	Drug	#	English	Japanese
	• Yes	Device	1	%	X
	E2B Field	☐ Vaccine	2	% (V/V)	(V/V)X
elp Text (J)	Field Form Label	(J)	25		
救値を入力するためのユーザー定義されたフィールド です。	ユーザー定義者	佳号 1			

- Oracle Argus Safety Japan 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.

# 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).

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.



# 3 Code List Configuration

This chapter lists the Japanese-specific (J-specific) features in the Code List Configuration module of Oracle Argus Safety Japan Console:

Code Lists

# Code Lists

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

- General Functionality Changes
- Device Classification
- Device Outcome
- Device Reporting Category
- Emperor
- J Reportable Product Keyword
- License Category
- Literature Type
- Reporting Category
- Literary Citation
- Reporting Destination
- Manufacturers
- Reporter Information
- Flexible Data Re-Categorization

## **General Functionality Changes**

This section lists the Oracle Argus Safety Japan 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 Oracle Argus Safety Japan 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 an Oracle Argus Safety Japan user copies the data, the equivalent Japanese data is not copied.
  - When an Oracle Argus Safety Japan 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 Oracle Argus Safety Japan.
    - \*  $\exists \mathcal{L} \rightarrow \mathcal{L}$  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.

## **Device Classification**

The following is the screenshot of the Japan specific **Device Classification** code list is available under **Argus Console** > **Code Lists** > **Argus J** menu option.

The values in this code list are referred from the

LM\_PMDA\_DEVICE\_CLASSIFICATION table for device license for fields PMDA Device Classification 1, PMDA Device Classification 2, and PMDA Device Classification 3 under Argus Console > Products and Licenses > Product > License.

			Home Help Close
ORACLE	I show the second second		
Code Lists Business Configuration	Access Management System Configuration Tools		
CODE LIST MAINTENANCE			
Browser	Device Classification Filter		
Organized by Code List ~	Field	Value	
Code List	Contains	The	
- Payire Classification	Total Number of Rows (14)		
- Device Outcome	Device Classification	Device Classification (J)	Display
Device Opticaties Catagory	Biogenous	生物由来医療機器	Yes
	Combination products (Drugs)	コンビネーション製品(医薬品)	Yes
I Dependent Keyward	Combination products (Tissue-Engineered Medical Products)	コンビネーション製品(再生医療等製品)	No
Calence Calence	Controlled Medical Device	管理医療機器	Yes
- Cicerse Category	Generic Medical Device	一般医療機器	Yes
- Lterature Type	High Level Controlled Medical Device (Class III)	高度管理医療機器(クラスⅡ)	Yes
	High Level Controlled Medical Device (Class IV)	高度管理医療機器(クラスⅣ)	Yes
	Other	その他	Yes
	Reiteration Use Medical Device	反復使用医療機器	Yes
	Single Use Medical Device	単回使用医療機器	Yes
	Specific Biogenous	特定生物由来医療機器	Yes
	Stand-alone software (Class II)	単体プログラム(クラスⅡ)	Yes
	Stand-alone software (Class III)	単体ブログラム(クラスⅢ)	Yes
	Stand-alone software (Class IV)	単体ブログラム(クラスⅣ)	Yes
	Add Rea Davido Classification		Add New Copy Dolots Pee
	Pevice Classification		
Help Text		Display	
The values entered here and marked as Display will	Provide Classification (J)		
appear in the Case Form - Product Device tab - PMDA			
sonte include conte constitution diop-dominist			



Field Name	Description
Device Classification	Allows user to enter device classification value in English.
Display	Allows user to display or hide a device classification in Oracle Argus Safety.
Device Classification (J)	Allows user to enter device classification value in Japanese.

#### Table 3-1 Device Classification code list - Field Description

#### Note:

The Combination products (Tissue- Engineered Medical Products) device classification's **Display** is set to **No**. Hence, this record appears in the flex-code list with **Display** checkbox as unchecked.

### **Device Outcome**

The following is the screenshot of the Japan specific **Device Outcome** code list available under Argus Console > Code Lists > Argus J menu option.

These code list values are used to select the outcome for a device in the case form under Product > Device > Device Information > Device Outcome.

ORACLE							Home Help Close
Code Lists Business Configurat	on Access Management	System Configuration	Tools				
CODE LIST MAINTENANCE							
Browser	Device Outcome Filter						
Organized by Code List	✓ I Field		Contains	Value			
🖃 🤷 Code List						-	
Device Classification	Total Number of Rows (5)						
- Device Outcome	Device Outcome			Device Outcome (J)			Display
Device Reporting Category	Death			火し			Yes
Emperor	Other			不回復 その他			Yes Ves
- DI Reportable Product Keyword	Renwered			回復			Ves
License Category	Resolving			軽快			Yes
Literature Type							
						Add New Copy	Delete Print
	Add New Device Outcome						
	Pevice Outcome						
Help Text				Dis	play		
The values entered here and marked as Display will	Device Outcome (J)						
appear in the Case Form - Product Device tab - PM Device - Medical Device Outcome drop-down list	JA						
							Save

#### Table 3-2 Device Outcome code list - Field Description

Field Name	Description
Device Outcome	Allows user to enter device outcome value in English.
Display	Allows user to display or hide a device outcome in Oracle Argus Safety.



Table 3-2	(Cont.) Device Outcome code list - Field Description
-----------	--

Field Name	Description
Device Outcome (J)	Allows user to enter device outcome value in Japanese.

# **Device Reporting Category**

The following is the screenshot of the Japan specific **Device Reporting Category** code list available under Argus Console > Code Lists > Argus J menu option.

ORACLE				Home Hatp Close
Code Lists Business Configuration	Access Management System Configuration	Tools		
Contraction Consignment	receive management of operation of management			
CODE LIST MAINTENANCE				
Browser	Device Reporting Category Filter			
Organized by Code List	Y Feid	Value Value		
🖃 🚰 Code List			1 1700	
- Device Classification	Total Number of Rows (11)			
- Device Outcome	Device Reporting Category	Device Reporting Cat	agory (J)	Display
Paulice Reporting Category	Domestic defect case report	不具合症例報告	(国内)	Yes
- Emporer	Domestic infection case report	感染症症例報告	(国内)	Yes
- D Reportable Breduct Keyword	Foreign defect case report	不具合症例報告	(外国)	Yes
A Reportable Product Reymond	Foreign infection case report	感染症症例報告	(外国)	Yes
Cicelise Category	Infection Report	感染症報告		No
Lterature Type	Malfunction with health damage	副作用報告		No
	Malfunction without health damage	不具合報告		No
	Measures in Foreign Country Report	外国措置報告		No
	Medical device research report	研究報告調査報告	1	Yes
	Research Report	研究報告		No
	Survey report of foreign safety measures	外国措置調査報告	t i i i i i i i i i i i i i i i i i i i	Yes
				Ad Nov Cov Data Per
				Control Copy Control Film
	Add New Device Reporting Category			
	Povice Reporting Category		Display	
Help Text	Provide Reporting Category (J)			
The values entered here and marked as Display will access in the Case Form - Product Device tab - PMDA	Note: "Add New" and "Conv" are not allowed for this Code List	litem		
Device - Medical Device Reporting Category drop-down list				Save

The values entered here and marked as **Display** appears in the Case Form > Product Device tab > PMDA Device > Medical Device Reporting Category drop-down list.

It is covered by the back-end PL/SQL APIs for Device Reporting Category data table updates and audit-logging.

Table 3-3	Device Reporting	<b>Category code</b>	list - Field Description
-----------	------------------	----------------------	--------------------------

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 Oracle Argus Safety.
Dev Report Category	Displays the abbreviation of the reporting category.
Device Reporting Category (J)	Allows user to enter Device Reporting Category value in Japanese.



# Emperor

Code Lists Business Configuration	Access Management	System Configuration Tools		
CODE LIST MAINTENANCE				
Browser	Emperor Filter			
Organized by Code List V	Field	Value		
Refer Code List		Contains V	Filter	
Device Classification	Total Number of Rows (5)			
	Emperor Name (J)	Emperor Name	Date In Office	Date Entry Abbreviation Display
Device Outcome	令和	Reiwa	01-May-2019	R Yes
Emperation Concepting Concepting	大正	Taisho	30-Jul-1912	T Yes
Desideble Desideble Kenned	平成	Heisei	08-Jan-1989	H Yes
S Reportable Product Reyword	明治	Meiji	01-Jan-1868	M Yes
License Category	昭和	Syowa	25-Dec-1926	S Yes
	Add Hore Femore		Add New	Copy Deets Paint
	Emperor Name (J)		Pate in Office	
Help Text	line (o)			Display
This field allows the user to configure the value of	Emperor Name		Date Entry Abbreviation	
Emperor				

This dialog box allows you to add and configure various Japanese Emperor Data/Era.

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 officesDate format DD-MON-YYYY
Display	You can select to display the record in Administrator route in the <b>Products</b> 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 <b>Argus Safety</b> and <b>Console Date</b> 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



# 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.



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 <b>Select</b> 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 <b>Select</b> , 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.



# License Category

Code Lists	Business Configuration	Access Management	System Configuration	Tools					
CODE LIST MAIN	TENANCE								
Browner	ENANCE	License Category Filter							
Diowaci		Field				Value			
Organized by Code	e List		~	Contains	~		Filter		
🖃 🚰 Code List		·		•					
Device Class	sification	Total Number of Rows (16)							
Device Outco	ome	License Category (J)			License Catego	ry		E2B Code	Display
Device Repo	orting Category	PMS 期間中(要指導)			During post-mark	ceting surveillance (PMS) (Instruction	on required drugs)		Yes
Carefor		一变治験中			During clinical tri	al for partial change		4	Yes
··· 📴 J Reportable	Product Keyword	一変治験中(新有効成分	6、投与経路、剤型、配	合剤など)	Under clinical tria n, modification, e	al for partial change (New active ing .tc.)	redients, admin, formulatio	4	Yes
🚔 License Cat	tegory	一変治験中(用法・用量	量/効能・効果の変更/削除	ŝ)	Under clinical tria dness)	al for partial change (clinical study f	or change on indication/list	4	Yes
Literature Ty	pe	再審査期間中(要指導)			During re-examin	nation period (Instruction required d	rugs)		Yes
· Reporting Ca	ategory	国内既承認 (被験薬除く	)		Approved (Exclu	ding Study Drug)			No
		国内既承認(被験薬除く	()		Approved (Drugs stigational drugs)	out of drugs defined their usage in	the protocol excluding inve	9	Yes
		国内既承認(被験薬除く	0		Approved (Drugs stigational drugs)	out of drugs defined their usage in	the protocol excluding inve	8	Yes
		国内未承認(被験薬除く	)		Unapproved (Exi	cluding Study Drug)			No
		国内未承認(被験薬除。	0		Unapproved (Dru rugs)	igs out of their usage in the protoco	ol excluding investigational	d	Yes
		国内未承認(被験薬除。	$\bigcirc$		Unapproved (Dru rugs)	igs out of their usage in the protoco	ol excluding investigational	<sup>d</sup> 9	Yes
		報告対象外			Not reportable				Yes
		市販直後調査中			During early post	-marketing phase vigilance		1	Yes
		承認2年以内			Within 2 years af	ter approval		2	Yes
		未承認			Unapproved			3	Yes
		該当なし			Not applicable			5	Yes
		Add New License Category							
		V License Category (1)					E2B Code		
Male Test		Cooline Category (J)					220 0000		Display
This field allows the use	the section of the value of	License Category							_
This relu allows the use	in to compute the value of								

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

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 <b>Products</b> screen.
License Category	This represents the label for column of text boxes for entering the License Category in English.
PROTECTED	Internal Field - Protected

## Literature Type

Use the following procedure to configure action taken:

- 1. From the Oracle Argus Safety 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						a restance mana regigen men sup	(	PU PPEER DEL PIDE	i)	
Code Lists Business Configuration	on Access Management	System Configuration	Tools							
ODE LIST MAINTENANCE										
	Literature Type Filter									
rganized by Code List	• Field		-		Value		( researching )			
Code List		-	Contains	-			u.f.iteca			
Device Reporting Category	Total Number of Roses (2)									
- Can Emperor	Literature Type				Literature Type (.B.			Die	ienlar	_
J Reportable Product Keyword	JAPIC				JAPIC			Ye	es	
- Category	VMDIS				海外医業情報研究会	ê.		Ye	es	
Literature Type										
Reporting Category										
	5									
	Cr.									
	9									
	5									
	0									
	Q									
	a									
	Þ									
	2									
	\$						Add Nam	Catty	Detety II	Peri
	D						Add Street	Esty.	Frith 1	Prin
	D Add How L Bernham Type						Add Neer	[][:	Driety]	Par
	Add Hore Literature Type						Add New 3		Prints ][	Prim
	Add How Literature Type W Literature Type						Add New		Prints	Past
o Teat	Add New Literature Type T. Genetice Type				50	Skapley	Add New	CH17	Prints [	Pasi
p Test	Add How Life ratios Type V. Life ratios Type V. Life ratios Type (J)				<b>⊽</b> 0	Skeptery	Add New 3	cary 1	Fritz II.	Past
o 1 end.	Add Nove Literature Type Viterature Type Viterature Type ()				F 0	Yaqıbay	Add Steer		State	Pate
y Text	Add How Life value Type P Life value Type P Life value Type ()					Skepkey	Add New	- cary - N	Sente	Prin

- 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.

## **Reporting Category**

Use the following procedure to configure action taken:

- From the Oracle Argus Safety 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.

E LIST MAINTENANCE	Describer Colores Filter					
	Reporting Category Filter		Velue			
ized by Code List	V d	N	value Value	Filter		
Code List		•][•	-	- Internet		
Desire Reporting Category	Total Number of Rows (1)	ລ				
Emporer	0	Developing the		Description	COD 0. 1	01.1
Designed and the second	Report Category	Description (J)	+====(**)	Description	EZD Code	Display
J Reportable Product Reymord	2	日本の市場の市場でし	「印刷(数)	Case reports on intections in Japan (post-marketing)	2	Tes
License Category	0	国際通貨用金が採着し、	(1)用((数) (二)用((数)	Case reports on adverse drug reactions in Japan (post-marketing)	2	res
Literature Type	u	ZUTERDARE C	(148KUK)	Case reports on intectors in loreign coordines (post-marketing)	3	res
Reporting Category	D	外国副作用症例報告(	市販後)	<ul> <li>case reports on auverse drug reactions in toreign countries (post-man a)</li> </ul>	4	Yes
	E	「「「「「「「」」」の「「「」」」の「「「」」」の「「」」の「「」」の「「」	(2)	Besearch reports on infections (nost-marketion)	5	Yes
	F	高能田研究報告 (市販	(80) (84)	Research reports on infectional (post-marketing)	6	Yes
	G	外国における製造等の	中止、回収、廃棄等の措置報告(市販	Reports on corrective action such as discontinuation of manufacturing, all disposal in foreign countries (post-marketing)	rec 7	Yes
	н	国内感染症症例報告(	(治験)	Case reports on infections in Japan (clinical trial)	8	Yes
	1	国内副作用存例報告(注	(188)	Case reports on adverse drug reactions in Japan (clinical trial)	9	Yes
	4	外国感染症症例操作	588)	Case reports on infections in foreign countries (clinical trial)	10	Yes
	ĸ	外国副作用控例報告(	3(ske)	Case reports on adverse drug reactions in foreign countries (clinical tri	a0 11	Yes
		·····································	1010	Research reports on infections (clinical trial)	12	Yes
	M	周修田研究報告 (金融	1	Research reports on adverse drug reactions (clinical trial)	13	Yes
	N	外国における製造等の	中止、回収、廃棄等の措置報告(治	Reports on corrective action such as discontinuation of manufacturing, all, disposal in foreign countries (clinical trial)	rec 14	Yes
	0	医莱部外品研究報告		Research reports on guasi-drugs	15	Yes
	P	化粧品研究報告		Research reports on cosmetics	16	Yes
					Add Name II Come	II Dable II
	111N D				And them II could	I over I
	Add New Reporting Catego	iy .				
	V Reporting Category		Description (J)	E2B Cod	•	V Display
			Description			
			o contrapoon			



- 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.

## Literary Citation

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

this English screen to the Japanese pop-up.

- 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
- 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 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 Oracle Argus Safety user copies the data, the equivalent Japanese data is not copied.
- When Oracle Argus Safety Japan user copies the data:
  - Copy of is appended in front of the data in the Journal field of English UI.
  - $\neg \exists \mathcal{L} \rightarrow \neg$  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 popup 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:

DELEVE				Co	ode List Ma	intenance
KELSIS					09-May-2007	16:49 GMT+
Literature Citations						
As of 09 May 2007						
Journal	Author	Title	Vol	Year	Pages	
雑誌名	著者名	標題	휸	発行年	頁	
Journal	Will Smith	Title				
ジャーナル	ウィル スミス	タイトル	Vol-2	2007	999	

### 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:

- The PMDA-DEVICE MESSAGE TEMPLATE standard device profile uses similar framework as E2B R3. This profile has elements related to both Form 8 and Form 10 XML report.
- In the Message Profile drop-down list, the PMDA E2B R3 profile (*ICH-ICSR V3.0 MESSAGE TEMPLATE PMDA*) is made available to the users for configuration.
- In the ACK profile, users can select the PMDA E2B R3 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).

The Argus Console > Code list > Reporting Destination > Agency Information (tab) has been enhanced:

- Check Agency Information > Authorized Representative, if you are an authorized representative.
- Attachments under Report Transmissions is set as Single(default) and disabled.

To print these fields, go to **Reporting Destination** > **Local Company Contact**.

### 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 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 Oracle Argus Safety Japan user copies the data, the equivalent Japanese data is not copied.
- When the Oracle Argus Safety Japan user copies the data:
  - Copy of is appended in front of the data in the Name field of the English UI.
  - $\exists \mathcal{L} \rightarrow \mathbf{v}$  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.

## **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



ike this:			
Ent2-報告者情報の変更 Webpage Dialog			
報告者情報の変更			
敬称 名	❤ 姓	サフィックス ID	職種
		±0 ₩9	*
報告者の種類	✔ □ 医療専門家	하····································	市区町村
住所		都道府県	郵便番号
住所っ		중각유무	スの他の委託妥早
11/12	<u> </u>	电动曲方	てい他の电話番号
FAX番号	Eメール	優先する連絡方法	
			の受取人
施設(0)			追加 削除
			1
注:この日本語ポップアップ・スクリーン上。	ご行われた変更は11保存」ホタンを選択すること	こより英語のメイン・スクリーンに反映さ	れます。
	10.4		
	保存 取:	ii	

- 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 Oracle Argus Safety user copies the data, the equivalent Japanese data is not copied.
- When the Oracle Argus Safety Japan user copies the data:
  - **Copy of** is appended in front of the data in the **Name** field of the English UI.
  - $\exists \mathcal{L} \rightarrow \mathcal{L}$  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	S Y S				Code List Maintenance
					03-May-2007 10.45 0M177
Reporters As of 09 May 2007	7				
Name Reporter ID Occupation	Health Prof Reporter Type Department	Institution	Address City, State, Postal Code Country	Phone Att. Phone Fax	Email Electronic Transmission Receipt Preferred Method
名前 報告者 D 職種	医皮専門家 報告者の種類 避暑	施設	国 住所	電話番号 その他の電話番号 Fax	Eメール 電子伝達の受取人 優先する連絡方法
Dr First Last 121 Investigator Dr. 野村 鴉男 121 調査員	No Company Representative Safe ty Division しいしえ 会社代表 安全性部門	Kaiser Hospital Tokyo University Hospital Yokohama University Hospital カイザーホスピタル 燈台病院 横浜医学大学病院	123 Main Street City, CA 8976 UNITED STATES 米国 8976 カリフォルニア州メイン市 メインストリート 123	341-908-9087 453-908-9087 564-786-9087	abc@yahoo.com

- 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.

### Flexible Data Re-Categorization

The flexible data re-categorization feature allows Oracle Argus Safety Japan and its associated applications, such as Oracle Argus Mart and Oracle 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 Oracle Argus Safety Console > **Code List** > **Flex Data Re-Categorization**.

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

- Reporting Category (LM\_RPT\_CATEGORY)
- License Category (LM\_LIC\_CATEGORY)
- Dev Phase (LM\_DEV\_PHASE)
- Risk Category of OTC Drug (LM\_RISK\_CATEGORY\_OTC)
- Route for Acquiring OTC Drug (LM\_ROUTE\_ACQUIRE\_OTC)
- Device Reporting Category (LM\_DEVICE\_RPT\_CATEGORY)
- Device Classification (LM\_PMDA\_DEVICE\_CLASSIFICATION)
- Device Outcome (LM\_PMDA\_DEVICE\_OUTCOME)

## 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
Case reports on infections in Japan (post-marketing)	AA
Case reports on adverse drug reactions in Japan (post-marketing)	AB
Case reports on infections in foreign countries (post-marketing)	AC
Case reports on adverse drug reactions in foreign countries (post-marketing)	AD
Research reports on infections (post-marketing)	AE
Research reports on adverse drug reactions (post-marketing)	AF
Reports on corrective action such as discontinuation of manufacturing, recall, disposal in foreign countries (post-marketing)	AG
Case reports on infections in Japan (clinical trial)	DA
Case reports on adverse drug reactions in Japan (clinical trial)	DB
Case reports on infections in foreign countries (clinical trial)	DC
Case reports on adverse drug reactions in foreign countries (clinical trial)	DD
Research reports on infections (clinical trial)	DE
Research reports on adverse drug reactions (clinical trial)	DF
Reports on corrective action such as discontinuation of manufacturing, recall, disposal in foreign countries (clinical trial)	DG
Research reports on quasi-drugs	BC
Research reports on cosmetics	BD



# 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
During early post-marketing phase vigilance	1
Within 2 years after approval	2
Unapproved	3
During clinical trial for partial change	4
Not applicable	5
During re-examination period (Instruction required drugs)	6
During post-marketing surveillance (PMS) (Instruction required drugs)	7

## 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 study	0
Phase I	1
Phase II	2
Phase III	3
Phase I/II	4
Phase II/III	5
Under application	7
Others	8

## 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 1 OTC drugs	01
Class 2 OTC drugs	02
Designated second-class OTC drugs	2S
Class 3 OTC drugs	03
Instruction required drugs	04



RISK_CATEGORY	E2B_R3
Pharmacy-compounded drugs	05

## 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
Mail-order sales through the Internet	I
Household distribution	Н
Other mail-order sales (telephone, etc.)	Т
Over-the-counter sales at pharmacies	S
Information could not be obtained despite confirmation	ASKU
	This denotes a Null flavor value.
Unclear because of unconfirmability due to unavoidable reasons	UNK
	This denotes a Null flavor value.

## Device Reporting Category (LM\_DEVICE\_RPT\_CATEGORY)

The Device Reporting Category codelist is available in the Flexible Data Re-Categorization menu option.

The values of the Device Reporting Category flexible codelist are displayed for the Case Form field under the PMDA Device Information section, in the Medical Device Reporting Category drop-down list.

Device Reporting Category	Dev Report Category
Domestic infection case report	DA
Domestic defect case report	DB
Foreign infection case report	DC
Foreign defect case report	DD
Medical device research /survey report	DF
Survey report of foreign safety measures	DG
Infection Report	-
Malfunction with health damage	-
Malfunction without health damage	-
Measures in Foreign Country Report	-
Research Report	-



# Device Classification (LM\_PMDA\_DEVICE\_CLASSIFICATION)

The Device Classification codelist is available in the Flexible Data Re-Categorization menu option.

The values are referred from the LM\_PMDA\_DEVICE\_CLASSIFICATION table for the device license for the PMDA Device Classification 1, PMDA Device CLassification 2 and PMDA Device Classification 3 fields.

Device Classification	Display
High Level Controlled Medical Device (Class IV)	Yes
High Level Controlled Medical Device (Class III)	Yes
Controlled Medical Device	Yes
Generic Medical Device	Yes
Combination products (Drugs)	Yes
Stand-alone software (Class IV)	Yes
Stand-alone software (Class III)	Yes
Stand-alone software (Class II)	Yes
Combination products (Tissue-Engineered Medical Products)	No
Biogenous	Yes
Specific Biogenous	Yes
Other	Yes
Single Use Medical Device	Yes
Reiteration Use Medical Device	Yes

## Device Outcome (LM\_PMDA\_DEVICE\_OUTCOME)

The Device Outcome codelist is available in the Flexible Data Re-Categorization menu option.

These codelist values are used to select the outcome for a device in the Case Form under Product > Device > Device Information > Device Outcome.

Device Outcome	Display
Death	Yes
Not Recovered	Yes
Resolving	Yes
Recovered	Yes
Other	Yes