

# Oracle Argus Safety

## Flexible Reporting Extensibility Guide



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# Preface

This preface contains the following sections:

- [Audience](#)
- [Documentation accessibility](#)
- [Diversity and Inclusion](#)
- [Related resources](#)
- [Access to Oracle Support](#)

## Audience

This guide assumes that your organization has the expertise to perform the job functions listed in this section. If your staff lacks these skills, we recommend that you engage Oracle Life Sciences Consulting.

- [Oracle Database Administrators](#)
- [System Administrators](#)

## Oracle Database Administrators

Customizing the database package supplied with Oracle Argus FAR requires a level of knowledge equivalent to having mastered the material in Oracle's DBA Architecture and Administration course. You must be able to read SQL\*Plus scripts and edit them. You must be able to run SQL scripts and review logs for Oracle errors.

## System Administrators

Customizing and maintaining an Oracle Argus Safety BI Periodic Reporting requires mastery of the following tools:

- Microsoft Windows Operating System
- Unix or Linux based Operating Systems
- OBIEE and (or) Oracle BI Publisher
- Oracle Web Logic Administration

## Documentation accessibility

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

## Diversity and Inclusion

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

## Related resources

For information about Oracle Argus patches, see [My Oracle Support](#).

All documentation and other supporting materials are available on the [Oracle Help Center](#).

## Access to Oracle Support

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

### **Cloud customers receive support assistance through Support Cloud**

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

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

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

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

### **On-premises customers receive support assistance through My Oracle Support**

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



# 1

## Introduction

*Oracle Argus Safety Flexible Reporting Extensibility Guide* leverages the capabilities of the Oracle Analytics Publisher reporting solution for Oracle Argus Safety Reports. This solution helps customers overcome the challenges of periodic reporting to meet a variety of business needs.

This document provides Oracle Argus Safety–Oracle Analytics Publisher integration details, describes the BI Publisher Periodic Reports framework, and describes out-of-the-box periodic report details along with data models, algorithms, and methods to customize the report as per customer needs.

This document also talks about the PMDA (R3) Paper Reports Framework using Oracle Analytics Publisher.

# 2

## Overview

In this chapter, know more about:

- [Flexible Reports - What's in the Box](#)
- [Output Formats](#)
- [Scheduling](#)
- [Report Templates](#)
- [Database Code Wrapping](#)

## Flexible Reports - What's in the Box

Periodic Reports

- Periodic Benefit Risk Assessment Report (PBRER)
- Development Safety Update Report (DSUR)
- The Post Marketed Aggregate Report (PMAR, also called PSUR)

Expedited Reports

- PMDA R3 Paper Forms 1-6

## Output Formats

Out-of-the-box Argus Safety BI Publisher reports support the following output formats by default:

- PDF
- RTF

You can also get the output in an XML format. The out-of-the-box reports are not designed to support the CSV format. However, you can prepare a custom report supporting the CSV format.

## Scheduling

Oracle Argus Flexible Reporting Framework supports Quartz scheduler.

## Report Templates

Out-of-the-box (OOTB) Argus Flexible reports use RTF templates.

## Database Code Wrapping

All Oracle Argus Safety objects are code wrapped. However, to facilitate and encourage customers to handle their own customizations, the system does not wrap database code under the (BIP Owner User).

Oracle recommends that customers use the APIs to alter or extend the functionality. Using the APIs enables upward compatibility and Oracle support.

# 3

## Flexible Aggregate Reporting Framework

This chapter discusses Flexible Aggregate Reporting framework.

For more information, see:

- [Generic Architecture](#)

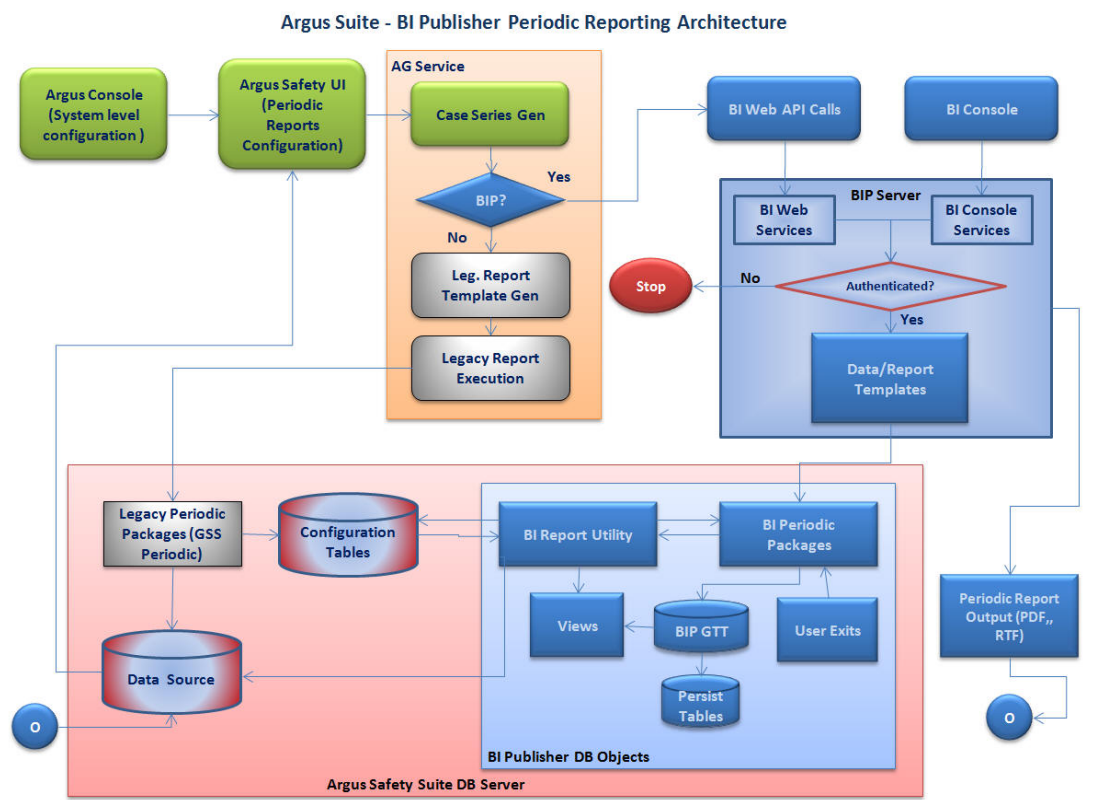
### Generic Architecture

The Oracle Analytics Publisher Periodic Reporting functionality is an Oracle Argus Safety add-on feature that you can enable.

For more information on enabling this feature, refer to the Enabling and Configuring Oracle Analytics Publisher Periodic Reporting section in the *Argus Safety Install Guide*.

Figure 3-1 displays the architecture of BI Publisher Periodic Reporting with Oracle Argus Safety.

**Figure 3-1 Argus Flexible Aggregate Reporting Architecture**



Oracle Analytics Publisher reports can be executed from Oracle Argus Safety UI or through the Oracle Analytics Publisher console. The following table explains the core components involved in the architecture diagram.

**Table 3-1 Core Components of the Architecture Diagram**

Component	Functionality
Argus Web Console	The first piece of the application for configuring Oracle Argus Safety. Handles the following: <ul style="list-style-type: none"><li>- Enabling the BIP module</li><li>- Supplying the necessary BIP security credentials and setting up the persist duration</li><li>- Setting up the report template path</li></ul>
Argus Web	Provides the report configuration for ICH PSUR and CTPR reports. Supplies the criteria that generates the case series. The batch print screen runs either a legacy periodic report or a BIP report based on user selection. It also lets you generate or reuse already generated case series.
AG Service	Internally invokes the BIP Periodic report through WebServices and runs the report in the background.
Argus Database - BIP Schema	New schema created during the schema creation that holds all objects used for generating the periodic reports. The objects in the schema are responsible for generating the data needed.
BIP Server	Server where Oracle Analytics Publisher reports are located and executed. Report output is temporarily stored in the BIP server.

For more information on the Oracle Argus Safety Web Console, Oracle Argus Safety Web, and AG Service, refer to the *Oracle Argus Safety User's Guide*.

 **Note:**

The Oracle Access Manager server, if chosen, also needs authentication.

# 4

## Flexible Aggregate Reporting - Database

In this chapter:

- [Database Architecture](#)
- [Argus Application Schema Objects](#)
- [Access Grants to Oracle Analytics Publisher Owner](#)

### Database Architecture

Oracle Analytics Publisher Periodic Reporting is a customizable Oracle Argus Safety feature. The following sections explain the database components and changes specific to Oracle Analytics Publisher reports:

- [Flexible Aggregate Reporting - Database Objects](#)
- [Tables](#)
- [Views](#)
- [Database Link](#)
- [Java Stored Procedure](#)
- [Packages](#)
- [Database Jobs](#)

### Flexible Aggregate Reporting - Database Objects

Installing the Oracle Argus Safety database prompts for the creation of the BIP Owner schema. This schema contains all database objects needed for Oracle Analytics Publisher Flexible Reporting. It also has access to some Oracle Argus Safety schema objects through synonyms.



#### Note:

You cannot update case data from the BIP Publisher Owner schema. You can only update the Periodic Report status related tables such as **CMN\_REG\_REPORTS**, **PER\_REPORT\_QUEUE** and **PER\_REPORT\_STS**. The system updates the **CASE\_REG\_REPORTS** table for final reports. The system accesses the report blob tables from the BIP Owner to store the report output in Oracle Argus Safety.

The schema name is configurable at the time of creation. The system makes an entry in the Common Profile switches to store this schema name for reference by Oracle Argus Mart.

For report generation, this schema holds:

- [Tables](#)

- Views
- The unzip utility function
- A Java object
- Packages
- Database links
- Database jobs

## Tables

Tables in the BIP schema populate the case data:

- **Global Temporary tables (GTT)** temporarily store data for report output generation. These are the only tables used in the BIP data model.
- **RM\_ tables** store persist data and are copies of the GTT tables. The system stores parameters in these tables based on the Persist data.
- **Configuration tables** handle parameters and transactions.
- **SUPPORT tables** store information such as parameters and their values, case series details, and BIP job details.

Table 4-1 provides the list of tables in the BIP Owner schema and their users.

**Table 4-1 List of Tables in BIP Owner Schema**

Table Name	Type	Purpose
RPT_AGG_PARAMS	SUPPORT	Stores the list of parameters that are passed down to run the report.
RPT_AGG_CASE_SERIES	SUPPORT	Stores case series information.
RPT_AGG_CS_CASES	SUPPORT	Stores all cases in the case series that are selected for BIP report generation. For example, Main case series, Cumulative case series, Section 6.2 case series, Ad hoc1 case series, and so on.
RPT_AGG_BIP_JOB	SUPPORT	Stores BIP job information and other transactional data. This table data is retained without purging.
GTT_RPT_AGG_CASE	Global Temp	Stores case information.
GTT_RPT_AGG_DRUG	Global Temp	Stores drug related information.
GTT_RPT_AGG_EVENT	Global Temp	Stores event related information.
GTT_RPT_AGG_EV2DRUG	Global Temp	Stores event to drugs related assessment details.
GTT_RPT_AGG_HEALTHAUT HID	Global Temp	Stores health authority details.
GTT_RPT_AGG_UNIQ_CASE S	Global Temp	Maintains a list of unique cases.
GTT_RPT_AGG_DET_LIST	Global Temp	Temporary support table that fetches assessment data.

**Table 4-1 (Cont.) List of Tables in BIP Owner Schema**

Table Name	Type	Purpose
GTT_RPT_AGG_DRUGNAME S	Global Temp	Stores the drug names for reporting.
GTT_RPT_AGG_BIP_BLOB	CONFIG	Copies and holds the report output blob between the BIP Owner schema and the BIP Metadata repository database.
RPT_AGG_JOB_EXEC_STS	CONFIG	Used to avoid multiple report jobs fetching the report output at the same time.
RM_RPT_AGG_CASE	PERSIST	Persist table for GTT_RPT_AGG_CASE.
RM_RPT_AGG_DET_LIST	PERSIST	Persist table for GTT_RPT_AGG_DET_LIST.
RM_RPT_AGG_DRUG	PERSIST	Persist table for GTT_RPT_AGG_DRUG.
RM_RPT_AGG_DRUGNAME S	PERSIST	Persist table for GTT_RPT_AGG_DRUGNAMES.
RM_RPT_AGG_EV2DRUG	PERSIST	Persist table for GTT_RPT_AGG_EV2DRUG.
RM_RPT_AGG_EVENT	PERSIST	Persist table for GTT_RPT_AGG_EVENT.
RM_RPT_AGG_HEALTHAUT HID	PERSIST	Persist table for GTT_RPT_AGG_HEALTHAUTHID.
RM_RPT_AGG_PARAMS	PERSIST	Persist table for RPT_AGG_PARAMS.
RM_RPT_AGG_UNIQ_CASE S	PERSIST	Persist table for GTT_RPT_AGG_UNIQ_CASES.
RPT_AGG_PARAMS	SUPPORT	Stores the list of parameters that are passed down to run the report.
RPT_AGG_CASE_SERIES	SUPPORT	Stores case series information.
RPT_AGG_CS_CASES	SUPPORT	Stores all cases of the case series that are selected for BIP report generation. For example, Main case series, Cumulative case series, Section 6.2 case series, Ad hoc1 case series, and so on.
RPT_AGG_BIP_JOB	SUPPORT	Stores BIP job information and other transactional data. Table data is retained without purging.
GTT_RPT_AGG_CASE	Global Temp	Stores case information.
GTT_RPT_AGG_DRUG	Global Temp	Stores drug related information.
GTT_RPT_AGG_EVENT	Global Temp	Stores event related information.
GTT_RPT_AGG_EV2DRUG	Global Temp	Stores event to drugs related assessment details.
GTT_RPT_AGG_HEALTHAUT HID	Global Temp	Stores health authority details.
GTT_RPT_AGG_UNIQ_CASE S	Global Temp	Maintains a list of unique cases.
GTT_RPT_AGG_DET_LIST	Global Temp	Temporary support table that fetches assessment data.



**Table 4-1 (Cont.) List of Tables in BIP Owner Schema**

Table Name	Type	Purpose
GTT_RPT_AGG_DRUGNAME S	Global Temp	Stores drug names for reporting.
GTT_RPT_AGG_BIP_BLOB	CONFIG	Copies and holds the report output blob between the BIP Owner schema and the BIP Metadata repository database.
RPT_AGG_JOB_EXEC_STS	CONFIG	Used to avoid multiple report jobs fetching the report output at the same time. This table should not contain any row when the reports are not running. If it does, the completed reports will not be pushed back into Oracle Argus Safety database.
RM_RPT_AGG_CASE	PERSIST	Persist table for GTT_RPT_AGG_CASE.
RM_RPT_AGG_DET_LIST	PERSIST	Persist table for GTT_RPT_AGG_DET_LIST.
RM_RPT_AGG_DRUG	PERSIST	Persist table for GTT_RPT_AGG_DRUG.
RM_RPT_AGG_DRUGNAME S	PERSIST	Persist table for GTT_RPT_AGG_DRUGNAMES.
RM_RPT_AGG_EV2DRUG	PERSIST	Persist table for GTT_RPT_AGG_EV2DRUG.
RM_RPT_AGG_EVENT	PERSIST	Persist table for GTT_RPT_AGG_EVENT.
RM_RPT_AGG_HEALTHAUT HID	PERSIST	Persist table for GTT_RPT_AGG_HEALTHAUTHID.
RM_RPT_AGG_PARAMS	PERSIST	Persist table for RPT_AGG_PARAMS.
RM_RPT_AGG_UNIQ_CASE S	PERSIST	Persist table for GTT_RPT_AGG_UNIQ_CASES.

For details about tables, columns, and column mappings with Oracle Argus Safety, refer to the *Argus Flexible Reporting Data Model.xls*.

## Views

The BIP Reporting data model uses the views in the BIP Owner schema to fetch data from Global Temporary tables. These views are:

- V\$RPT\_ALL\_CLINICALSUMMARY
- V\$RPT\_CASESUMMARY
- V\$RPT\_CLINICALSUMMARY
- V\$RPT\_SECT61SUMMARY
- V\$RPT\_NONINT

Additionally, the following log views are provided to enable debugging and troubleshooting:

- V\$RPT\_ALL\_CLINICALSUMMARY\_LOG
- V\$RPT\_CASESUMMARY\_LOG

- V\$RPT\_CLINICALSUMMARY\_LOG
- V\$RPT\_SECT61SUMMARY\_LOG
- V\$RPT\_NONINT\_LOG

## Database Link

A default database link appears when you enable Oracle Analytics Publisher Periodic reporting. This link is created between the Oracle Analytics Publisher Owner schema and the BI Publisher Repository database and copies the report output blob to the Oracle Argus Safety database.

## Java Stored Procedure

The scheduled Flexible Periodic report outputs are stored in the BIP metadata repository in a compressed format. The BIP Owner schema uses a Java stored procedure to decompress the report output before storing it in the Oracle Argus Safety schema.

## Packages

The Oracle Analytics Publisher Owner schema holds the following package types:

- Utility package
- Data load package
- User exit package

For more information, see:

- [PKG\\_AGG\\_RPT\\_UTIL Utility Package](#)
- [PKG\\_AGG\\_RPT Data Load Package](#)
- [PKG\\_AGG\\_RPT\\_USER\\_EXIT User Exit Package](#)

## PKG\_AGG\_RPT\_UTIL Utility Package

The utility package holds minor utility features for the data load. Table 4-2 provides a list of functions and procedures and their usage.

**Table 4-2 Utility Package Details**

Procedure/Function	Usage
f_get_query_details	Populates the case series or query prompts that the user can access.
f_print_as_text	Determines the water mark.
f_get_cs_name	Returns the case series name for a Case Series ID.
f_get_agency_name	Gets the agency name for the passed Agency ID.
p_fetchrptoutput	Copies the report output data into Argus tables, updates CMN_REG_REPORTS, updates the report status tables and stores the submission details of the final report.
f_get_duration	Returns a formatted duration for printing in a report. For example, 10 days.

**Table 4-2 (Cont.) Utility Package Details**

Procedure/Function	Usage
f_get_codelist_val	Gets the code list display value.
f_get_enterprises	Gets the Active Enterprise list on the BIP console.
f_get_cmn_profile_flag	Fetches the cmn_profile value on key.
f_ConvertBlobToClob	Converts the blob data into clob.

## PKG\_AGG\_RPT Data Load Package

The data load package handles the data extraction and derivations that prepare the data for reporting. Table 4-3 provides the complete list of procedures and functions present in this package.

**Table 4-3 Data Load Package Details**

Procedure/Function	Usage
Global Variables	Describes all parameters shown or hidden on the BIP report screen as package level variables. Parameter values are automatically stored by the BIP report during execution.
Lexical Variables	Normal package variables described according to the lexical parameters used in the BIP report.
p_pop_psur_case_temp	Populates the temp table GTT_RPT_AGG_CASE.
p_pop_psur_drug_temp	Populates the temp table GTT_RPT_AGG_DRUG.
p_pop_psur_event_temp	Populates the temp table GTT_RPT_AGG_EVENT.
p_pop_psur_ev2drug_temp	Populates the table GTT_RPT_AGG_EV2DRUG.
p_pop_psur_healthauthids_temp	Populates the temp table GTT_RPT_AGG_HEALTHAUTHID.
p_pop_psur_drugnames_temp	Populates the table GTT_RPT_AGG_DRUGNAMES.
f_before_data	The main function invoked from BI Publisher. Called from the Before Report trigger of the BI Publisher report.
f_get_report_id	Retrieves the PN_REG_REPORT_ID parameter value.
p_set_report_id	Sets the PN_REG_REPORT_ID parameter value to the global variable so it can be retrieved through f_get_report_id in BIP reports.
p_check_cs_case_ctr	Checks the counts of cases needed for the trailer page.
p_ins_rpt_status	Inserts the record into PER_RPT_STATUS for log reporting.
p_upd_rpt_status	Updates the status of the report on completion with success or failure.
f_after_report	Final trigger invoked by Oracle Analytics Publisher.
f_get_evtseriouscr_list	Gets the event seriousness criteria list.
f_get_dose_stringlist	Generates the dose string list.
f_get_uniq_patient_id	Obtains the unique patient ID.

**Table 4-3 (Cont.) Data Load Package Details**

Procedure/Function	Usage
p_updclinicaldrugrole	Updates the clinicaldrugrole column in GTT_RPT_AGG_DRUG table.
p_update_gtt_tables	Updates the GTT tables for follow-up.
FindAggRptJobID	Local procedure that hits the Oracle Analytics Publisher metadata repository tables, obtains the blob data, converts into clob for easy processing, and arrives at the Job ID through the supplied parameters to the BIP reports. The Job ID is then inserted into the RPT_AGG_BIP_JOB table.
pop_user_security_tables	Populates user security tables based on the user-security level.
p_populate_cover_params	Fills in the data for the RPT_AGG_PARAMS table needed for the cover page.
p_populate_listedness	Determines and populates listedness for each case-event-product based on the chosen algorithm.
p_copy_rpt_case_series	Copies all case series required for report execution into the RPT_AGG_CASE_SERIES and RPT_AGG_CS_CASES tables.
p_populate_dlp_cases	Populates DLP cases.
p_set_lex_conditions	Handles the conditions used to set lexical parameters.
p_pop_log_tables	Populates all RM_ tables.
p_pop_concurrency_errors	Populates the Concurrency Error Handling that mentions whether the case series is modified while a report is in progress.

## PKG\_AGG\_RPT\_USER\_EXIT User Exit Package

Customers can place their code directly in this package to modify the data loaded. For example, the customer can modify the loaded case data by calling the user exit p\_modify\_case\_temp.

Table 4-4 describes the procedures and functions in the user exit package.

**Table 4-4 User Exit Package Details**

Procedure/Function	Usage
p_modify_case_temp	Called at the end of the case population procedure. You can customize the populated cases here.
p_modify_event_temp	Called at the end of the event population procedure. You can customize the populated events here.
p_modify_drug_temp	Called at the end of the drug population procedure. You can customize the populated drugs here.
p_modify_evt_assess_temp	Called at the end of the assessment population procedure. You can customize the populated assessment here.
p_modify_healthauthids_temp	Called at the end of the health authority details population procedure. You can customize the populated health authority IDs here.
p_modify_drugnames_temp	Called at the end of the drug name details population procedure. You can customize the populated drug name here.

**Table 4-4 (Cont.) User Exit Package Details**

Procedure/Function	Usage
p_modify_rm_case_temp	Called after loading the RM_RPT_AGG_CASE table.
p_modify_rm_event_temp	Called after loading the RM_RPT_AGG_EVENT table.
p_modify_rm_drug_tem	Called after loading the RM_RPT_AGG_DRUG table.
p_modify_rm_evt_assess_tem p	Called after loading the RM_RPT_AGG_EV2DRUG table.
p_modify_rm_healthauthids_te mp	Called after loading the RM_RPT_AGG_HEALTHAUTHID table.
p_modify_rm_drugnames_tem p	Called after loading the RM_RPT_AGG_DRUGNAMES table.

**Figure 4-1 General Structure of a User Exit**

```

-----
-- PROCEDURE : p_modify_case_temp - custom procedure to modify Case data
-----
-- Parameter(s) : None
-----

PROCEDURE p_modify_case_temp IS
BEGIN
  pkg_rpt_log.p_rep_execution_log (NULL, 'p_modify_case_temp', 'Execution of P_MODIFY_CASE_TMP started.');
```

```

  NULL;
  pkg_rpt_log.p_rep_execution_log (NULL, 'p_modify_case_temp', 'Execution of P_MODIFY_CASE_TMP completed successfully.');
```

```

END p_modify_case_temp;
-----
```

## Database Jobs

The Oracle Analytics Publisher Owner holds the following database jobs. You must create these jobs manually during the installation and configuration of Flexible Periodic Reports.

For more information on installation and configuration, refer to the *Oracle Argus Safety Installation Guide*.

For more information on the database jobs, see:

- [Report Output Pusher](#)
- [Persist Data Cleaner](#)

## Report Output Pusher

This job decompresses and pushes the report output from Oracle Analytics Publisher metadata through the utility procedure p\_fetchreportoutput.

The output is connected to the configuration using the configuration ID, BIP report name, and the draft/final option. The new output replaces the output with the same combination of key values. Oracle recommends you execute this job every 3 minutes. However, you can customize execution according to your needs.

For large customers who run multiple concurrent reports, you can execute job runs every 3-10 minutes. For small customers who run only a few reports the whole day, you can execute runs on an hourly basis.

If required, you can customize the job to push the completed report output to other data sources instead of the Oracle Argus Safety database.

## Persist Data Cleaner

A database job is needed to purge the data present in the Persist (RM) tables that exceeds the persist duration mentioned during the report scheduling or as mentioned in the Argus Console.

This job is not needed if you prefer not to use the Persist data mechanism. This can be set to run once a day or once a week based on the data load.

## Argus Application Schema Objects

The Oracle Argus Safety Application schema (argus\_app) has been enhanced to support Oracle Analytics Publisher Aggregate Reporting.

For more information, see:

- [Tables](#)
- [Packages](#)

## Tables

Table 4-5 describes the database tables added to the Oracle Argus Safety database to handle the internal operations related to Oracle Analytics Publisher Periodic Reporting.

**Table 4-5 Oracle Argus Safety Database tables**

Table Name	Purpose
CFG_RPT_AGG_PARAMS	Contains the parameters passed for each report, segregates the parameters that are part of the report header, and selects the default values.
SAFETY_ERR_LOG	Stores errors, warnings and debugs that occur during execution. Pushes errors into the Oracle Argus Safety error log.
CFG_BIP_REPORT_PARAMETERS	Stores the list of parameters that are passed in through the Oracle Analytics Publisher WebServices API.

## Packages

Packages related to case series have been updated to store case series data.

The **GSS\_UTIL** package has been updated to find if a user's access has expired.

A new package, **pkg\_rpt\_log**, is called from Oracle Analytics Publisher packages and stores the error, warning and debug messages in the SAFETY\_ERR\_LOG table. Additionally, it stores the error messages in the traditional Oracle Argus Safety error log tables by calling **Pkg\_Console\_Common.p\_error\_log**.

## Access Grants to Oracle Analytics Publisher Owner

You must provide access to the Argus database objects so the BIP schema can access them.

- SELECT access for Case related, Code list, and Configuration tables.
- SELECT, INSERT, UPDATE access for process tables such as **CMN\_REG\_REPORTS**, **PER\_RPT\_QUEUE**, **PER\_RPT\_STS**, **CMN\_SUB\_REPORTS**, and so on.
- EXECUTE access for various common packages such as **PKG\_RLS** and **GSS\_UTIL**.



### Note:

You need access for compiling BIP Packages in the BIP Owner schema.

# 5

## Flexible Aggregate Reporting Design

In this chapter:

- [Flexible Aggregate Reporting Design Structure](#)
- [Aggregate Report Data Flow](#)

### Flexible Aggregate Reporting Design Structure

This section provides an overview of the Oracle Analytics Publisher Periodic Reporting data model and report layout. Oracle recommends you go through Oracle Analytics Publisher guides for more information.

Each report in Oracle Argus FAR has the following categories:

- BI Publisher data model comprising parameters and XML file triggers
- BI Publisher Layout templates
- Database package

For more information, see:

- [Oracle Analytics Publisher Data Model](#)
- [BI Publisher Report Layout](#)

### Oracle Analytics Publisher Data Model

The Oracle Analytics Publisher data model comprises:

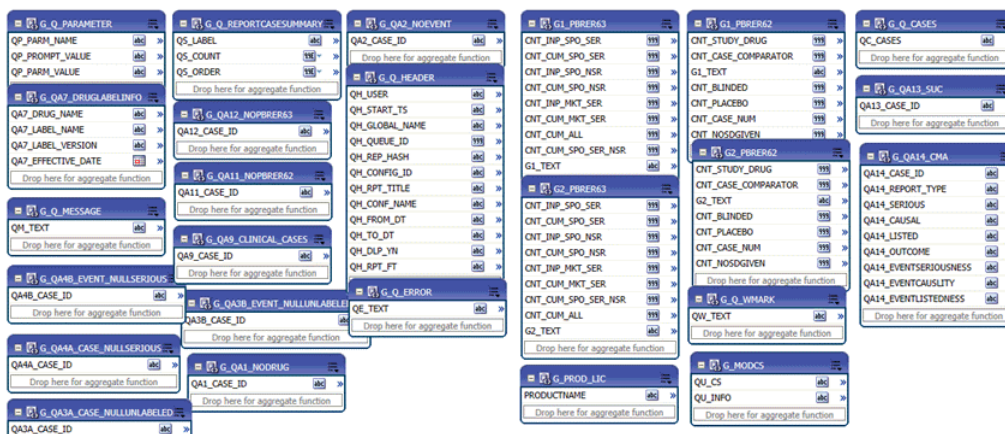
- [Data Sets](#)
- [Event Triggers](#)
- [Parameters](#)

#### Data Sets

Each BIP report has its own data sets. A data set is the XML data file used to generate the report output. Figure 5-1 displays the data set of the Periodic Benefit Risk Assessment Report (PBRER).



Figure 5-1 Data Sets



Each box represents a query that can fill in a group.

## Event Triggers

The Before data trigger and the After data trigger are the two event trigger types.

The Before data trigger is the starting point of the report after submission. The Before data trigger executes the **pkg\_agg\_rpt.f\_before\_data** procedure. You can customize trigger names per your requirements.

The Before data trigger call to the **pkg\_agg\_rpt.f\_before\_data** package passes the following arguments:

- XDO User name: The user logged in.
- Template ID: 1 represents PBRER, 2 represents PMAR, and 3 represents DSUR.

You can create multiple Before data triggers, and the system executes them in the arranged order.

The After data type trigger fires after the completion of the Before data triggers. OOTB reports call an empty function in this trigger so that the end user can modify the function.

## Parameters

Parameters are part of the data model. Figure 5-2 displays the parameters of the PBRER.

Figure 5-2 PBRER Parameters

Name	Data Type	Default Value	Parameter Type	Row Placement	Reorder
PN_ENTERPRISE_ID	Integer		Menu	1	
PN_REPORT_FORM_ID	Integer	-999999999	Menu	1	
PV_PRINT_AS	String	Draft	Menu	1	
PN_MAIN_CS_ID	Integer	-999999999	Menu	2	
PN_62_CS_ID	Integer	-999999999	Menu	2	
PN_CUM_CS_ID	Integer	-999999999	Menu	2	
PN_AGENCY	Integer	-999999999	Menu	3	
PN_PRT_UNBLIND	Integer	1	Menu	3	
PN_LABELING	Integer		Menu	3	
PN_PRT_PT	Integer	0	Menu	4	
PN_ONLY_DIAG	Integer	0	Menu	4	
PN_INC_FOLLOWUP	Integer	1	Menu	4	
PN_PRT_IDNT_EVTS	Integer	1	Menu	5	
PN_INCL_UNLCK	Integer	0	Menu	5	
PN_INCL_CMA	Integer	1	Menu	5	
PV_RPT_TITLE	String	PBRER	Text	6	
PV_RPT_HASH	String		Text	6	
PV_RPT_FT	String	Confidential	Text	6	
PN_LOG_MSG	Integer	0	Menu	7	
PV_SYM_SUSAR	String	**	Text	7	
PV_SYM_SPIE	String	†	Text	7	

The data model has the following types of parameters:

- Text
- Menu (list of values)
- Date

Text parameters are the simplest form. If you provide a default value, the system considers it automatically when no value is passed.

Menu parameters are LOVs and are associated with attached queries. For example, the AGENCY parameter is associated with the query in Figure 5-3.

Figure 5-3 Menu Parameters

```
select d.display_name, d.display_id from table(pkg_agg_rpt_util.f_get_query_details (:xdo_user_name, :PN_ENTERPRISE_ID,'LV_AGENCY',1) ) d
UNION ALL
select '--SELECT--' display_name, '-999999999' display_id from dual
order by 1,2
```

Oracle Argus Safety does not use date type parameters.

**Note:**

The default values take precedence even if there is a value present in the report configuration and you did not select a value during report execution.

You may see many -999999999 values as the default values. Inputting a value of -999999999 would show the -- *SELECT* -- record on the BIP Parameters screen. When no value is selected, the report tries to fetch any default value present in the report configuration.

For example, for **Main Case Series**, when the parameter value is not selected and is left at -- *SELECT* --, the report selects the main case associated with the report configuration.

**Enterprise ID** and **Report Configuration Name** are mandatory parameters. The report fails if either of these parameters is not submitted.

For more information on the list of parameters used in Flexible Aggregate Reporting, refer to the *Oracle Argus Safety Flexible Reporting Extensibility Guide*.

## BI Publisher Report Layout

Oracle Analytics Publisher Periodic Reporting uses Rich Text Format (RTF) for its templates. The layout maps the data sets and displays data at run time. You can also design the data model so the template calls other layouts within itself.

Figure 5-4 displays a portion of the PBRER data model. The report template calls other templates from the Cover and Summary pages.

**Figure 5-4 PBRER Data Model**

```

|<?import:xdoxsl:///Argus Safety/Cover Trailer/cover_rst.xsb?>
<?import:xdoxsl:///Argus Safety/Cover Trailer/trailer_rst.xsb?>
<?import:xdoxsl:///Argus Safety/PBRER/Reports/pbrer_qa_trailer_rst.xsb?>
<?import:xdoxsl:///Argus Safety/PBRER/Reports/pbrer_header_summary_rst.xsb?>
<?start.body?>
Page 1<?call@inlines.cover?>
<?end.call?>
<?end.body?>

```

Run Date: QH\_START\_TS  
By: QH\_USER  
Page 1/1

QH\_RPT\_FT

```

<?//LIST_G_Q_WMARK/G
Q_WMARK/QW TEXT?>

```

## Aggregate Report Data Flow

This section explains the flow of data from the time the user creates the report configuration until the report is executed completely.

For more information, see:

- [Oracle Argus Safety UI Entry](#)
- [Oracle Analytics Publisher Data Flow](#)

## Oracle Argus Safety UI Entry

To configure a report, navigate to the Periodic Report Configuration screen and enter the required configuration. The system saves this data in the required configuration tables.

You can either generate the case series or run the BIP report in a single step. A case series is generated in both cases.

For an ICH PSUR configuration, the following case series can be generated:

- Main Case Series
- Cumulative Case Series
- Section 6.2 Case Series
- Ad hoc Case series (1-4) when ad hoc listings are supplied

For a CTPR configuration, only Main Case Series and Cumulative Case Series tables are present.

The case series are stored in the case series tables.

## Oracle Analytics Publisher Data Flow

If you run the report from the Oracle Argus Safety UI directly, the system passes only the Enterprise ID, Report Configuration, Print As, and Reg Report ID parameters. Other parameters are picked up if no default values are provided at the BIP level.

1. Navigate to the BIP report that displays the parameter page.
2. Select the mandatory parameter ENTERPRISE ID.  
This selection executes the associated LOV query.

The selected value is verified by the query present in the CFG\_RPT\_AGG\_PARMS table for the parameter.

After verification, the enterprise ID is set for the session.

3. Select the mandatory parameter REPORT\_CONFIGURATION.  
This parameter determines whether the report will be in the Data Lock Point (DLP).

If the case series parameters are not selected, the default case series associated with this report configuration is set automatically.

This parameter is an LOV and the query present in the CFG\_RPT\_AGG\_PARMS table for the parameter validates the selected value.

4. Input the other parameters, and click **Submit**.  
This invokes the Before data trigger that calls the **f\_beforedata** function of the **pkg\_agg\_rpt** package.

This function:

1. Sets up all parameter values from the Oracle Analytics Publisher to Package variables.
2. Validates whether the mandatory parameters have been supplied.

3. Checks if the user's access has expired.
4. Determines whether the BIP report call is made from the Oracle Argus Safety UI or from the BIP console.
5. Handles case, study, or site security.
6. Finds the BIP report job.
7. Inserts records in CMN\_REG\_REPORTS.
8. Inserts records in PER\_RPT\_QUEUE and PER\_RPT\_STATUS.
9. Obtains the default values of all parameters using CFG\_RPT\_AGG\_PARAMS.
10. Determines whether the report is DLP.
11. Populates the data for listedness, drugs, events, event to drugs, and case data.
12. After the case data has been populated, fills in the health authority details and drug names.
13. Sets up the lexical parameters, if any.
14. Based on the persist data common switches, fills in the data for MART tables:
  - a. PERSIST\_BIP\_DATA: whether data from GTT needs to be moved to RM tables.
  - b. PERSIST\_DURATION: number of days for which the data is to be left at RM tables.

This results in the package filling in the complete data for data sets.

1. After the PLSQL code is complete, the BI report internally generates the data XML, renders the pages, and stores the output in its repository data.
2. The database job calls the **pkg\_rpt\_util.p\_fetchrptoutput** function, which obtains the list of reports that are run based on the RPT\_AGG\_BIP\_JOB table.
3. The database then queries the BIP Metadata Repository (MDR) and verifies that the report is complete. If the report has failed, the database updates the failure status and proceeds to the next report.
4. If the report is successful, the database checks if the Draft/Final tables are updated.
5. The system copies the report output blob to the reporting tables. It updates **CMN\_REG\_REPORTS** and the corresponding records in the **PER\_RPT\_QUEUE** and **PER\_RPT\_STATUS** tables.

After this operation is complete, you can view the report output in BIP and Oracle Argus Safety.

 **Note:**

The report output in BIP might be completed earlier than in Oracle Argus Safety UI. This is because the job picks up the output and pushes it to the Argus database.

# 6

## Extending a Flexible Aggregate Report

This chapter describes the options available for extending an out-of-the-box Oracle Analytics Publisher Periodic report.



### Note:

Oracle encourages customers to extend reports for their use but is not obliged to support the custom or extended code and is not responsible for any loss or damage caused by the extended code.

Oracle Analytics Publisher Periodic Reporting has the following customizable layers:

- Database layer
- Oracle Analytics Publisher layer

This further comprises:

- Data Model layer
- Report Layout layer

For more information, see:

- [Database Layer](#)
- [Extending the Oracle Analytics Publisher Data Model](#)
- [Creating a Custom Report](#)
- [Blinding Functionality](#)
- [Flexible Data Re-categorization](#)

## Database Layer

Objects specific to Oracle Analytics Publisher Reporting are present in a separate schema created during the installation of the Oracle Argus Safety database. This schema only has a limited set of objects and access privileges. Table 6-1 illustrates these objects and privileges.

**Table 6-1 Objects and Access Privileges**

Element	Description
Tables	<ul style="list-style-type: none"><li>• Global Temporary tables populate the report.</li><li>• RM tables persist data for Oracle Argus Mart OBIEE dashboards.</li><li>• Configuration tables store report parameter prompts and case series data.</li></ul>

**Table 6-1 (Cont.) Objects and Access Privileges**

Element	Description
Packages	<p>There are 3 packages:</p> <ul style="list-style-type: none"> <li>The main package loads the temp table data.</li> <li>The utility package holds the commonly used functions while loading the temp table data.</li> <li>The user exit package customizes the loaded temp table data.</li> </ul> <p>None of the packages are wrapped.</p>
Views	Used for grouping and accessed in the Oracle Analytics Publisher data model.
Access Grants	<p>Oracle Analytics Publisher has read-only access to the following objects in the Oracle Argus Safety application schema:</p> <ul style="list-style-type: none"> <li>List and configuration tables</li> <li>Case series tables</li> <li>Case tables</li> <li>Common packages such as gss, gss_util, gss_periodic, p_initialize_access and gss_wnds</li> </ul> <p>It has INSERT and SELECT access to:</p> <ul style="list-style-type: none"> <li>CMN_REG_REPORTS</li> <li>PER_RPT_QUEUE</li> <li>PER_RPT_STATUS</li> <li>CMN_PER_SUB_CHILD</li> <li>CASE_REG_REPORTS</li> <li>Report output tables</li> </ul>
Invoker Rights	BIP packages are created with Invoker rights with CURRENT_USER as the AUTHID.
Enterprise Security	<p>The new schema implements the Oracle Argus Safety enterprise security features.</p> <p>For data selection, call gss_util.set_context (uname, enterprise).</p>

For more information, see:

- [Configuration Extensibility](#)
- [Extending with User Exits](#)
- [Extending Global Temporary Tables](#)
- [Extending using Custom Objects](#)
- [Adding or Modifying a View](#)
- [Adding a Column to the Existing Table](#)

## Configuration Extensibility

You can update the out-of-the-box data in the **CFG\_RPT\_AGG\_PARAMS** table to modify report names. This configuration change is used for:

- Updating the parameter prompt text in the report output.
- Modifying the order of displaying report parameter prompts.
- Validating details of the parameter.

**Note:**

These are configuration changes and do not impact any other functionality. Also, there is no UI for this table. You can use any database tool connecting to the Oracle Argus Safety application schema.

## Extending with User Exits

You can use user exits to customize BIP Periodic Report data present in the GTT and RM Tables. Every population algorithm contains a user exit at the end during the database selection. A user exit lets you:

- Update Records
- Insert Records
- Delete Records

Table 6-2 contains the list of user exits.

**Table 6-2 List of User Exits**

Procedure	Usage
p_modify_case_temp	Executed at the end of case population procedure. Customization to populated cases can be done here.
p_modify_event_temp	Executed at the end of event population procedure. Customization to populated cases can be done here.
p_modify_drug_temp	Executed at the end of drug population. Customization of populated drugs can be taken up here.
p_modify_evt_assess_temp	Executed at the end of event assessment population. Customization of populated event assessment data can be taken up here.
p_modify_healthauthids_tem p	Executed at the end of Health authority details population.
p_modify_drugnames_temp	Executed at the end of drug name details population.

There is also a user exit for each RM table.



**Figure 6-1 Extending with User Exits**

```
Procedure pop_rpt_agg_case
<var1>
...
...
<varn>
Begin
  data load queries;
  ..
  ..
  ..
  data load statements;
  --[ User Exit Call ]--
  pkg_agg_rpt_user_exit.p_modify_case_temp;
Exception
  <exceptions>
End;
```

Figure 6-2 displays the structure of an out-of-the-box user exit.

**Figure 6-2 Structure of an Out-of-the-box User Exit**

```
Procedure pop_rpt_agg_case
<var1>
...
...
<varn>
Begin
  data load queries;
  ..
  ..
  ..
  data load statements;
  --[ User Exit Call ]--
  pkg_agg_rpt_user_exit.p_modify_case_temp;
Exception
  <exceptions>
End;
```

**Figure 6-3 Structure of an Out-of-the-box User Exit**

```

-----
-- PROCEDURE : p_modify_case_tmp - custom procedure to modify Case data
-----

-- Parameter(s) : None
-----

PROCEDURE p_modify_case_tmp IS
BEGIN
  pkg_rpt_log.p_rep_execution_log (NULL, 'p_modify_case_tmp', 'Execution of P_MODIFY_CASE_TMP started. ');
  NULL;
  pkg_rpt_log.p_rep_execution_log (NULL, 'p_modify_case_tmp', 'Execution of P_MODIFY_CASE_TMP completed successfully. ');
END p_modify_case_tmp;
-----

```

An out-of-the-box user exit only has a null statement between the log handlers. You can add logic (as necessary) to insert, update, or delete rows from corresponding or related tables.

A sample extension requirement is shown below:

### Requirement

Update the CUSTOMCASE01 column using truncated or formatted study name value based on a condition.

### Solution

Modify the p\_modify\_case\_tmp user exit. Write the following update statement within the p\_modify\_case\_tmp procedure:

```

Update GTT_RPT_AGG_CASE
Set CUSTOMCASE01 = Uformat(studyname)
Where <condn>

```

## Extending Global Temporary Tables

You might not need to extend the Global Temporary tables as the out-of-the-box table itself contains multiple flexible columns. Each GTT and RM table contains:

- 15 columns of type VARCHAR2 (4000)
- 4 columns to support DATE fields. The data type is VARCHAR2(8)
- 2 clob columns

You can fill these columns by using user exits.

## Extending using Custom Objects

You must retain the integrity of the reports while extending out-of-the-box periodic report database objects. You must create a new custom schema (using the naming standard BIP\_CUSTOM) where you can deploy your custom objects.

For more information, see:

- [Adding New Columns to GTT or RM Tables](#)
- [Filling Custom Tables](#)
- [Filling Custom Views](#)

- [Filling Custom Packages](#)

## Adding New Columns to GTT or RM Tables

To add new columns to GTT and RM tables:

1. Create a replica of the GTT in the custom schema. For example, if the customer needs new columns in the `GTT_RPT_AGG_CASE` table, create the replica of this table in the custom schema, named `XX_GTT_RPT_AGG_CASE`.
2. Add the new columns to the replica table in the custom schema.
3. Grant the new table access to the out-of-the-box BIP schema.
4. Create a synonym for this object (public synonym). The BIP schema can access this new object.
5. Modify the user exit package corresponding to this GTT to fill in the new custom table and logistics to load the additional two columns.

## Filling Custom Tables

Follow the same procedure for filling custom tables. You do not need to replicate a table from the BIP schema.

## Filling Custom Views

You might need to deploy custom views for solving complicated logistics. This functionality is limited to accessing the objects of the BIP schema only.

To fill custom views, perform the following steps:

1. Create the view in the custom schema.
2. Grant BIP schema access to the view.
3. Create a synonym for the view (public synonym).

You can use this view either in the BIP schema or in the BI data model.

## Filling Custom Packages

Follow the same procedure for filling custom packages.

## Adding or Modifying a View

You can create your own view in the custom schema. If these views directly access BIP schema objects, you might need to provide grants. After the BIP schema is created, it has access to this view and can be utilized in the package through user exits.

## Adding a Column to the Existing Table

Temp tables provide custom columns for customer use. However, there might be instances when you want to add further tables. You can do this in the following ways:

- Adding the columns directly into the table and manipulating it.

- If you are not allowed to add directly, you can create a replica of the table in the custom schema along with the new columns needed.

The BIP schema is provided a grant for the new object and a synonym is created.

Then, the data can be inserted in the new table.

## Extending the Oracle Analytics Publisher Data Model

### Note:

While extending Oracle Analytics Publisher reports, irrespective of whether the extension is in the data model layer or the layout, Oracle recommends taking a complete backup of the report in another catalog folder and then proceeding with the extension.

For more information, see:

- [Data Model Query Naming Convention](#)
- [Data Model Nested Queries](#)
- [Data Structure Groups](#)
- [DSUR Summary Table Naming Conventions](#)
- [Case Series Tables](#)
- [Lexical Parameters](#)

## Data Model Query Naming Convention

The Oracle Analytics Publisher data model queries follow a standard naming convention:

Q<Query level no>\_<Report section identification>

For example,

Q1\_DSURLINELISTING: First level query of the DSUR line listing section.

Q1\_MAINDSURSUMTAB: First level query of DSUR Main Summary tabulation.

Q2\_DEATHDSURSUMTAB: Second level query of DSUR Fatal Summary Tabulation.

Q4\_CMAINDSURSUMTAB: Fourth level query of DSUR Cumulative Main ST.

Q2\_CONSUMTAB: Second level query of Consumer ST.

## Data Model Nested Queries

BIP Periodic reports follow the model of Nested queries.

Consider the PBRRER 6.2 Cumulative Summary Tabulation queries.

### Query 1: Q1\_PBRER62

```
SELECT ct.soc g1pbrer62soc,  
       COUNT (ct.CASE_STUDY_DRUG) cnt_study_drug,
```

```

COUNT (ct.CASE_COMPARATOR) cnt_case_comparator,
COUNT (ct.case_blinded) cnt_blinded,
COUNT (ct.case_placebo) cnt_placebo,
COUNT (ct.case_nosdgiven) cnt_nosdgiven,
COUNT (ct.case_num) cnt_case_num
FROM v$rpt_clinicalsummary ct
WHERE ct.REG_REPORT_ID = pkg_agg_rpt.f_get_report_id
AND (ct.Sec62cumflag = 'Y' AND NVL(ct.sec63nonintcumflag,'N') <> 'Y')
AND (ct.casetype = 'C' AND ct.eventseriousflag = 'Y')
AND ct.Clinicaldrugrole != 6
GROUP BY ct.ev_socdisplaynbr,ct.soc
ORDER BY ct.ev_socdisplaynbr,ct.soc;

```

In QUERY 1, the column SOC is given an alias *g1pbrer62soc*

Grouping: g1 -> Group 1

pbrer62 -> Report section

soc -> Column name

Sorting: Order by SOCDISPLAYNBR and SOC. Users can modify the sorting columns by changing the data model queries for each group.

#### Query 2: Q2\_PBRER62

```

SELECT ct.reaction g2pbrer62reaction,
COUNT (ct.CASE_STUDY_DRUG) cnt_study_drug,
COUNT (ct.CASE_COMPARATOR) cnt_case_comparator,
COUNT (ct.case_blinded) cnt_blinded,
COUNT (ct.case_placebo) cnt_placebo,
COUNT (ct.case_nosdgiven) cnt_nosdgiven,
COUNT (ct.case_num) cnt_case_num
FROM v$rpt_clinicalsummary ct
WHERE ct.REG_REPORT_ID = pkg_agg_rpt.f_get_report_id
AND (ct.Sec62cumflag = 'Y' AND NVL(ct.sec63nonintcumflag,'N') <> 'Y')
AND (ct.casetype = 'C' AND ct.eventseriousflag = 'Y')
AND ct.clinicaldrugrole != 6
AND ct.soc = :g1pbrer62soc
GROUP BY ct.reaction
ORDER BY ct.reaction;

```

In the above QUERY 2 the column REACTION given an alias "g2pbrer62reaction"

Grouping:g2 -> Group 2

pbrer62 -> Report section

reaction -> Column name.

Sorting: Order by Event Reaction, Users can modify the sorting columns by changing the data model queries for each group.

In Query 2, the group1 column SOC is passed in the where condition *AND ct.soc = :g1pbrer62soc*.

Hence, Query 2 fetches rows only for the SOCs from Query 1. This NESTED query model is used throughout BIP Periodic reports.

## Data Structure Groups

For Queries 1 and 2, the sample data structure is depicted below. This can be found in Datamodel -> Code tab.

Query 1 -> Q1\_PBRER62 is source for the group G1\_PBRER62 and the group G2\_PBRER62 is NESTED under G1\_PBRER62.

```
<group name="G1_PBRER62" label="" source="Q1_PBRER62">
  <element name="CNT_STUDY_DRUG" value="CNT_STUDY_DRUG" label="CNT_STUDY_DRUG"
  dataType="xsd:double" breakOrder="" fieldOrder="2"/>
  <element name="CNT_CASE_COMPARATOR" value="CNT_CASE_COMPARATOR"
  label="CNT_CASE_COMPARATOR" dataType="xsd:double" breakOrder="" fieldOrder="3"/>
  <element name="G1_TEXT" value="G1PBRER62SOC" label="G1PBRER62SOC"
  dataType="xsd:string" breakOrder="" fieldOrder="1"/>
  <element name="CNT_BLINDED" value="CNT_BLINDED" label="CNT_BLINDED"
  dataType="xsd:double" breakOrder="" fieldOrder="4"/>
  <element name="CNT_PLACEBO" value="CNT_PLACEBO" label="CNT_PLACEBO"
  dataType="xsd:double" breakOrder="" fieldOrder="5"/>
  <element name="CNT_CASE_NUM" value="CNT_CASE_NUM" label="CNT_CASE_NUM"
  dataType="xsd:double" breakOrder="" fieldOrder="7"/>
  <element name="CNT_NOSDGIVEN" value="CNT_NOSDGIVEN" label="CNT_NOSDGIVEN"
  dataType="xsd:double" breakOrder="" fieldOrder="6"/>
  <group name="G2_PBRER62" label="" source="Q2_PBRER62">
  <element name="CNT_STUDY_DRUG" value="CNT_STUDY_DRUG" label="CNT_STUDY_DRUG"
  dataType="xsd:double" breakOrder="" fieldOrder="2"/>
  <element name="CNT_CASE_COMPARATOR" value="CNT_CASE_COMPARATOR"
  label="CNT_CASE_COMPARATOR" dataType="xsd:double" breakOrder="" fieldOrder="3"/>
  <element name="G2_TEXT" value="G2PBRER62REACTION" label="G2PBRER62REACTION"
  dataType="xsd:string" breakOrder="" fieldOrder="1"/>
  <element name="CNT_BLINDED" value="CNT_BLINDED" label="CNT_BLINDED"
  dataType="xsd:double" breakOrder="" fieldOrder="4"/>
  <element name="CNT_PLACEBO" value="CNT_PLACEBO" label="CNT_PLACEBO"
  dataType="xsd:double" breakOrder="" fieldOrder="5"/>
  <element name="CNT_CASE_NUM" value="CNT_CASE_NUM" label="CNT_CASE_NUM"
  dataType="xsd:double" breakOrder="" fieldOrder="7"/>
  <element name="CNT_NOSDGIVEN" value="CNT_NOSDGIVEN" label="CNT_NOSDGIVEN"
  dataType="xsd:double" breakOrder="" fieldOrder="6"/>
  </group>
</group>
```

There can be multiple rows in the group G2\_PBRER62 for one row from G1\_PBRER62.

For group columns such as SOC (QUERY 1) and REACTION (QUERY 2), the element names vary.

In the sample data structure, the element name G1\_TEXT denotes that it is a group column and the value is *G1PBRER62SOC* alias name given in QUERY 1.

For QUERY 2 the element name G2\_TEXT denotes that it is the second group column and the value is *G2PBRER62REACTION* alias name given in QUERY 2.

## DSUR Summary Table Naming Conventions

Let us consider the DSUR Main summary tabulation data structure to explain the naming conventions and drug key table functionality.

1. The first group name is *G1\_DSURSUMTAB*. It is different for all DSUR summary sections.

For fatal summary tabulation, the group name is *G1\_DSURSUMTAB1*.

For Cumulative main ST section, the group name is *G1\_DSURSUMTAB3*.

For Cumulative fatal ST section, the group name is *G1\_DSURSUMTAB4*.

The grouping column is Follow-Up text. The element name is *G1\_TEXT1* and is used in *dsur\_sum.rtf*.

2. The second group name is *G2\_DSURSUMTAB*. The second (and subsequent) group names are the same for all DSUR summary tabulation sections. This effectively uses the DSUR summary sub-template. The grouping column is Sponsor study Number. The element name is *G2\_TEXT1* and is used in *dsur\_sum.rtf*.
3. *G3\_DRUGKEY* is the third group which prints Study and Comparator drugs in a table format.

**Figure 6-4 Study and Comparator Drugs Format**

Drug Role	Column Number	Drug Name
Study ID: Study Name		
IMP Treatment	1	Prod1+Prod2
IMP Treatment	2	Prod3
Comparator Treatment	1	Prod4

In the summary tabulation, IMP 1 is printed under IMP Treatment1 and IMP 2 is printed under IMP Treatment2. The titles are configurable (flexible code list: *BIP\_PROD\_CATEGORY*).

4. The fourth group name is *G4\_DSURSUMTAB*. It is the same for all DSUR summary tabulation sections. The grouping column is SOC. The element name is *G4\_TEXT1* and is used in *dsur\_sum.rtf*.
5. The fifth group name is *G5\_DSURSUMTAB*. It is the same for all DSUR summary tabulation sections. The grouping column is Event Reaction. The element name is *G5\_TEXT1* and is used in *dsur\_sum.rtf*. The Column title appears from the code list *BIP\_PROD\_CATEGORY* and element name is *G5\_TEXT2*.

```
<group name="G1_DSURSUMTAB" label="G1_DSURSUMTAB" source="Q1_MAINDSURSUMTAB">
  <element name="G1_TEXT3" value="G1MAINDSURPSURFOLLOWUPFLAG"
label="G1MAINDSURPSURFOLLOWUPFLAG" dataType="xsd:string" breakOrder=""
fieldOrder="1"/>
  <element name="G1_TEXT1" value="G1MAINDSURPSURFOLLOWUPTEXT"
label="G1MAINDSURPSURFOLLOWUPTEXT" dataType="xsd:string" breakOrder=""
fieldOrder="2"/>
  <element name="CNT_CASEID" value="CNT_CASEID"
label="CNT_CASEID" dataType="xsd:double" breakOrder="" fieldOrder="3"/>
  <group name="G2_DSURSUMTAB" label="G2_DSURSUMTAB"
source="Q2_MAINDSURSUMTAB">
  <element name="G2_TEXT1"
value="G2MAINDSURSPONSORSTUDYNUMB" label="G2MAINDSURSPONSORSTUDYNUMB"
dataType="xsd:string" breakOrder="" fieldOrder="1"/>
  <element name="CNT_CASEID" value="CNT_CASEID"
label="CNT_CASEID" dataType="xsd:double" breakOrder="" fieldOrder="2"/>
  <group name="G3_DRUGKEY" label="G3_DRUGKEY"
```

```

source="Q3_DRUGKEY1">
    <element name="G3_DRUGROLE" value="G3_DRUGROLE"
label="G3_DRUGROLE" dataType="xsd:string" breakOrder="" fieldOrder="2"/>
    <element name="G3_COLUMNNUMBER" value="G3_COLUMNNUMBER"
label="G3_COLUMNNUMBER" dataType="xsd:double" breakOrder="" fieldOrder="3"/>
    <element name="G3_DRUGNAME" value="G3_DRUGNAME"
label="G3_DRUGNAME" dataType="xsd:string" breakOrder="" fieldOrder="4"/>
    <element name="G3_STUDYID" value="G3_STUDYID"
label="G3_STUDYID" dataType="xsd:string" breakOrder="" fieldOrder="1"/>
</group>
<group name="G4_DSURSUMTAB" label="G4_DSURSUMTAB"
source="Q4_MAINDSURSUMTAB">
    <element name="G4_TEXT1" value="G4MAINDSURSOC"
label="G4MAINDSURSOC" dataType="xsd:string" breakOrder="" fieldOrder="1"/>
    <element name="CNT_CASEID" value="CNT_CASEID"
label="CNT_CASEID" dataType="xsd:double" breakOrder="" fieldOrder="2"/>
    <group name="G5_DSURSUMTAB" label="G5_DSURSUMTAB"
source="Q5_MAINDSURSUMTAB">
    <element name="G5_TEXT1" value="G5BMAINDSURREACTION"
label="G5BMAINDSURREACTION" dataType="xsd:string" breakOrder="" fieldOrder="1"/>
    <element name="G5_TEXT2" value="G5MAINDSURLISTCOL"
label="G5MAINDSURLISTCOL" dataType="xsd:string" breakOrder="" fieldOrder="2"/>
    <element name="G5_TEXT4" value="G5MAINDSURORD"
label="G5MAINDSURORD" dataType="xsd:double" breakOrder="" fieldOrder="3"/>
    <element name="CNT_CASEID" value="CNT_CASEID"
label="CNT_CASEID" dataType="xsd:double" breakOrder="" fieldOrder="4"/>
    </group>
    </group>
</group>
</group>

```

## Case Series Tables

The procedure `pkg_agg_rpt.p_copy_rpt_case_series` copies all case-series required for report execution into the `RPT_AGG_CASE_SERIES` and `RPT_AGG_CS_CASES` tables.

For more information, see:

- [Common Queries \(lexicals\) Used in Reports](#)

## Common Queries (lexicals) Used in Reports

The following queries are available in the package header `pkg_agg_rpt`.

**Table 6-3 pkg\_agg\_rpt Queries**

Value	Description
Q_MESSAGE	Returns all WARNING type log messages that appear in the trailer section <b>Warning Messages</b> .
Q_ERROR	All ERROR type messages appear in trailer page under <b>Error Messages</b> section.
Q_CASES	Lists Cases of only Main Case series from the BIP tables <code>RPT_AGG_CASE_SERIES</code> and <code>RPT_AGG_CS_CASES</code> on the Cover page.
Q_REPORTCASESUMMARY	Returns Totals section on the Trailer page. The Total of valid and invalid case count appears (only cases from MAIN CASE SERIES are considered).
Q_WMARK	Populates water marks for the reports. For example, <i>DRAFT</i> , <i>INTERNAL</i> .



**Table 6-3 (Cont.) pkg\_agg\_rpt Queries**

Value	Description
Q_MODCS	Case Series Modification history appears on the cover page for all BIP reports.
Q_HEAD	Fetches reg_report_id, report title, report hash, report footer, report from and to date, Previous date and DLP/Non-DLP values for printing on the Cover page as headers.
Q_TITLE	Defines titles for the DSUR Main line listing and Cumulative Summary tabulations based on the parameter <code>Print Serious Adverse Events</code> or <code>Reactions</code> .

The following queries are used in QA sections of the reports.

**Table 6-4 QA Section Queries**

Element	Description
Q_QA1	Lists case numbers without any qualifying drugs. Considers all cases not available in the <code>GTT_RPT_AGG_DRUG</code> table but available in <code>GTT_RPT_AGG_CASE</code> .
Q_QA2	Lists Case numbers without any qualifying events. Considers all cases not available in the <code>GTT_RPT_AGG_EVENT</code> table but available in <code>GTT_RPT_AGG_CASE</code> .
Q_QA3	Lists Case numbers with undefined case level unlabeledness. Considers all cases with the column <code>GTT_RPT_AGG_CASE.CASEUNLABELEDNESSCODE</code> value set to NULL.
Q_QA4	Lists Case numbers with undefined event level unlabeledness. Considers all cases with the column <code>GTT_RPT_AGG_EVENT.EVENTUNLABELEDNESSCODE</code> value set to NULL.
Q_QA5	Lists Case numbers with undefined Case level seriousness. Considers cases with column <code>GTT_RPT_AGG_CASE.CASESERIOUSFLAG</code> value set to NULL.
Q_QA6	Lists Case numbers with undefined Event level seriousness. Considers cases with column <code>GTT_RPT_AGG_EVENT.EVENTSERIOUSFLAG</code> value set to NULL.
Q_QA7	Lists the Labels configured for drugs in the drug list. The query is different for PMAR, PBRER and DSUR and is available in the data models.
Q_QA9	Lists Non-Clinical Case numbers (where the column <code>GTT_RPT_AGG_CASE.CASETYPE</code> != 'C')
Q_QA13	Summary of Unlocked Cases.
Q_QA14	Cases with Missing Assessment.

## Lexical Parameters

The following lexical parameter code is available in the `pkg_agg_rpt` package.

- 1. Include only HCP cases in summary tabulation:** For value 1 (YES/HCP, AND ct.casemedicallyconfirmflag =Y), only medically confirmed cases are shown.

```
IF PN_HCP_ONLY = 1 THEN
    GL_ST_FILTER_HCP:= ' AND ct.casemedicallyconfirmflag ='Y';
ELSE
    GL_ST_FILTER_HCP:= ' ';
END IF;
```

The variable `GL_ST_FILTER_HCP` is used in the Data model of the PMAR Summary Tabulation sections to filter HCP cases.

- 2. Include Follow-up cases from summary tabulations:** To filter out Follow-up cases in summary tabulation sections.

```
IF PN_INC_FOLLOWUP = 1 THEN
    GL_ST_EXCLUDE_FOLLOWUP := ' ';
ELSE
    GL_ST_EXCLUDE_FOLLOWUP := ' AND ct.psurfollowupflag ='N';
END IF;
```

- 3. Exclude Non-Serious cases from summary tabulations:** If the report parameter *Exclude non serious cases from summary tabulations* is set to **Y**, Grouping and Counts based on Non-Serious events that are part of serious cases are still printed. Only Non-serious cases and corresponding events are ignored based on the parameter value of **Y**.

```
IF PN_EXC_NS_ST = 1 THEN
    GL_ST_FILTER_SERIOUS := ' AND ct.caseseriousflag = 'Y'; --' AND
ct.eventseriousflag ='Y';
ELSE
    GL_ST_FILTER_SERIOUS := ' ';
END IF;
```

- 4. List cases in the line listing under SOC for each diagnosis:** Line Listing-> List Cases only once, under the primary event and List Cases under all events, details under the primary event.

**Table 6-5 List cases in the line listing under SOC for each diagnosis**

Value	Description
GL_LL_MAIN_NONPRI_CASEREF	PMAR main line listing section uses this variable.
GL_LL_ADHOC1_NONPRI_CASER EF	PMAR Adhoc1 line listing section uses this variable.
GL_LL_ADHOC2_NONPRI_CASER EF	PMAR Adhoc2 line listing section uses this variable.
GL_LL_ADHOC3_NONPRI_CASER EF	PMAR Adhoc3 line listing section uses the variable.
GL_LL_ADHOC4_NONPRI_CASER EF	PMAR Adhoc4 line listing section uses the variable.
GL_LL_PRI_CASESOC_ONLY	To print case details under primary case SOC.
GL_LL_DSUR_PRI_CASESOC_ON LY	DSUR reports.
GL_LL_DSURMAIN_NONPRI_CAS EREF	DSUR reports.
L_LL_DSURDTH_NONPRI_CASER EF	DSUR reports.

Code snippet:

```

        IF PN_LL_SOC = 1 THEN
            GL_LL_MAIN_NONPRI_CASEREF          := ' AND EXISTS (SELECT 1 FROM
gtt_rpt_agg_event pdt WHERE pdt.reg_report_id = pc.reg_report_id AND
pdt.case_id = pc.case_id AND pdt.soc = :g4mainsoc) ';
            GL_LL_ADHOC1_NONPRI_CASEREF       := ' AND EXISTS (SELECT 1 FROM
gtt_rpt_agg_event pdt WHERE pdt.reg_report_id = pc.reg_report_id AND
pdt.case_id = pc.case_id AND pdt.soc = :g4adhocsoc) ';
            GL_LL_ADHOC2_NONPRI_CASEREF       := ' AND EXISTS (SELECT 1 FROM
gtt_rpt_agg_event pdt WHERE pdt.reg_report_id = pc.reg_report_id AND
pdt.case_id = pc.case_id AND pdt.soc = :g4adhoc2soc) ';
            GL_LL_ADHOC3_NONPRI_CASEREF       := ' AND EXISTS (SELECT 1 FROM
gtt_rpt_agg_event pdt WHERE pdt.reg_report_id = pc.reg_report_id AND
pdt.case_id = pc.case_id AND pdt.soc = :g4adhoc3soc) ';
            GL_LL_ADHOC4_NONPRI_CASEREF       := ' AND EXISTS (SELECT 1 FROM
gtt_rpt_agg_event pdt WHERE pdt.reg_report_id = pc.reg_report_id AND
pdt.case_id = pc.case_id AND pdt.soc = :g4adhoc4soc) ';
            GL_LL_PRI_CASESOC_ONLY             := ' ';
            GL_LL_DSUR_PRI_CASESOC_ONLY        := ' ';
            GL_LL_DSURMAIN_NONPRI_CASEREF     := ' AND EXISTS (SELECT 1 FROM
gtt_rpt_agg_event pdt WHERE pdt.reg_report_id = pc.reg_report_id AND
pdt.case_id = pc.case_id AND pdt.soc = :g5asrsoc) ';
            GL_LL_DSURDTH_NONPRI_CASEREF      := ' AND EXISTS (SELECT 1 FROM
gtt_rpt_agg_event pdt WHERE pdt.reg_report_id = pc.reg_report_id AND
pdt.case_id = pc.case_id AND pdt.soc = :g12asrsoc) ';
            ELSE
                GL_LL_MAIN_NONPRI_CASEREF     := ' AND pc.primarycasesoc
= :g4mainsoc ';
                GL_LL_ADHOC1_NONPRI_CASEREF   := ' AND pc.primarycasesoc
= :g4adhocsoc ';
                GL_LL_ADHOC2_NONPRI_CASEREF   := ' AND pc.primarycasesoc
= :g4adhoc2soc ';
                GL_LL_ADHOC3_NONPRI_CASEREF   := ' AND pc.primarycasesoc
= :g4adhoc3soc ';
                GL_LL_ADHOC4_NONPRI_CASEREF   := ' AND pc.primarycasesoc
= :g4adhoc4soc ';
                GL_LL_PRI_CASESOC_ONLY         := ' AND pc.primarycasesoc = pe.soc
';
                GL_LL_DSUR_PRI_CASESOC_ONLY    := ' AND pc.primarycasesoc = pe.soc
';
                GL_LL_DSURMAIN_NONPRI_CASEREF := ' AND pc.primarycasesoc
= :g5asrsoc ';
                GL_LL_DSURDTH_NONPRI_CASEREF  := ' AND pc.primarycasesoc
= :g12asrsoc ';
            END IF;
    
```

5. Print Serious Adverse Events or Reactions: Filters out related events.

```

    IF PN_SAR_SAE = 1 THEN
        GL_SAR_SAE_PBRER_COND := ' AND (ct.eventcorelatedcode = 'Y' OR
ct.eventrptrelatedcode = 'Y') ';
        GL_SAR_SAE_DSUR_COND := ' AND (ct.eventcorelatedcode = 'Y' OR
ct.eventrptrelatedcode = 'Y') ';
        GL_SAR_SAE_DSUR_LL    := ' AND (pet.eventcorelatedcode = 'Y' OR
pet.eventrptrelatedcode = 'Y') ';
        ELSE
            GL_SAR_SAE_PBRER_COND := ' ';
            GL_SAR_SAE_DSUR_COND := ' ';
            GL_SAR_SAE_DSUR_LL    := ' ';
        END IF;
    
```

## Creating a Custom Report

### Adding a new code list ID REPORT\_TEMPLATE and Decoding Context REPALG for custom FAR

This section provides guidelines to create a new custom BIP report using the existing data extraction packages. Only 3 algorithms, PMAR, PBRER, and DSUR, can be used for any new custom reports using the data extraction packages. Any new algorithm logic (other than the 3 mentioned above) must be added by the user in the data extraction package.

To create a new custom BIP report:

1. Go to Oracle Argus Safety UI > Oracle Argus Safety Console > **Code Lists** > **Flexible Data Re-Categorization**.
2. Select the code list ID as REPORT TEMPLATE and click **Search**.
3. Enter a new row by clicking **Add New** and entering the necessary details.

Code List Name  
REPORT\_TEMPLATE Search

Report Template - REPORT\_TEMPLATE Add Attribute Remove Attribute

REPCONFIG	REPPATH	REPPATH	REP_TEMPLATE	UI	REPALG
PSUR	21	/Argus Safety/PBRER/Reports/pbrer.xdo	PBRER	3	PBRER
PSUR	21	/Argus Safety/CUSTOM/cust_rtf.xdo	CUST	3	PBRER
PSUR	22	/Argus Safety/PMAR/Reports/pmar.xdo	PMAR	2	PMAR
CTPR	121	/Argus Safety/DSUR/Reports/dsur.xdo	DSUR	2	DSUR
PSUR	2		PSUR	1	
CTPR	12		CTPR	1	
CTPR	122		SUSAR	0	
IND	3		IND	0	
NDA	4		NDA	0	

Add New Save Copy Export to Excel Cancel

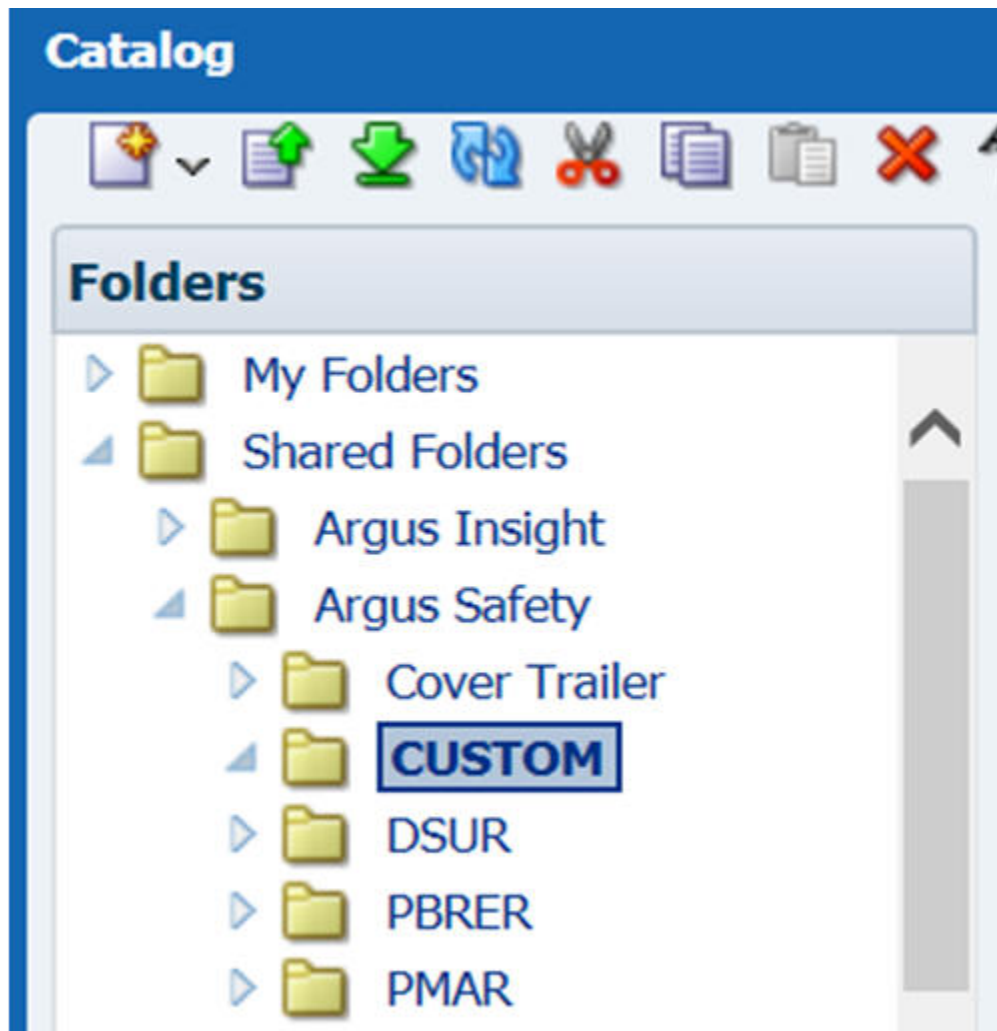
The REPPATH value must be entered correctly. For the REPTEMPLATE value, enter whatever must appear in the UI (Report Configuration, such as CUST).

4. Once this entry is made, the details can be seen in the database under code\_list\_detail\_discrete table.

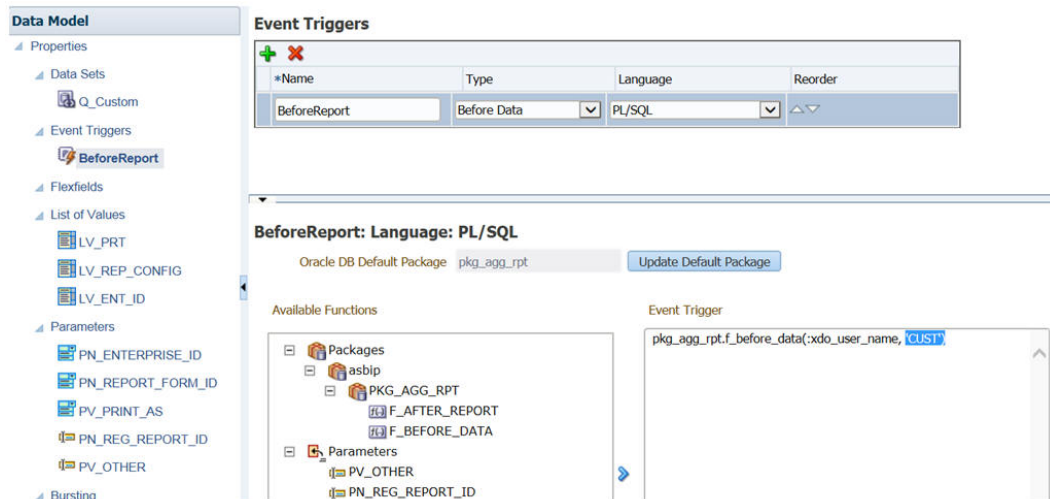
```
select * from code_list_detail_discrete where code_list_id = 'REPORT_TEMPLATE' and code = 100000;
```

CODE_LIST_ID	DECODE_CONTEXT	CODE	DISPLAY_VALUE	PREFERRED	SORT	LAST_UPDATE_TIME	ENTERPRISE_ID	DELETED
1	REPORT_TEMPLATE REPALG	100000	FBRER	0	(null)	28-APR-16	1	(null)
2	REPORT_TEMPLATE REPONFIG	100000	FSUR	0	(null)	28-APR-16	1	(null)
3	REPORT_TEMPLATE REPPFORMTYPE	100000	21	0	(null)	28-APR-16	1	(null)
4	REPORT_TEMPLATE REPPATH	100000	/Argus Safety/CUSTOM/cust_rtf.xdo	0	(null)	28-APR-16	1	(null)
5	REPORT_TEMPLATE REPTEMPLATE	100000	CUST	0	(null)	28-APR-16	1	(null)
6	REPORT_TEMPLATE UI	100000	3	0	(null)	28-APR-16	1	(null)

- Log in to Oracle Analytics Publisher and create a new folder under Oracle Argus Safety as per the value you entered in the REPPATH. In the example used, it is mentioned as CUSTOM and so the folder created is called CUSTOM.



- You can prepare the custom data model and report template as per your requirements. You must ensure that the Before Report Event Trigger under Data Model contains the same value as mentioned in the REPTEMPLATE (such as CUST).



7. Apply the changes and Save. Configure/create a report under Argus Safety Report configuration section and print/run the report. The new REPTEMPLATE value appears in the drop-down list.
8. Once the report is generated, you can take the output from the Argus Report Configuration.

PSUR	PBRER SD1 DLP	01-JAN-2000 / 05-APR-2016	FINAL	sumand	05-APR-2016	Not specified
PBRER					05-APR-2016	
PSUR	PMAR SD1 DLP	01-JAN-2000 / 05-APR-2016	DRAFT	sumand	05-APR-2016	Not specified
PMAR					05-APR-2016	
PSUR	PBRER SD1	01-JAN-2000 / 05-APR-2016	DRAFT	sumand	05-APR-2016	Not specified
PBRER					14-APR-2016	

## Blinding Functionality

The flexible reports have a parameter named Print Unblinded Data which is used to determine the contents to be printed in the report. This parameter is not applicable for restricted users. The below given table provides the user access to unblind the data and results.

**Table 6-6 User Access to Unblinded Data and Results**

Study Status	Case or Code Broken	User Access to Blinded Information	Print Unblinded Data	Result
Blinded	Blinded	No	No	Blinded
Blinded	Blinded	No	Yes	Blinded
Blinded	Blinded	Yes	Yes	Blinded
Blinded	Blinded	Yes	No	Blinded
Blinded	Unblinded	No	No	Blinded
Blinded	Unblinded	No	Yes	Blinded
Blinded	Unblinded	Yes	Yes	Unblinded

**Table 6-6 (Cont.) User Access to Unblinded Data and Results**

Study Status	Case or Code Broken	User Access to Blinded Information	Print Unblinded Data	Result
Blinded	Unblinded	Yes	No	Blinded
Unblinded	Blinded	No	No	Blinded
Unblinded	Blinded	No	Yes	Blinded
Unblinded	Blinded	Yes	Yes	Blinded
Unblinded	Blinded	Yes	No	Blinded
Unblinded	Unblinded	No	No	Unblinded
Unblinded	Unblinded	No	Yes	Unblinded
Unblinded	Unblinded	Yes	Yes	Unblinded
Unblinded	Unblinded	Yes	No	Unblinded

## Flexible Data Re-categorization

The flexible data re-categorization feature is used in OOB BIP Aggregate reports to provide the user with greater control and flexibility on the values they want to print in the report. These code lists are configurable through the Oracle Argus Safety console.

This code list data storage design can be leveraged to add new and custom code lists or values by applications and customers without adding new database tables and columns.

The following code lists are provided for BIP aggregate reports:

- **REPORT\_TEMPLATE:** Use this code list to manage the BIP report templates available in the system (OOB and Custom) and assign an Oracle Argus Safety periodic configuration (ICH PSUR or CTPR) with which you can execute this report template. Whenever a new report template is added in BIP, the system modifies this code list to provide the report template name, path and corresponding Oracle Argus Safety configuration.
- **ADHOC\_LINE\_LISTING:** All list names added to the *ad hoc line listing* code list are available in the UD Summaries tab and can be used to attach memorized reports to a particular line listing section of periodic reports. You can rename these using the Flexible Re-categorization UI. The system provides four ad hoc line listings by default. You can increase them using this code list if you have more ad hoc line listing sections in your report. After configuring them, use the Oracle Argus Safety UI to attach UD summaries with line listings of your custom report.
- **SOC\_DISPLAY\_ORDER:** Use this code list to reorder the printing of SOCs in various tabulations.
- **STATE\_2, STATE\_3 and STATE\_4:** These code lists have been modified to print follow-up text, relatedness text, and so on. You can further modify these code list and add new attributes for use in custom reports. For example, you can use the CAUSAL attribute for printing the RELATEDNESS of an event. These are printed as Yes/No or Related/Unrelated using this attribute.

- **AGGREGATE\_REPORT\_FORMAT:** Use this code list to define the report formats to use with BIP reports. Ensure that you use formats that are supported by the Oracle Analytics Publisher.
- **DOSAGE\_STRING\_FORMAT:** Use this code list to restrict or add the dosage string formats that are available while BIP report is being executed. You can add more dosage string formats using custom code.  
Table C-1 contains the dosage string formats provided out-of-the-box and the print values for each dosage string.

**Table 6-7 Out-of-the-box Dosage String Formats and Print Values**

Code	EN
Do	Dose
DoFo	Dose, Formulation
DoFoFr	Dose, Formulation, Frequency
DoFoFrRt	Dose, Formulation, Frequency, Route
DoFoRt	Dose, Formulation, Route
DoFr	Dose, Frequency
DoRt	Dose, Route

- **UNIQUE\_PATIENT\_ID\_FORMAT:** Use this code list to restrict or add unique patient ID formats available while the BIP report is executing. You can add new unique patient ID formats using custom code.

Table C-2 contains the unique patient ID formats that are provided out-of-the-box and the values they print for patient ID.

**Table 6-8 Unique Patient IDs and Print Values**

Code	EN
CePt	Center, Patient
InPt	Investigator, Patient
Pt	Patient
StCelnPt	Study, Center, Investigator, Patient
StCePt	Study, Center, Patient
StCnCelnPt	Study, Country name, Center, Investigator, Patient
StCnCePt	Study, Country name, Center, Patient
StCoCelnPt	Study, Country ISO Code, Center, Investigator, Patient
StCoCePt	Study, Country ISO code, Center, Patient
StInPt	Study, Investigator, Patient

- **LABELING\_ALGORITHM:** Use this code list to define new labeling algorithms using custom code. For more information on out-of-the-box algorithms, refer to Labeling Algorithms.
- **EventSeriousness:** A new code list for EVENTSERIOUSNESS is provided as part of the factory data. This code list prints the actual value of seriousness defined against a serious event.



- **ORGAN\_IMPAIRED\_HLT:** Use this code list to define high-level terms that are scanned through to find out whether the event reported falls under the organ impairment section. This can be used in custom reports.
- **BIP\_DFLT\_VALUES:** Use this code list to configure the default values for important fields used in various grouping and tabulations, for example, to handle or print an event without SOC. The value configured in this code list corresponding to SOC is used in the PBRER/DSUR tabulation for events with undefined SOC.
- **Report Type Code list:** This code list has been modified to add new attributes and group existing report types into various categories. For example, existing Oracle Argus Safety report types have been grouped into the categories of solicited and non-solicited using the **CASETYPETEXT** attribute.

Updates to Listedness, Seriousness and LM\_CAUSALITY code list have been made for printing flags or text values in different line listings.

# 7

## PMDA E2B (R3) Paper Forms - Framework

This chapter discusses the Oracle Analytics Publisher based PMDA (R3) Paper forms architecture.

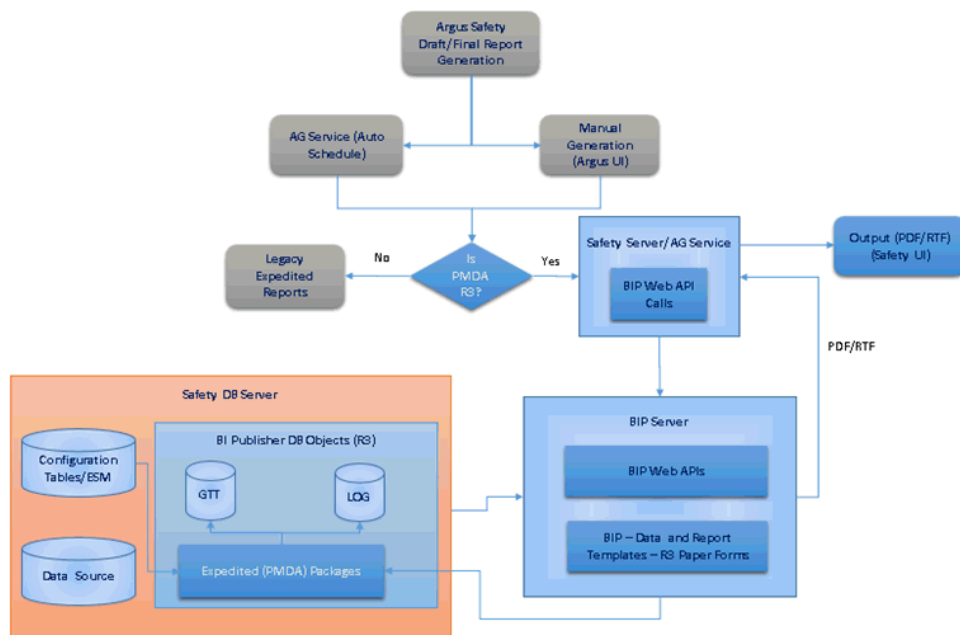
For more information, see:

- [Generic Architecture - PMDA \(R3\) Paper Reports](#)

### Generic Architecture - PMDA (R3) Paper Reports

The PMDA (R3) Paper forms utilize the Oracle Analytics Publisher technology for report generation. Reports can be generated either in the PDF or RTF format. The following diagram displays the high level architecture of the PMDA (R3) Paper forms through the Oracle Analytics Publisher.

#### Argus PMDA (R3) Paper Reporting Architecture



The following table explains the core components involved in the architecture diagram.

Component	Functionality
Safety Server	The server where Oracle Argus Safety Application is installed. When a PMDA (R3) Paper report generation request is made manually, this server makes a call to the BI Publisher server (through BI Publisher Web APIs) and obtains the PDF/RTF Report output generated by the BI Publisher Server.

<b>Component</b>	<b>Functionality</b>
AG Service	When a PMDA (R3) Paper report generation request is done through auto scheduling, this server makes a call to the BI Publisher server (through BI Publisher Web APIs) and obtains the PDF/RTF Report output generated by the BI Publisher Server.
BI Publisher Server	The server where (R3) Paper report templates are located and executed. Report output is pushed back to Argus once generated using Web APIs.
Safety DB Server	ESM: E2B generated XML is available in the SAFETYREPORT table of ESM owner schema, which is taken into BIP owner schema to generate PMDA (R3) paper reports. Data Source: Database where Oracle Argus Safety Case and configuration data resides. BIP DB Objects (R3): The BIP Owner schema where all packages, temp tables, and log tables that aid the PMDA E2B (R3) Paper reports generation are located.

# 8

## PMDA (R3) Paper Report - Database

In this chapter:

- [PMDA E2B \(R3\) Paper Report - DB Architecture](#)

### PMDA E2B (R3) Paper Report - DB Architecture

This section describes the following database objects that are needed for Flexible PMDA E2B (R3) Paper Report generation:

- [DB Objects](#)
- [Tables](#)
- [Java Objects](#)
- [Packages](#)
- [Argus Application Schema](#)
- [ACCESS GRANTS to Oracle Analytics Publisher Owner](#)

### DB Objects

Installing the Oracle Argus Safety database prompts for the creation of the BIP Schema Owner. This schema contains all database objects needed for Oracle Analytics Publisher PMDA (R3) Paper Reports.

For report generation, this schema holds:

- Tables
- Packages
- Java objects

### Tables

The (R3) specific tables in the schema hold the generated E2B (R3) XML data and also helps in effective data handling.

- **Global Temporary tables (GTT)** temporarily store data for report output generation. These are the only tables used in the BIP data model.
- **Log Tables** store logging information based on the configuration in the CFG\_RPT\_AGG\_PARAMS. This table <RPT\_EXPD\_XML\_LOG> is populated while executing the PMDA (R3) Paper reports based on the parameter 'Populate Log Tables Yes/No' in the configuration table being 1.

Table 8-1 List of Tables in BIP Owner Schema specific to PMDA (R3) Paper Reports.

Table Name	Type	Purpose
GTT_RPT_EXPD_XML	Global Temp	Stores the E2B XML data from the SAFETYREPORT table in ESM Schema owner.
GTT_RPT_EXPD_XML_L AB	Global Temp	Extracted lab tests data from the XML is stored in this table. Data pertains to a single case for a user in a session.
GTT_RPT_EXPD_LAB_M AT	Global Temp	Matrix formatted lab test data is stored here. Data pertains to a single case for a user in a session.
RPT_EXPD_XML_LOG	Log	Log data for GTT_RPT_EXPD_XML.
RPT_EXPD_XML_LAB_L OG	Log	Log data for GTT_RPT_EXPD_XML_LAB.
RPT_EXPD_LAB_MAT_L OG	Log	Log data for GTT_RPT_EXPD_LAB_MAT.

Data is logged into the log tables if the report needs to be debugged. For this, the parameter **Populate Log Tables Yes/No** is set to 1 in the CFG\_RPT\_AGG\_PARAMS table present in the Argus application schema. The default value is 0.

For details about tables, columns, and column mappings with Oracle Argus Safety, refer to the *Argus Flexible Reporting Data Model.xls*.

## Java Objects

The XML Data from the ESM Owner is manipulated as needed for the (R3) Output. This manipulation is performed using a Java stored procedure E2BXmlParser.

## Packages

The Oracle Analytics Publisher Owner schema holds the following package types:

- [PKG\\_EXPD\\_RPT\\_UTIL - Utility Package](#)
- [PKG\\_EXPD\\_RPT - Data Load Package](#)

## PKG\_EXPD\_RPT\_UTIL - Utility Package

This package contains all the accessory procedures and functions required for generating PMDA (R3) paper reports.

Utility Package Details

Procedure/ Function	Usage
f_get_biprep_path	Obtains the BIP report path from configured flexible code lists.
f_get_codelist_code	Obtains the Code list CODE from the CODE_LIST_DETAIL_DISCRETE table.
p_get_expd_rpt_params	Obtains the records from the CFG_RPT_AGG_PARAMS table for the PMDA (R3) Paper report template (Default template id is 11).
f_get_rpt_ctr	Obtains the count from the RPT_SAVED_MSG table for the report to be generated.

Procedure/ Function	Usage
f_get_codelist_val	Obtains the Code list Display_Value from CODE_LIST_DETAIL_DISCRETE table.
f_get_rpt_catg	Function to get the Reporting Category from CMN_REG_REPORTS.
f_get_ja_date	Function to convert varchar date column in lab matrix to Japanese date format.
p_get_blinded_text	Procedure to get the blinded text and blinded text element for B.4.k.2.2.

## PKG\_EXPD\_RPT - Data Load Package

This package is used to populate PMDA (R3) Global temporary tables referred to in the Oracle Analytics Publisher data model to generate the PMDA (R3) Paper report.

### Data Load Package Details

Procedure/Function	Usage
p_ins_expd_rpt	This procedure extracts and inserts XML data from ESM owner's SAFETYREPORT table and stores it in GTT_RPT_EXPD_XML.
p_upd_expd_rpt_decode	This procedure replaces the code value in the xml with decoded descriptions.
p_upd_blinded_elements	Based on the profile, the elements marked for blinded are masked in the XML Data.
p_upd_decade	Handles the patient or parent age when the age unit is in decades.
p_upd_j10_element	Based on the profile, this procedure masks the j10 element in the XML.
f_upd_null_flavor	Null flavor handling for common elements.
p_upd_meddra_terms	Handles the MedDRA terms in the XML.
f_get_m2_descj	Obtains the DESCRIPTION_J value from CFG_M2.
p_upd_country_codes	Updates the country codes in the XML.
f_get_pmda_title	Generates the Title of the report.
f_before_data	This function Populates temp tables used by the report.
f_get_report_id	Function to get the PN_REG_REPORT_ID parameter value.
p_set_report_id	Procedure to set the PN_REG_REPORT_ID parameter value to Global variable.
f_after_report	Function to delete the unwanted rows from the tables.
P_lab_matrix	This Procedure inserts necessary data for Lab Matrix.
p_upd_drug_trtmnt	This Procedure updates XML data for drugtreatmentduration.

## Argus Application Schema

List of tables used for PMDA (R3) Paper forms from the Argus Schema:

---

<b>Table Name</b>	<b>Purpose</b>
CFG_RPT_AGG_PA RAMS	Contains the parameters passed for each report, segregates the parameters that are part of the report header, and selects the default values.
SAFETY_ERR_LOG	Stores errors, warnings, and debugs that occur during execution. Pushes errors into the Oracle Argus Safety error log.

---

## ACCESS GRANTS to Oracle Analytics Publisher Owner

The following objects from ESM\_OWNER schema must be given access to the BIP Owner schema for PMDA (R3) Paper report generation.

SELECT access for the following tables:

- SAFETYREPORT
- CFG\_M2
- CFG\_E2B
- V\$SAFETYREPORT
- V\$CFG\_M2
- V\$CFG\_E2B

EXECUTE access for the following packages:

- ESM\_PMDA\_UTL
- ESM\_UTL

# 9

## PMDA (R3) Paper Report Design

In this chapter:

- [Oracle Analytics Publisher Periodic Reports Design Structure](#)
- [PMDA \(R3\) Data Model](#)
- [PMDA \(R3\) Paper Report templates](#)

### Oracle Analytics Publisher Periodic Reports Design Structure

This section provides an overview of the PMDA (R3) Paper forms data model and report layout. Oracle recommends you go through Oracle Analytics Publisher guides for more information.

Each report in PMDA (R3) paper reports has the following categories:

- Oracle Analytics Publisher data model comprising parameters and XML file triggers
- Oracle Analytics Publisher Layout templates
- Database packages

### PMDA (R3) Data Model

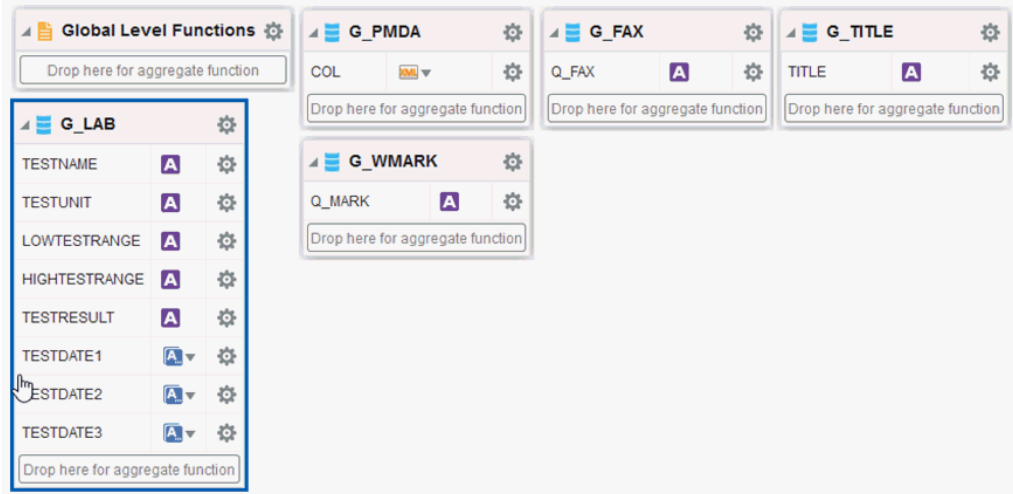
The Oracle Analytics Publisher data model comprises:

- [Data Set](#)
- [Event Triggers](#)
- [Parameters](#)

#### Data Set

Common data set is used for all PMDA (R3) report forms. A data set is the XML data file used to generate the report output. The graphic below displays the data set of the PMDA (R3) data model.





In the above diagram, each box represents a query.

Query	Description
G_PMDA	The main query used to fetch the data from the XML present in GTT_RPT_EXPDP_XML
G_FAX	Fetches the fax titles from profiles.
G_TITLE	Fetches and derives the main report titles.
G_WMARK	Prints the <i>Draft</i> on the top right corner of the report depending on the report executed.
G_LAB	Fetches the lab test data for Form 2-3 section.

## Event Triggers

The Before data trigger and the After data trigger are the two event trigger types.

The Before data trigger is the starting point of the report after submission. The Before data trigger executes the pkg\_expd\_rpt.f\_before\_data procedure. You can customize trigger names per your requirements.

The Before data trigger call to the pkg\_expd\_rpt.f\_before\_data package passes the following arguments:

- XDO User name: The user logged in.

You can create multiple Before data triggers, and the system executes them in the arranged order.

The After data type trigger fires after the completion of the Before data triggers.

## Parameters

Parameters are part of the data model. The graphic below displays the parameters of the PMDA (R3) Paper report.

	PARAMETER	PARAMETER_LABEL
1	PN_ENTERPRISE_ID	Enterprise Id
2	PN_REPORT_FORM_ID	Report Configuration Name
3	PN_PRINT_AS	Print As
4	PN_REG_REPORT_ID	**System Parameter**
5	PV_MKT_INV	Marketed or Investigational
6	PN_REPORT_ID	**System Parameter**
7	PN_AGENCY_ID	Agency ID
8	PN_LICENCE_ID	License ID
9	PN_PRODUCT_ID	Product ID
10	PN_J10_BLIND	J10 Blinded
11	PN_PRT_UNBLIND	Print Blinded
12	PN_POP_LOG_TBLS	Populate Log Tables Yes/No
13	PV_XDO_USER_NAME	User Name
14	PN_PRT_FAXHEADER	Include Fax Header
15	PV_RPT_CATG	License Category
16	PN_IMP_R3	E2B R3 Imported Case

This data model contains only Text type parameters.

Parameter	Description
PN_REPORT_FORM_ID	This is the report form ID passed from the Argus UI to the BIP report. OOTB values are: 81: Marketed Form (1,2) 82: Marketed Form (3,4) 83: Marketed Form (5,6) 84: Investigational Form (1,2) 85: Investigational Form (3,4) 86: Investigational Form (5,6)
PN_PRINT_AS	The watermark text is printed based on this parameter. For final report, no watermark is printed. The default value is Draft.
PV_MKT_INV	The parameter is either M for Marketed or I for Investigational.

Parameter	Description
PN_J10_BLIND	J10 element must be updated if the PN_J10_BLIND is 1, irrespective of the Blinded flag.
PN_PRT_UNBLIND	If the user is authorized to access the blinded data, then he can either print/not print the blinded data based on this parameter. For restricted users, this parameter is unused.
PN_IMP_(R3)	This parameter is used to identify whether the report is to be generated through case import. 0 - Regular cases 1 - E2B Imported cases, but case is pending for save
PN_RPT_FAXHEADER	Header value for FAX obtained from the profile configuration.
PV_RPT_CATG	Report Category value used in deriving the PMDA Report title.
PN_REG_REPORT_ID	This is a system parameter and should not be changed.
PN_REPORT_ID	This is a system parameter and should not be changed.

All these parameters are passed from the Oracle Argus Safety UI when the report is either run manually or through AG Services. Some parameters have been added but currently are not used by the report.



**Note:**

User cannot execute the PMDA (R3) paper report directly from Oracle Analytics Publisher. It can only be executed from Oracle Argus Safety.

## PMDA (R3) Paper Report templates

There are 3 RTF templates for PMDA (R3).

- Form 1-2
- Form 3-4
- Form 5-6



**Form\_1\_2** Last Modified 2/7/17 6:23 AM  
Expand More ▼



**Form\_3\_4** Last Modified 2/7/17 6:23 AM  
Expand More ▼



**Form\_5\_6** Last Modified 2/7/17 6:23 AM  
Expand More ▼

For more information, see:

- [Oracle Argus Safety UI Entry](#)

## Oracle Argus Safety UI Entry

The PMDA (R3) Paper forms are configured under the new flexible code list LM\_REPORT\_FORMS\_EXPEDITED. The path of reports can be configured in these code lists as shown below.

The top screenshot shows the 'Flexible Re-Categorization Code Lists' interface for the code list 'LM\_REPORT\_FORMS\_EXPEDITED'. It displays a table with the following data:

CODE	REPORT_FORM_ID	FORM_DESC	AGENCY_ID	RPT_TYPE
1	01	医薬品 副作用報告 別紙様式 1 / 2 (Mktg 1, 2)	0	0
2	02	医薬品 研究報告検査報告書 別紙様式 3 / 4 (Mktg 3, 4)	0	0
3	03	医薬品 外国での複製報告 別紙様式 5 / 6 (Mktg 5, 6)	0	0
4	04	治験薬 副作用報告 別紙様式 1 / 2 (Inv 1, 2)	0	0
5	05	治験薬 研究報告検査報告書 別紙様式 3 / 4 (Inv 3, 4)	0	0
6	06	治験薬 外国での複製報告 別紙様式 5 / 6 (Inv 5, 6)	0	0

The bottom screenshot shows the same code list configuration but with a different table view. The columns are EREPORT, REPTOOL, BIPREPTYP, REPTEMPLATE, and REPPATH. The data is as follows:

EREPORT	REPTOOL	BIPREPTYP	REPTEMPLATE	REPPATH
0	BIP	11	R3	%EXPEDITED_PMDA/ExpeditedQC/pmda_1_2/Reports/pmda_1_2.xdo
0	BIP	11	R3	%EXPEDITED_PMDA/ExpeditedQC/pmda_3_4/Reports/pmda_3_4.xdo
0	BIP	11	R3	%EXPEDITED_PMDA/ExpeditedQC/pmda_5_6/Reports/pmda_5_6.xdo
0	BIP	11	R3	%EXPEDITED_PMDA/ExpeditedQC/pmda_1_2/Reports/pmda_1_2.xdo
0	BIP	11	R3	%EXPEDITED_PMDA/ExpeditedQC/pmda_3_4/Reports/pmda_3_4.xdo
0	BIP	11	R3	%EXPEDITED_PMDA/ExpeditedQC/pmda_5_6/Reports/pmda_5_6.xdo

The columns present in this code list are used as shown here:

Column	Description
CODE	This is auto generated.
RPT_TYPE	0 = Expedited, 1 = Periodic.
FORM_CATEGORY	This column is used to identify the category of report forms e.g. for all PMDA forms, it is 1; otherwise 0.
REPPATH	The report path of the Oracle Analytics Publisher.
BIPREPTYP	Report template value to be matched with CFG_RPT_AGG_PARAMS. Default value is 11.

The remaining columns are currently not used.

# 10

## Extending PMDA (R3) Report

This chapter describes the options available for extending PMDA (R3) Paper Reports.



### Note:

Oracle encourages customers to extend reports for their use but is not obliged to support the custom or extended code and is not responsible for any loss or damage caused by the extended code.

For more information, see:

- [Database Layer](#)
- [Extending the Oracle Analytics Publisher Data Model](#)
- [Extending through E2B PMDA Profile](#)
- [Configuring Blinding for PMDA \(R3\)](#)

## Database Layer



### Note:

Oracle recommends you do not change the order of calling the procedures/functions in the `f_before_data`.

Objects specific to BIP Periodic Reporting are present in a separate schema created during the installation of the Oracle Argus Safety database. This schema only has a limited set of objects and access privileges. The following graphic illustrates these objects and privileges.

```
select parameter, parameter_label, UI, default_value, datatype
from cfg_rpt_agg_params where report_template = 11 order by display_ord;
```

statement Output x Query Result x

SQL | All Rows Fetched: 16 in 0.177 seconds

PARAMETER	PARAMETER_LABEL	UI	DEFAULT_VALUE	DATATYPE
1 PN_ENTERPRISE_ID	Enterprise Id	Y	(null)	INTEGER
2 PN_REPORT_FORM_ID	Report Configuration Name	Y	(null)	INTEGER
3 PN_PRINT_AS	Print As	Y	(null)	INTEGER
4 PN_REG_REPORT_ID	**System Parameter**	Y	(null)	INTEGER
5 PV_MKT_INV	Marketed or Investigational	Y	(null)	STRING
6 PN_REPORT_ID	**System Parameter**	Y	(null)	INTEGER
7 PN_AGENCY_ID	Agency ID	N	(null)	INTEGER
8 PN_LICENCE_ID	License ID	N	(null)	INTEGER
9 PN_PRODUCT_ID	Product ID	N	(null)	INTEGER
10 PN_J10_BLIND	J10 Blinded	Y	(null)	INTEGER
11 PN_PRT_UNBLIND	Print Blinded	Y	(null)	INTEGER
12 PN_POP_LOG_TBLS	Populate Log Tables Yes/No	N	1	INTEGER
13 PV_XDO_USER_NAME	User Name	N	(null)	STRING
14 PN_PRT_FAXHEADER	Include Fax Header	Y	(null)	INTEGER
15 PV_RPT_CATG	License Category	Y	(null)	STRING
16 PN_IMP_R3	E2B R3 Imported Case	Y	0	INTEGER

The parameters with UI = Y is passed from Oracle Argus Safety UI.

PMDA paper reports have fixed report format and style. However, they can be customized from the BIP perspective.

## Extending the Oracle Analytics Publisher Data Model

### Note:

While extending BI Publisher reports, irrespective of whether the extension is in the data model layer or the layout, Oracle recommends taking a complete backup of the report in another catalog folder and then proceeding with the extension

Query 1: Q\_PMDA: This query fetches data from gtt\_rpt\_expd\_xml where the modified XML data is present.

```
SELECT x.e2b_xml.getClobVal() col from gtt_rpt_expd_xml x where
report_id=:PN_REPORT_ID
```

Query 2: Q\_LAB: This query fetches lab data from gtt\_lab tables which get populated from the XML.

```
select CASE is_header WHEN 0 THEN testname||CASE WHEN Testnamellt IS NOT
NULL THEN ' (||Testnamellt||)' END ELSE testname END testname,
testunit, lowtestrange, hightestrange, testresult, testdate1, testdate2,
testdate3
from gtt_rpt_expd_lab_mat
where report_id = :pn_report_id
order by header_seq_num, data_ord_num
```

Query 3: &Q\_FAX\_HEAD, Lexical parameter where the query resides in the package.

```
SELECT VALUE Q_FAX
FROM Cmn_Profile
WHERE KEY = CASE :PN_REPORT_FORM_ID
WHEN 81 THEN 'MKT_FORM_1_2_J'
WHEN 82 THEN 'MKT_FORM_3_4_J'
WHEN 83 THEN 'MKT_FORM_5_6_J'
WHEN 84 THEN 'INV_FORM_1_2_J'
WHEN 85 THEN 'INV_FORM_3_4_J'
WHEN 86 THEN 'INV_FORM_5_6_J'
ELSE ''
END
AND NVL(:PN_PRT_FAXHEADER, 0) = 1;
```

Query 4: To print the report title the below function is called in the query.

```
select pkg_expd_rpt.f_get_pmda_title(:PN_REPORT_FORM_ID) TITLE from dual;
```

Query 5: &Q\_WMARK

```
SELECT NVL(default_value,'Draft') Q_MARK
FROM cfg_rpt_agg_params
WHERE report_template = (SELECT b.display_value
FROM code_list_detail_discrete a, code_list_detail_discrete b
WHERE a.code_list_id = 'LM_REPORT_FORMS_EXPEDITED'
AND a.decode_context='REPORT_FORM_ID'
AND b.decode_context='BIPREPTYP'
AND a.code_list_id = b.code_list_id
AND a.code = b.code
AND a.display_value = :PN_REPORT_FORM_ID)
AND parameter = 'PN_PRINT_AS'
AND :pn_print_as = 1;
```

Element	Description
Q_WMARK	Populates water marks for the reports. For example, DRAFT.
Q_FAX_HEAD	Fetches Fax titles from cmn_profile table.

There are no lexical parameters used in PMDA reports.

# Extending through E2B PMDA Profile

1. Modifying the Profile: Using the screenshot below as reference, modify any element for which validation Category is *Do not Enter* to say *Optional*. Here, the element `mhlwadmicsremarks1` has been modified.

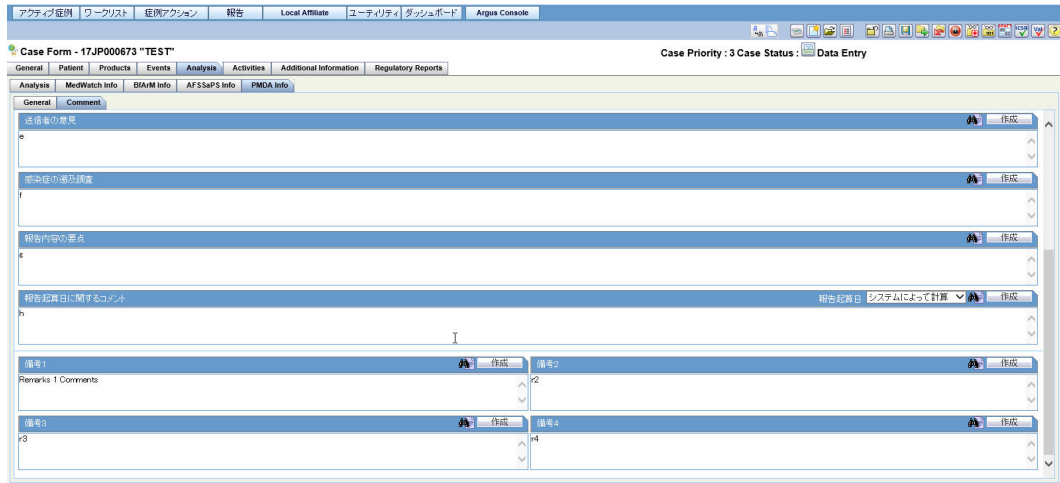
Reporting Category	Reporting Category Desc	Primary Validation Category	Additional Validations
AA	Case reports on infections in Japan (post-marketing)	Do not Enter	Select
AB	Case reports on adverse drug reactions in Japan (post-marketing)	Optional	Select
AC	Case reports on infections in foreign countries (post-marketing)	Do not Enter	Select
AD	Case reports on adverse drug reactions in foreign countries (post-marketing)	Do not Enter	Select
AE	Research reports on infections (post-marketing)	Do not Enter	Select
AF	Research reports on adverse drug reactions (post-marketing)	Do not Enter	Select
AG	Reports on corrective action such as discontinuation of manufacturing, recall, disposal in	Do not Enter	Select
BC	Research reports on quasi-drugs	Do not Enter	Select
BD	Research reports on cosmetics	Do not Enter	Select
DA	Case reports on infections in Japan (clinical trial)	Do not Enter	Select
DB	Case reports on adverse drug reactions in Japan (clinical trial)	Do not Enter	Select
DC	Case reports on infections in foreign countries (clinical trial)	Do not Enter	Select
DD	Case reports on adverse drug reactions in foreign countries (clinical trial)	Do not Enter	Select
DE	Research reports on infections (clinical trial)	Do not Enter	Select
DF	Research reports on adverse drug reactions (clinical trial)	Do not Enter	Select
DG	Reports on corrective action such as discontinuation of manufacturing, recall, disposal in	Do not Enter	Select

2. Make sure the correct Profile is selected for your agency.

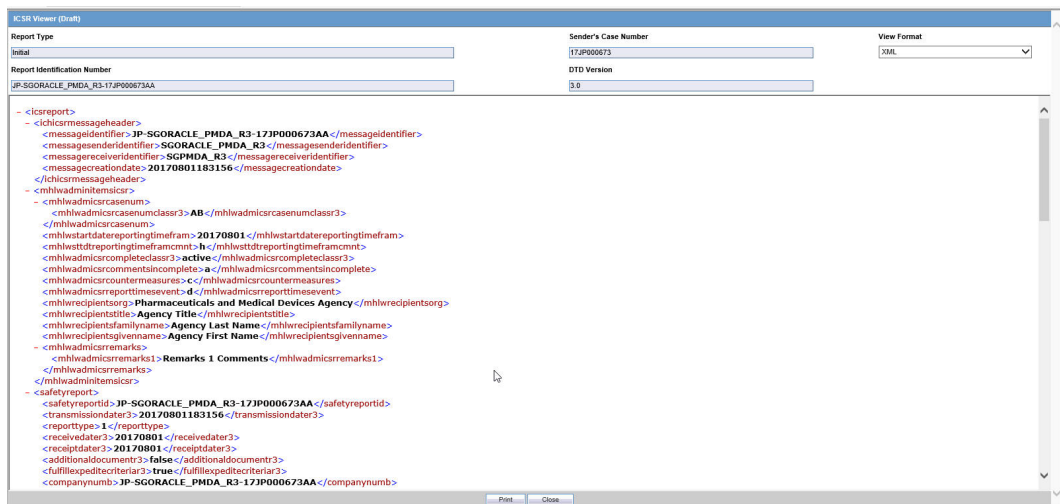
Agency Name	Agency Name (J)	Agency Type	Department	Registration #	Contact Type	FAX	FAX Cover
Copy of SGPMDA_R3	Pharmaceuticals and Medical Devices Agency	Regulatory Authority	HSSGBU	3234231	Manufacture	878078991	
SGPMDA_R3	Pharmaceuticals and Medical Devices Agency	Regulatory Authority	HSSGBU	3234231	Manufacture	878078991	

3. Create a case with the remarks entered.

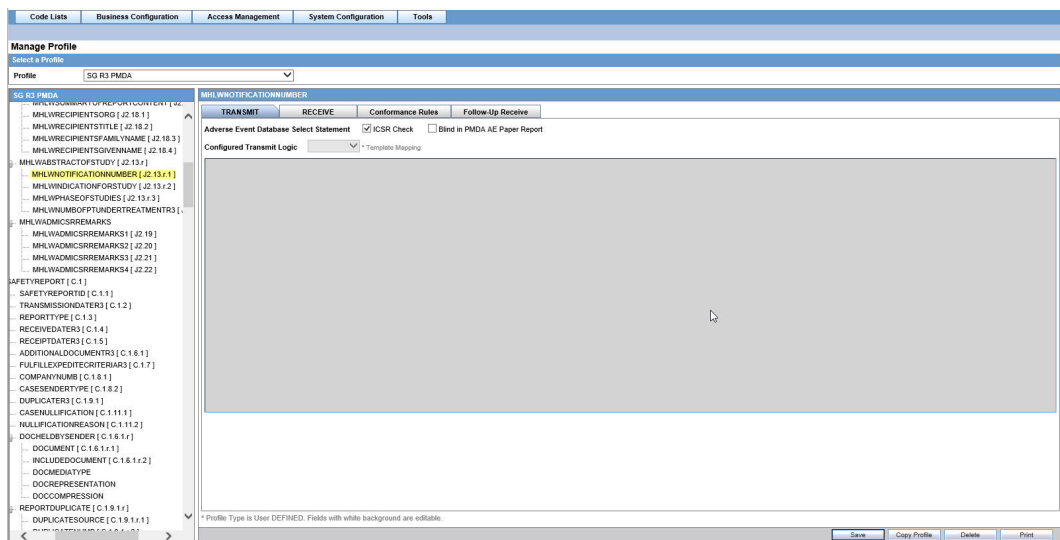




4. Before profile modifications, the `mhlwadmicsremarks` element does not have the `remarks1` column.



5. After executing the report with correct agency, the remarks column is updated in the XML.



## Configuring Blinding for PMDA (R3)

Go to **Argus Console > Manage Profile > PMDA (R3)** profile.

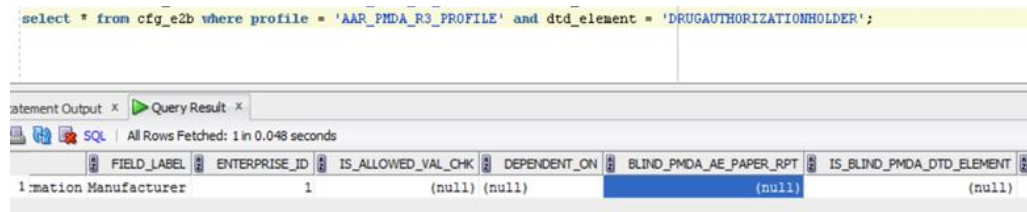
Select an element for which blinding option is to be checked. Check the **Blind in PMDA AE Paper Report**.

The elements for which the check box is checked always print blinded information to the restricted user. Whereas for the privileged user, the `Print Blinded` parameter is applicable based on this value and either blinded or un-blinded information is displayed in the report.

For example, consider the DTD element `DRUGAUTHROIZATIONHOLDER`.



By updating the `cfg_e2b` table, the **Blind in PMDA AE Paper Report** check box is enabled.



Execute the following update statements by logging in as an `ARGUS_APP` user.

Execute the statements for a particular (R3) profile.

```
UPDATE cfg_e2b
  SET blind_pmda_ae_paper_rpt = 1
  WHERE profile = 'AAR_PMDA_R3_PROFILE' and dtd_element =
'DRUGAUTHROIZATIONHOLDER';
```

```
UPDATE cfg_e2b
  SET is_blind_pmda_dtd_element = 1
  WHERE profile = 'AAR_PMDA_R3_PROFILE' and dtd_element =
'DRUGAUTHROIZATIONHOLDER';
```

Once updated from the profile, the check box is enabled.

Please enter values for lexical references in SQL

\*&GL\_ORDERBY1:   flex field

OK Cancel

Scenario #1: If the user executes the PMDA (R3) paper report without checking the **Blind in PMDA AE Paper Report** checkbox, the UnBlinded (actual) information is printed.

```
<drug>
  <druguniversallyuniqueid>3cacdbc2-0f95-40cb-9b3b-aa2133e8597</druguniversallyuniqueid>
  <drugcharacterization>被疑薬</drugcharacterization>
  <mhlwstatuscategoryofnewdrugs>一変治験中</mhlwstatuscategoryofnewdrugs>
  <medicinalproduct>SG BIJ (SGBProduc )</medicinalproduct>
  <obtaindrugcountry>日本</obtaindrugcountry>
  <invproductblinded>有</invproductblinded>
  <drugauthorizationnumb>SGBI</drugauthorizationnumb>
  <drugauthorizationcountry>日本</drugauthorizationcountry>
  <drugauthorizationholder>Oracle J</drugauthorizationholder>
```

### Actual Report

別紙様式第1

Draft

治験薬 副作用 症例報告書 (国内)					
識別番号	DB				
販売名/治験成分記号 承認番号(承認国)	SGBI01 SGBI DruGAuthHolder: Oracle J	有効成分名	SG SStudy Name BJ		
症例識別子情報					
世界に固有の症例識別子	JP-ORACLE PMDA-SG R3_02AA	第一送信者	その他	送信者の国	アメリカ
安全性報告識別子	JP-ORACLE PMDA-SG R3_02AA			送信者の種類	製薬企業
過去に伝送された症例か	過去の伝送の情報源及び症例識別子				
本報告と関連する報告の識別子					
管理情報					
緊急報告の基準を満たすか	7日	報告の種類	試験からの報告	即時報告	
第一報入手日	2017年09月18日	最新情報入手日	2017年09月18日	報告書作成日	2017年09月19日
報告起算日	2017年09月18日	報告起算日に関するコメント	a		
完了/未完了区分	未完了	未完了に対するコメント	a		
報告対象外		理由			
報告の破棄/修正		理由			

Scenario 2:

The screenshot shows the 'Manage Profile' interface. The 'Profile' dropdown is set to 'AAR\_PMDA\_R3\_PROFILE'. The left pane shows a tree view with 'DRUGAUTHORIZATIONHOLDER' selected. The right pane shows configuration options for 'DRUGAUTHORIZATIONHOLDER', including 'TRANSMIT', 'RECEIVE', 'Conformance Rules', and 'Follow-Up Receive'. Under 'Conformance Rules', the 'Blind in PMDA AE Paper Report' checkbox is checked.

As displayed in cmn\_profile, the blinded value is printed.

```
SELECT *
FROM cmn_profile
WHERE KEY = 'PMDA_PR_BLIINDED_TXT';
```

Query Result x

SQL | All Rows Fetched: 1 in 0.049 seconds

ENTERPRISE_ID	SECTION	KEY	VALUE	TREE_NAME	KEY_TYPE	KEY_LABEL
1	SYSTEM	PMDA_PR_BLIINDED_TXT	ブラインド	Argus J/Reporting	1	Blinded text for PMDA AE Paper reports 1

XML generated after checkbox checked:

```
<drug>
<druguniversallyuniqueid>2ff99413-9169-4518-8574-71878d45ce10</druguniversallyuniqueid>
<drugcharacterization>被験薬</drugcharacterization>
<mhlwstatuscategoryofnewdrugs>一変治験中</mhlwstatuscategoryofnewdrugs>
<medicinalproduct>SGBI01</medicinalproduct>
<obtaindrugcountry>日本</obtaindrugcountry>
<invproductblinded>有</invproductblinded>
<drugauthorizationnumb>SGBI</drugauthorizationnumb>
<drugauthorizationcountry>日本</drugauthorizationcountry>
<drugauthorizationholder>ブラインド</drugauthorizationholder>
```

Actual Report

別紙様式第1

Draft

治験薬 副作用 症例報告書 (国内)					
識別番号	DB				
販売名/治験成分記号 承認番号(承認国)	SGBI01 SGBI DruGAuthHolder: ブラインド	有効成分名	SG SStudy Name BJ		
症例識別子情報					
世界に固有の症例識別子	JP-ORACLE_PMDA-SG_R3_02AA	第一送信者	その他	送信者の国	アメリカ
安全性報告識別子	JP-ORACLE_PMDA-SG_R3_02AA			送信者の種類	製薬企業
過去に伝送された症例か		過去の伝送の情報源及び症例識別子			
本報告と関連する報告の識別子					
管理情報					
緊急報告の基準を満たすか	7日	報告の種類	試験からの報告	即時報告	
第一報入手日	2017年09月18日	最新情報入手日	2017年09月18日	報告書作成日	2017年09月19日
報告起算日	2017年09月18日	報告起算日に関するコメント	a		
完了/未完了区分	未完了	未完了に対するコメント	a		
報告対象外		理由			
報告の破棄/修正		理由			

# A

## Troubleshooting

In this chapter:

- [Troubleshooting PMDA \(R3\) Paper Forms](#)
- [Troubleshooting Flexible Aggregate Reports](#)

### Troubleshooting PMDA (R3) Paper Forms

Issue	Cause	Resolution
Missing or invalid junk characters instead of Japanese characters	Japanese fonts are not installed in the BI Publisher Server	Follow <i>Oracle Argus Safety Installation Guide</i> section 13.2.1 Installing and Configuring East Asian Fonts
Error message: The server cannot be used due to a configuration error, please contact the administrator. If you are the administrator, please consult BI Publisher user guide for proper configuration. Error DetailResourceProvider is null"	The catalog privileges are not set properly.	Follow <i>Oracle® Argus Safety Installation Guide</i> section 13.3.3.2 Managing Folder Privileges
Unable to manually generate (R3) Paper report from Argus UI	The BIP Common user ID or password entered for the BIP Aggregate Reporting Common Profile Switch is wrong or empty	Make sure there is a user ID present in the BIP Reporting common profile switches. Verify that the BIP Common User and Password present in this switch can login to the BI Publisher console. Also, make sure that the user ID has complete access to all PMDA (R3) Paper Forms.
Unable to manually generate (R3) Paper report from Argus UI	The Report path in the REPORT_TEMPLATE is empty or has an incorrect path	The Report path present in the code list REPORT_TEMPLATE must have a proper value. The value can be verified by comparing it against the actual report path in the BIP Publisher catalogs. In Linux/Unix the report path is case sensitive.
Unable to manually generate (R3) Paper report from Argus UI	The endpoint address present in the Web.config file is incorrect	Confirm the following: <ul style="list-style-type: none"> <li>• The endpoint address is present</li> <li>• It points to the BI Publisher Server (including the port number).</li> <li>• No unnecessary space is present in the URL.</li> </ul> Services are properly mentioned SecurityService is mapped against SecurityService, and ScheduleService is mapped against SchedulingService and ReportService is mapped against ReportService
Unable to manually generate (R3) Paper report from Argus UI	Missing Argus UI user in the BI Publisher	Make sure that the Argus UI user exists and is allowed to login and run the required reports from BI Publisher Console

Issue	Cause	Resolution
Unable to generate (R3) Paper report through Auto Schedule (Reports are running fine manually)	The endpoint address present in the agproc.config file is incorrect	Confirm the following: <ul style="list-style-type: none"> <li>The endpoint address is present</li> <li>It points to the BI Publisher Server (including the port number).</li> <li>No unnecessary space is present in the URL.</li> </ul> Services are properly mentioned SecurityService is mapped against SecurityService, and ScheduleService is mapped against SchedulingService and ReportService is mapped against ReportService
Unable to generate (R3) Paper report through Auto Schedule (Reports are running fine manually)	Missing AG Service user (user ID used for <i>Batch report generation</i> ) in the BI Publisher	Make sure that the AG service user exists and is allowed to login and run the required reports from the BI Publisher Console
UserID: AG_batch_periodic_reports, Login to BIP Server failed Exception Details Message: The request channel timed out while waiting for a reply after 00:00:59.5468739. Increase the timeout value passed to the call to Request or increase the SendTimeout value on the Binding. The time allotted to this operation may have been a portion of a longer timeout	Timeout occurs while calling the BIP server	Add/Modify the following in C:\Program Files (x86)\Oracle\Argus\Argus Safety\ AGProc.config: <pre>&lt;binding name="SecurityServiceSoapBinding" maxReceivedMessageSize="2147483647" openTimeout="00:10:00" closeTimeout="00:10:00" sendTimeout="00:10:00" receiveTimeout="00:10:00"/&gt; &lt;binding name="ScheduleServiceSoapBinding" maxReceivedMessageSize="2147483647" openTimeout="00:10:00" closeTimeout="00:10:00" sendTimeout="00:10:00" receiveTimeout="00:10:00"/&gt; &lt;binding name="ReportServiceSoapBinding" maxReceivedMessageSize="2147483647" openTimeout="00:10:00" closeTimeout="00:10:00" sendTimeout="00:10:00" receiveTimeout="00:10:00"/&gt;</pre>

## Troubleshooting Flexible Aggregate Reports

Issue	Cause	Resolution
BIP Icons are not displayed against corresponding BIP specific fields/tabs in the Oracle Argus Safety UI - Periodic Reporting Configuration	Oracle Analytics Publisher Periodic reports are not enabled in the Argus Console	In the Oracle Argus Safety Console, navigate to <b>System Configuration &gt; Enabled Modules</b> . Make sure that BIP Aggregate Reporting is checked
BIP Icons are not displayed against corresponding BIP specific fields/tabs in the Oracle Argus Safety UI - Periodic Reporting Configuration	The page level cache is not refreshed	Restart the IIS server

Issue	Cause	Resolution
Oracle Analytics Publisher Periodic report does not Execute from Oracle Argus Safety UI and the status of the reports remains in "Pending" status in the Report Generation Screen	The BIP Common user ID or password entered for the BIP Aggregate Reporting Common Profile Switch is wrong or empty	Make sure there is a user ID present in the BIP Reporting common profile switches. Verify that the BIP Common User and Password present in this switch can login to the BI Publisher console. Also, make sure that the user ID has complete access to all BIP Periodic reports.
Oracle Analytics Publisher Periodic report does not Execute from Oracle Argus Safety UI and the status of the reports remains in "Pending" status in the Report Generation Screen	The Report path in the REPORT_TEMPLATE is empty or has an incorrect path	The Report path present in the code list REPORT_TEMPLATE must have a proper value. The value can be verified by comparing it against the actual report path in the BIP Publisher catalogs. In Linux/Unix the report path is case sensitive.
Oracle Analytics Publisher Periodic report does not Execute from Oracle Argus Safety UI and the status of the reports remains in "Pending" status in the Report Generation Screen	The endpoint address present in the AGProc.config file is incorrect	Confirm the following: <ul style="list-style-type: none"> <li>• The endpoint address is present</li> <li>• It points to the Oracle Analytics Publisher Server (including the port number).</li> <li>• No unnecessary space is present in the URL.</li> <li>• Services are properly mentioned SecurityService is mapped against SecurityService, and ScheduleService is mapped against SchedulingService</li> </ul>
Oracle Analytics Publisher Periodic report does not Execute from Argus UI and the status of the reports remains in "Pending" status in the Report Generation Screen	The Oracle Data Access version present in the AGProc.config file is incorrect	Refer to the <i>Oracle Argus Safety Installation Guide</i> and make sure the correct entry is provided.
Oracle Analytics Publisher Periodic report does not Execute from Argus UI and the status of the reports remains in "Pending" status in the Report Generation Screen	Missing Argus UI user in the Oracle Analytics Publisher	Make sure that the Oracle Argus Safety UI user exists and is allowed to login and run the required reports from BI Publisher console
The BIP Report fails with error: Report data size exceeds the maximum limit (<n> bytes). Stopped processing	The report exceeds the maximum data size specified for report generation	Log in to Oracle Analytics Publisher - <code>http://hostname:port/xmlpserver/</code> <ul style="list-style-type: none"> <li>• Go to <b>Administration &gt; Runtime Configuration &gt; Memory Guard</b> Update the parameters <code>Maximum Report Data Size for online reports</code> and <code>Maximum report data size for offline (scheduled) reports</code> as needed.</li> <li>• Go to <b>Administration &gt; Runtime Configuration &gt; Data Model</b> Update the <b>Maximum data size limit for data generation</b> value as required. Note that the value needs to be in bytes.</li> </ul>
Database connection errors	The Oracle Analytics Publisher report cannot utilize the JDBC provided	Make sure the JDBC connection name is in lowercase (asbip)



Issue	Cause	Resolution
Oracle Analytics Publisher Scheduled Report Output does not show up in the Argus application	Invalid or missing Report Output Pusher job	Make sure that the Report Output Pusher is running without any failure
Oracle Analytics Publisher Scheduled Report Output does not show up in the Argus application	Invalid database link AS_TO_BIPREP	Verify whether the database link AS_TO_BIPREP is valid and pointing to the proper DEV_BIPLATFORM metadata repository database
Oracle Analytics Publisher Scheduled Report Output does not show up in the Argus application	Unscheduled Reports	The reports are not scheduled in the BI Publisher, but being run (using the "open" option)
Error, ORA-01427: single-row sub-query returns more than one rowORA-06512: at "<bip_owner>.PKG_AGG_RPT" for p_updclinicaldrugrole procedure	Study configuration is having duplicate attributes	Check the study configuration and ensure that it does not have any duplicates
Error, ORA-20005: object statistics are locked (stattype = ALL) >> Error while copying case series - 1, USERNAME - <logged in user>.	Required tables are locked.	exec dbms_stats.unlock_table_stats('BIP_OWNER', 'GTT_RPT_AGG_UNIQ_CASES');
UserID: AG_batch_periodic_reports, Login to BIP Server failed Exception DetailsMessage: The request channel timed out while waiting for a reply after 00:00:59.5468739. Increase the timeout value passed to the call to Request or increase the SendTimeout value on the Binding. The time allotted to this operation may have been a portion of a longer timeout.	Timeout occurs while calling the BIP server	Add/Modify the following in C:\Program Files (x86)\Oracle\Argus\ArgusWeb\Bin\Argusvr2.config <pre>&lt;binding name="SecurityServiceSoapBinding" maxReceivedMessageSize="2147483647" openTimeout="00:10:00" closeTimeout="00:10:00" sendTimeout="00:10:00" receiveTimeout="00:10:00"/&gt; &lt;binding name="ScheduleServiceSoapBinding" maxReceivedMessageSize="2147483647" openTimeout="00:10:00" closeTimeout="00:10:00" sendTimeout="00:10:00" receiveTimeout="00:10:00"/&gt; &lt;binding name="ReportServiceSoapBinding" maxReceivedMessageSize="2147483647" openTimeout="00:10:00" closeTimeout="00:10:00" sendTimeout="00:10:00" receiveTimeout="00:10:00"/&gt;</pre>

Issue	Cause	Resolution
<p>UserID: &lt;AgUserID&gt;, Report Scheduling to BIP Server failed</p> <p>Exception DetailsMessage:            org.xml.sax.SAXException : SimpleDeserializer encountered a child element, which is NOT expected, in something it was trying to deserialize.            Stack Trace.....</p>	<p>Argusvr2.config entries are wrong</p>	<p>Verify the &lt;endpoint address&gt; elements are correctly configured, and set it right.</p> <p>(For more details, refer to the <i>Configure AG Service</i> and <i>Configure Web Service (Expedited Reports only)</i> sections in the <i>Oracle Argus Safety Installation Guide</i>.) <code>http://&lt;host&gt;:&lt;port&gt;/xmlpserver/services/v2/SecurityService</code> where the name attribute is set to <b>SecurityService</b></p> <p><code>http://&lt;host&gt;:&lt;port&gt;/xmlpserver/services/v2/ScheduleService</code> where the name attribute is set to <b>SchedulingService</b></p> <p><code>http://&lt;host&gt;:&lt;port&gt;/xmlpserver/services/v2/ReportService</code> where the name attribute is set to <b>ReportService</b></p>