Oracle® Argus Safety
Flexible Reporting Extensibility Guide
Release 8.1.1
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BI Publisher Periodic Reporting enables flexible handling of periodic reports in Argus Safety. The *Oracle Argus Safety Flexible Aggregate Reporting (Oracle Argus FAR) Guide* provides Argus Safety–BI Publisher integration details, and out-of-the-box periodic report details along with data models, algorithms, and methods to customize or extend these reports as needed.

**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 Health Sciences Consulting.

**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

**Where to Find More Information**

**Oracle Help Center**


**My Oracle Support**

The latest release notes, patches and white papers are on My Oracle Support (MOS) at [https://support.oracle.com](https://support.oracle.com). For help with using MOS, see [https://docs.oracle.com/cd/E74665_01/MOSHP/toc.htm](https://docs.oracle.com/cd/E74665_01/MOSHP/toc.htm).
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Argus Safety Flexible Reporting leverages the capabilities of the Oracle BI Publisher reporting solution for Argus Safety Reports. This solution helps customers overcome the challenges of periodic reporting to meet a variety of business needs.

This document provides Argus Safety–BI Publisher integration details, describes the BI Publisher Periodic Reports framework, and describes ways to customize the report as per customer needs.

This document also talks about the PMDA (R3) Paper Reports Framework using BI Publisher.
This chapter provides an overview of the product.

2.1 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

2.2 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.

2.3 Scheduling

Oracle Argus Flexible Reporting Framework supports Quartz scheduler.

2.4 Report Templates

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

2.5 Database Code Wrapping

All 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.
This chapter discusses Flexible Aggregate Reporting framework.

### 3.1 Generic Architecture

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

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

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

*Figure 3–1  Argus Flexible Aggregate Reporting Architecture*

BI Publisher reports can be executed from Argus Safety UI or through the BI Publisher console. Table 3-1 explains the core components involved in the architecture diagram.
<table>
<thead>
<tr>
<th>Component</th>
<th>Functionality</th>
</tr>
</thead>
</table>
| Argus Web Console          | The first piece of the application for configuring Argus Safety. Handles the following:  
- Enabling the BIP module  
- Supplying the necessary BIP security credentials and setting up the persist duration  
- Setting up the report template path |
| 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 BI Publisher reports are located and executed. Report output is temporarily stored in the BIP server.                         |

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

**Note:** The OAM server, if chosen, also needs authentication.
4.1 Database Architecture

BI Publisher Periodic Reporting is a customizable Argus Safety feature. The database components and changes specific to BIP reports are explained in the sections that follow.

4.1.1 Flexible Aggregate Reporting - Database Objects

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

For report generation, this schema holds:

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

4.1.2 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>
<thead>
<tr>
<th>Table Name</th>
<th>Type</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>RPT_AGG_PARAMS</td>
<td>SUPPORT</td>
<td>Stores the list of parameters that are passed down to run the report.</td>
</tr>
<tr>
<td>RPT_AGG_CASE_SERIES</td>
<td>SUPPORT</td>
<td>Stores case series information.</td>
</tr>
<tr>
<td>RPT_AGG_CS_CASES</td>
<td>SUPPORT</td>
<td>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.</td>
</tr>
<tr>
<td>RPT_AGG_BIP_JOB</td>
<td>SUPPORT</td>
<td>Stores BIP job information and other transactional data. This table data is retained without purging.</td>
</tr>
<tr>
<td>GTT_RPT_AGG_CASE</td>
<td>Global Temp</td>
<td>Stores case information.</td>
</tr>
<tr>
<td>GTT_RPT_AGG_DRUG</td>
<td>Global Temp</td>
<td>Stores drug related information.</td>
</tr>
<tr>
<td>GTT_RPT_AGG_EVENT</td>
<td>Global Temp</td>
<td>Stores event related information.</td>
</tr>
<tr>
<td>GTT_RPT_AGG_EV2DRUG</td>
<td>Global Temp</td>
<td>Stores event to drugs related assessment details.</td>
</tr>
<tr>
<td>GTT_RPT_AGG_HEALTHAUTHID</td>
<td>Global Temp</td>
<td>Stores health authority details.</td>
</tr>
<tr>
<td>GTT_RPT_AGG_UNIQ_CASES</td>
<td>Global Temp</td>
<td>Maintains a list of unique cases.</td>
</tr>
<tr>
<td>GTT_RPT_AGG_DET_LIST</td>
<td>Global Temp</td>
<td>Temporary support table that fetches assessment data.</td>
</tr>
<tr>
<td>GTT_RPT_AGG_DRUGNAMES</td>
<td>Global Temp</td>
<td>Stores the drug names for reporting.</td>
</tr>
<tr>
<td>GTT_RPT_AGG_BIP_BLOB</td>
<td>CONFIG</td>
<td>Copies and holds the report output blob between the BIP Owner schema and the BIP Metadata repository database.</td>
</tr>
<tr>
<td>RPT_AGG_JOB_EXEC_STS</td>
<td>CONFIG</td>
<td>Used to avoid multiple report jobs fetching the report output at the same time.</td>
</tr>
<tr>
<td>RM_RPT_AGG_CASE</td>
<td>PERSIST</td>
<td>Persist table for GTT_RPT_AGG_CASE.</td>
</tr>
<tr>
<td>RM_RPT_AGG_DET_LIST</td>
<td>PERSIST</td>
<td>Persist table for GTT_RPT_AGG_DET_LIST.</td>
</tr>
<tr>
<td>RM_RPT_AGG_DRUG</td>
<td>PERSIST</td>
<td>Persist table for GTT_RPT_AGG_DRUG.</td>
</tr>
<tr>
<td>RM_RPT_AGG_DRUGNAMES</td>
<td>PERSIST</td>
<td>Persist table for GTT_RPT_AGG_DRUGNAMES.</td>
</tr>
<tr>
<td>RM_RPT_AGG_EV2DRUG</td>
<td>PERSIST</td>
<td>Persist table for GTT_RPT_AGG_EV2DRUG.</td>
</tr>
<tr>
<td>RM_RPT_AGG_EVENT</td>
<td>PERSIST</td>
<td>Persist table for GTT_RPT_AGG_EVENT.</td>
</tr>
<tr>
<td>RM_RPT_AGG_HEALTHAUTHID</td>
<td>PERSIST</td>
<td>Persist table for GTT_RPT_AGG_HEALTHAUTHID.</td>
</tr>
<tr>
<td>RM_RPT_AGG_PARAMS</td>
<td>PERSIST</td>
<td>Persist table for RPT_AGG_PARAMS.</td>
</tr>
<tr>
<td>RM_RPT_AGG_UNIQ_CASES</td>
<td>PERSIST</td>
<td>Persist table for GTT_RPT_AGG_UNIQ_CASES.</td>
</tr>
</tbody>
</table>
For details about tables, columns, and column mappings with Argus Safety, refer to the Argus Flexible Reporting Data Model.xls.

### 4.1.3 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

4.1.4 Database Link

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

4.1.5 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 Argus Safety schema.

4.1.6 Packages

The BI Publisher Owner schema holds the following package types:
• Utility package
• Data load package
• 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>
<thead>
<tr>
<th>Procedure/Function</th>
<th>Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>f_get_query_details</td>
<td>Populates the case series or query prompts that the user can access.</td>
</tr>
<tr>
<td>f_print_as_text</td>
<td>Determines the water mark.</td>
</tr>
<tr>
<td>f_get_cs_name</td>
<td>Returns the case series name for a Case Series ID.</td>
</tr>
<tr>
<td>f_get_agency_name</td>
<td>Gets the agency name for the passed Agency ID.</td>
</tr>
<tr>
<td>p_fetchrptoutput</td>
<td>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.</td>
</tr>
</tbody>
</table>
Table 4–2  (Cont.) Utility Package Details

<table>
<thead>
<tr>
<th>Procedure/Function</th>
<th>Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>f_get_duration</td>
<td>Returns a formatted duration for printing in a report. For example, 10 days.</td>
</tr>
<tr>
<td>f_get_codelist_val</td>
<td>Gets the code list display value.</td>
</tr>
<tr>
<td>f_get_enterprises</td>
<td>Gets the Active Enterprise list on the BIP console.</td>
</tr>
<tr>
<td>f_get_cmn_profile_flag</td>
<td>Fetches the cmn_profile value on key.</td>
</tr>
<tr>
<td>f_ConvertBlobToClob</td>
<td>Converts the blob data into clob.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Procedure/Function</th>
<th>Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Variables</td>
<td>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.</td>
</tr>
<tr>
<td>Lexical Variables</td>
<td>Normal package variables described according to the lexical parameters used in the BIP report.</td>
</tr>
<tr>
<td>p_pop_psur_case_temp</td>
<td>Populates the temp table GTT_RPT_AGG_CASE.</td>
</tr>
<tr>
<td>p_pop_psur_drug_temp</td>
<td>Populates the temp table GTT_RPT_AGG_DRUG.</td>
</tr>
<tr>
<td>p_pop_psur_event_temp</td>
<td>Populates the temp table GTT_RPT_AGG_EVENT.</td>
</tr>
<tr>
<td>p_pop_psur_ev2drug_temp</td>
<td>Populates the table GTT_RPT_AGG_EV2DRUG.</td>
</tr>
<tr>
<td>p_pop_psur_healthauthids_temp</td>
<td>Populates the temp table GTT_RPT_AGG_HEALTHAUTHID.</td>
</tr>
<tr>
<td>p_pop_psur_drugnames_temp</td>
<td>Populates the table GTT_RPT_AGG_DRUGNAMES.</td>
</tr>
<tr>
<td>f_before_data</td>
<td>The main function invoked from BI Publisher. Called from the Before Report trigger of the BI Publisher report.</td>
</tr>
<tr>
<td>f_get_report_id</td>
<td>Retrieves the PN_REG_REPORT_ID parameter value.</td>
</tr>
<tr>
<td>p_set_report_id</td>
<td>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.</td>
</tr>
<tr>
<td>p_check_cs_case_ctr</td>
<td>Checks the counts of cases needed for the trailer page.</td>
</tr>
<tr>
<td>p_ins_rpt_status</td>
<td>Inserts the record into PER_RPT_STATUS for log reporting.</td>
</tr>
<tr>
<td>p_upd_rpt_status</td>
<td>Updates the status of the report on completion with success or failure.</td>
</tr>
<tr>
<td>f_after_report</td>
<td>Final trigger invoked by BI Publisher.</td>
</tr>
<tr>
<td>f_get_evtseriouscr_list</td>
<td>Gets the event seriousness criteria list.</td>
</tr>
<tr>
<td>f_get_dose_stringlist</td>
<td>Generates the dose string list.</td>
</tr>
<tr>
<td>f_get_uniq_patient_id</td>
<td>Obtains the unique patient ID.</td>
</tr>
</tbody>
</table>
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 

\texttt{p\_modify\_case\_temp}.

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

### Table 4-4 User Exit Package Details

<table>
<thead>
<tr>
<th>Procedure/Function</th>
<th>Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>\texttt{p_modify_case_temp}</td>
<td>Called at the end of the case population procedure. You can customize the populated cases here.</td>
</tr>
<tr>
<td>\texttt{p_modify_event_temp}</td>
<td>Called at the end of the event population procedure. You can customize the populated events here.</td>
</tr>
<tr>
<td>\texttt{p_modify_drug_temp}</td>
<td>Called at the end of the drug population procedure. You can customize the populated drugs here.</td>
</tr>
<tr>
<td>\texttt{p_modify_evt_assess_temp}</td>
<td>Called at the end of the assessment population procedure. You can customize the populated assessment here.</td>
</tr>
<tr>
<td>\texttt{p_modify_healthauthids_temp}</td>
<td>Called at the end of the health authority details population procedure. You can customize the populated health authority IDs here.</td>
</tr>
<tr>
<td>\texttt{p_modify_drugnames_temp}</td>
<td>Called at the end of the drug name details population procedure. You can customize the populated drug name here.</td>
</tr>
<tr>
<td>\texttt{p_modify_rm_case_temp}</td>
<td>Called after loading the RM_RPT_AGG_CASE table.</td>
</tr>
</tbody>
</table>
4.1.7 Database Jobs

The BI 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 these, refer to the Argus Safety Installation Guide.

### Report Output Pusher

This job decompresses and pushes the report output from BI 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 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.

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

<table>
<thead>
<tr>
<th>Procedure/Function</th>
<th>Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td><code>p_modify_rm_event_temp</code></td>
<td>Called after loading the RM_RPT_AGG_EVENT table.</td>
</tr>
<tr>
<td><code>p_modify_rm_drug_temp</code></td>
<td>Called after loading the RM_RPT_AGG_DRUG table.</td>
</tr>
<tr>
<td><code>p_modify_rm_evt_assess_temp</code></td>
<td>Called after loading the RM_RPT_AGG_EV2DRUG table.</td>
</tr>
<tr>
<td><code>p_modify_rm_healthauthids_temp</code></td>
<td>Called after loading the RM_RPT_AGG_HEALTHAUTHID table.</td>
</tr>
<tr>
<td><code>p_modify_rm_drugnames_temp</code></td>
<td>Called after loading the RM_RPT_AGG_DRUGNAMES table.</td>
</tr>
</tbody>
</table>
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.

4.2 Argus Application Schema Objects

The Argus Safety Application schema (argus_app) has been enhanced to support BI Publisher Aggregate Reporting.

4.2.1 Tables

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

<table>
<thead>
<tr>
<th>Table Name</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFG_RPT_AGG_PARAMS</td>
<td>Contains the parameters passed for each report, segregates the parameters that are part of the report header, and selects the default values.</td>
</tr>
<tr>
<td>SAFETY_ERR_LOG</td>
<td>Stores errors, warnings and debugs that occur during execution. Pushes errors into the Argus Safety error log.</td>
</tr>
<tr>
<td>CFG_BIP_REPORT_PARAMETERS</td>
<td>Stores the list of parameters that are passed in through the BI Publisher WebServices API.</td>
</tr>
</tbody>
</table>

4.2.2 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 BIP packages and stores the error, warning and debug messages in the SAFETY_ERR_LOG table. Additionally, it stores the error messages in the traditional Argus Safety error log tables by calling Pkg_Console_Common.p_error_log.

4.3 Access Grants to BI 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.
5.1 Flexible Aggregate Reporting Design Structure

This section provides an overview of the BI Publisher Periodic Reporting data model and report layout. Oracle recommends you go through BI 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

5.1.1 BI Publisher Data Model

The BI Publisher data model comprises:

- The data set for each report
- Event triggers
- Parameters and associated lists

5.1.1.1 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).
Each box represents a query that can fill in a group.

5.1.1.2 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.

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

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 Argus Safety Flexible Aggregate Reporting User's Guide.

5.1.2 BI Publisher Report Layout

BI 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

5.2 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.

5.2.1 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.
5.2.2 BI Publisher Data Flow

If you run the report from the 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 BI 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 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 Argus Safety.

---

**Note:** The report output in BIP might be completed earlier than in Argus UI. This is because the job picks up the output and pushes it to the Argus database.
Extending a Flexible Aggregate Report

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

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**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.

---

BI Publisher Periodic Reporting has the following customizable layers:

- Database layer
- BI Publisher layer
  
  This further comprises:
  
  - Data Model layer
  - Report Layout layer

### 6.1 Database Layer

Objects specific to BIP Periodic Reporting are present in a separate schema created during the installation of the 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**

<table>
<thead>
<tr>
<th>Tables</th>
<th>Packages</th>
<th>Views</th>
</tr>
</thead>
<tbody>
<tr>
<td>■ Global Temporary tables populate the report.</td>
<td>■ The main package loads the temp table data.</td>
<td>Used for grouping and accessed in the BI Publisher data model.</td>
</tr>
<tr>
<td>■ RM tables persist data for Argus Mart OBIEE dashboards.</td>
<td>■ The utility package holds the commonly used functions while loading the temp table data.</td>
<td></td>
</tr>
<tr>
<td>■ Configuration tables store report parameter prompts and case series data.</td>
<td>■ The user exit package customizes the loaded temp table data.</td>
<td>None of the packages are wrapped.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

Extending a Flexible Aggregate Report 6-1
6.1.1 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 Argus Safety application schema.

6.1.2 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

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>p_modify_case_temp</td>
<td>Executed at the end of case population procedure. Customization to populated cases can be done here.</td>
</tr>
<tr>
<td>p_modify_event_temp</td>
<td>Executed at the end of event population procedure. Customization to populated cases can be done here.</td>
</tr>
<tr>
<td>p_modify_drug_temp</td>
<td>Executed at the end of drug population. Customization of populated drugs can be taken up here.</td>
</tr>
<tr>
<td>p_modifyEvt_assess_temp</td>
<td>Executed at the end of event assessment population. Customization of populated event assessment data can be taken up here.</td>
</tr>
<tr>
<td>p_modify_healthauthids_temp</td>
<td>Executed at the end of Health authority details population.</td>
</tr>
<tr>
<td>p_modify_drugnames_temp</td>
<td>Executed at the end of drug name details population.</td>
</tr>
</tbody>
</table>

There is also a user exit for each RM table.

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

```plaintext
Procedure pcp_rpt_agg_case
  <var1>
  ...
  ...
  ...
  <var2>
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**

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_temp user exit. Write the following update statement within the p_modify_case_temp procedure:

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

6.1.3 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.

6.1.4 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.

6.1.4.1 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.

6.1.4.2 Filling Custom Tables

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

6.1.4.3 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.
6.1.4.4 Filling Custom Packages
Follow the same procedure for filling custom packages.

6.1.5 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.

6.1.6 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.

6.2 Extending the BI 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.

This section contains the following:
- Section 6.2.1, "Data Model Query Naming Convention"
- Section 6.2.2, "Data Model Nested Queries"
- Section 6.2.3, "Data Structure Groups"
- Section 6.2.4, "DSUR Summary Table Naming Conventions"
- Section 6.2.5, "Case Series Tables"
- Section 6.2.6, "Lexical Parameters"

6.2.1 Data Model Query Naming Convention

The BI 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.
### 6.2.2 Data Model Nested Queries

BIP Periodic reports follow the model of Nested queries.

Consider the PBRER 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.
Extending the BI Publisher Data Model

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 \( \text{AND ct.soc} = \text{G1PBRER62soc} \).

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

6.2.3 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.

```xml
<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>
```

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 \texttt{G2PBRER62REACTION} alias name given in QUERY 2.

### 6.2.4 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 \texttt{G1_DSURSUMTAB}. It is different for all DSUR summary sections.
   
   For fatal summary tabulation, the group name is \texttt{G1_DSURSUMTAB1}.
   
   For Cumulative main ST section, the group name is \texttt{G1_DSURSUMTAB3}.
   
   For Cumulative fatal ST section, the group name is \texttt{G1_DSURSUMTAB4}.
   
   The grouping column is Follow-Up text. The element name is \texttt{G1_TEXT1} and is used in \texttt{dsur_sum.rtf}.

2. The second group name is \texttt{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 \texttt{G2_TEXT1} and is used in \texttt{dsur_sum.rtf}.

3. \texttt{G3_DRUGKEY} is the third group which prints Study and Comparator drugs in a table format.

![Study and Comparator Drugs Format](image)

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 \texttt{G4_DSURSUMTAB}. It is the same for all DSUR summary tabulation sections. The grouping column is SOC. The element name is \texttt{G4_TEXT1} and is used in \texttt{dsur_sum.rtf}.

5. The fifth group name is \texttt{G5_DSURSUMTAB}. It is the same for all DSUR summary tabulation sections. The grouping column is Event Reaction. The element name is \texttt{G5_TEXT1} and is used in \texttt{dsur_sum.rtf}. The Column title appears from the code list BIP\_PROD\_CATEGORY and element name is \texttt{G5_TEXT2}.

```xml
<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" breakOrders="" fieldOrder="3"/>
</group>

<group name="G2_DSURSUMTAB" label="G2_DSURSUMTAB" source="Q2_MAINDSURSUMTAB">
  <element name="G2_TEXT1" value="G2MAINDSURSPONSORSTUDYNUMB" label="G2MAINDSURSPONSORSTUDYNUMB" breakOrders="" fieldOrder="1"/>
```
Extending a Flexible Aggregate Report

6.2.5 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.

6.2.5.1 Common Queries (lexicals) Used in Reports

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

<table>
<thead>
<tr>
<th>Table 6–3</th>
<th>pkg_agg_rpt Queries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q_MESSAGE</td>
<td>Returns all WARNING type log messages that appear in the trailer section Warning Messages.</td>
</tr>
<tr>
<td>Q_ERROR</td>
<td>All ERROR type messages appear in trailer page under Error Messages section.</td>
</tr>
<tr>
<td>Q_CASES</td>
<td>Lists Cases of only Main Case series from the BIP tables RPT_AGG_CASE_SERIES and RPT_AGG_CS_CASES on the Cover page.</td>
</tr>
<tr>
<td>Q_REPORTCASESUMMARY</td>
<td>Returns Totals section on the Trailer page. The Total of valid and invalid case count appears (only cases from MAIN CASE SERIES are considered).</td>
</tr>
<tr>
<td>Q_WMARK</td>
<td>Populates water marks for the reports. For example, DRAFT, INTERNAL.</td>
</tr>
</tbody>
</table>
Extending the BI Publisher Data Model

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

### Table 6–4 QA Section Queries

<table>
<thead>
<tr>
<th>Query</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q_QA1</td>
<td>Lists case numbers without any qualifying drugs. Considers all cases not available in the GTT_RPT_AGG_DRUG table but available in GTT_RPT_AGG_CASE.</td>
</tr>
<tr>
<td>Q_QA2</td>
<td>Lists Case numbers without any qualifying events. Considers all cases not available in the GTT_RPT_AGG_EVENT table but available in GTT_RPT_AGG_CASE.</td>
</tr>
<tr>
<td>Q_QA3</td>
<td>Lists Case numbers with undefined case level unlabeledness. Considers all cases with the column GTT_RPT_AGG_CASE.CASEUNLABELEDNESSCODE value set to NULL.</td>
</tr>
<tr>
<td>Q_QA4</td>
<td>Lists Case numbers with undefined event level unlabeledness. Considers all cases with the column GTT_RPT_AGG_EVENT.EVENTUNLABELEDNESSCODE value set to NULL.</td>
</tr>
<tr>
<td>Q_QA5</td>
<td>Lists Case numbers with undefined Case level seriousness. Considers cases with column GTT_RPT_AGG_CASE.CASESERIOUSFLAG value set to NULL.</td>
</tr>
<tr>
<td>Q_QA6</td>
<td>Lists Case numbers with undefined Event level seriousness. Considers cases with column GTT_RPT_AGG_EVENT.EVENTSERIOUSFLAG value set to NULL.</td>
</tr>
<tr>
<td>Q_QA7</td>
<td>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.</td>
</tr>
<tr>
<td>Q_QA9</td>
<td>Lists Non-Clinical Case numbers (where the column GTT_RPT_AGG_CASE.CASETYPE != 'C')</td>
</tr>
<tr>
<td>Q_QA13</td>
<td>Summary of Unlocked Cases.</td>
</tr>
<tr>
<td>Q_QA14</td>
<td>Cases with Missing Assessment.</td>
</tr>
</tbody>
</table>

### 6.2.6 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  := ' ';
   ```
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`.

```sql
IF PN_EXC_NS_ST = 1 THEN
  GL_ST_FILTER_SERIOUS := ' AND ct.caseseriousflag = 'Y'; --' AND
counter.loadflag = '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>
<thead>
<tr>
<th>Table 6–5</th>
<th>List cases in the line listing under SOC for each diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>GL_LL_MAIN_NONPRI_CASEREF</td>
<td>PMAR main line listing section uses this variable.</td>
</tr>
<tr>
<td>GL_LL_ADHOC1_NONPRI_CASEREF</td>
<td>PMAR Adhoc1 line listing section uses this variable.</td>
</tr>
<tr>
<td>GL_LL_ADHOC2_NONPRI_CASEREF</td>
<td>PMAR Adhoc2 line listing section uses this variable.</td>
</tr>
<tr>
<td>GL_LL_ADHOC3_NONPRI_CASEREF</td>
<td>PMAR Adhoc3 line listing section uses the variable.</td>
</tr>
<tr>
<td>GL_LL_ADHOC4_NONPRI_CASEREF</td>
<td>PMAR Adhoc4 line listing section uses the variable.</td>
</tr>
<tr>
<td>GL_LL_PRI_CASESOC_ONLY</td>
<td>To print case details under primary case SOC.</td>
</tr>
<tr>
<td>GL_LL_DSUR_PRI_CASESOC_ONLY</td>
<td>DSUR reports.</td>
</tr>
<tr>
<td>GL_LL_DSURMAIN_NONPRI_CASEREF</td>
<td>DSUR reports.</td>
</tr>
<tr>
<td>GL_LL_DSURDTH_NONPRI_CASEREF</td>
<td>DSUR reports.</td>
</tr>
</tbody>
</table>

**Code snippet:**

```sql
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_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 = :g5asrsoc) ';
```
Creating a Custom Report

6.3 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 Argus Safety UI -> Argus 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.

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.
5. Log in to BI Publisher and create a new folder under 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.

6. 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.

### 6.4 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>
<thead>
<tr>
<th>Study Status</th>
<th>Case or Code Broken</th>
<th>User Access to Blinded Information</th>
<th>Print Unblinded Data</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blinded</td>
<td>Blinded</td>
<td>No</td>
<td>No</td>
<td>Blinded</td>
</tr>
<tr>
<td>Blinded</td>
<td>Blinded</td>
<td>No</td>
<td>Yes</td>
<td>Blinded</td>
</tr>
<tr>
<td>Blinded</td>
<td>Blinded</td>
<td>Yes</td>
<td>No</td>
<td>Blinded</td>
</tr>
<tr>
<td>Blinded</td>
<td>Unblinded</td>
<td>No</td>
<td>Yes</td>
<td>Blinded</td>
</tr>
<tr>
<td>Blinded</td>
<td>Unblinded</td>
<td>No</td>
<td>Yes</td>
<td>Unblinded</td>
</tr>
<tr>
<td>Blinded</td>
<td>Unblinded</td>
<td>Yes</td>
<td>Yes</td>
<td>Blinded</td>
</tr>
<tr>
<td>Unblinded</td>
<td>Blinded</td>
<td>No</td>
<td>No</td>
<td>Blinded</td>
</tr>
<tr>
<td>Unblinded</td>
<td>Blinded</td>
<td>No</td>
<td>Yes</td>
<td>Blinded</td>
</tr>
<tr>
<td>Unblinded</td>
<td>Blinded</td>
<td>Yes</td>
<td>Yes</td>
<td>Blinded</td>
</tr>
</tbody>
</table>
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 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 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 Argus Safety configuration.

- **ADHOC_LINE_LISTING**: All list names added to the adhoc_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 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 BI 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

<table>
<thead>
<tr>
<th>Code</th>
<th>EN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do</td>
<td>Dose</td>
</tr>
<tr>
<td>DoFo</td>
<td>Dose, Formulation</td>
</tr>
<tr>
<td>DoFoFr</td>
<td>Dose, Formulation, Frequency</td>
</tr>
<tr>
<td>DoFoFrRt</td>
<td>Dose, Formulation, Frequency, Route</td>
</tr>
<tr>
<td>DoFoRt</td>
<td>Dose, Formulation, Route</td>
</tr>
<tr>
<td>DoFr</td>
<td>Dose, Frequency</td>
</tr>
<tr>
<td>DoRt</td>
<td>Dose, Route</td>
</tr>
</tbody>
</table>

- **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

<table>
<thead>
<tr>
<th>Code</th>
<th>EN</th>
</tr>
</thead>
<tbody>
<tr>
<td>CePt</td>
<td>Center, Patient</td>
</tr>
<tr>
<td>InPt</td>
<td>Investigator, Patient</td>
</tr>
<tr>
<td>Pt</td>
<td>Patient</td>
</tr>
<tr>
<td>StCeInPt</td>
<td>Study, Center, Investigator, Patient</td>
</tr>
<tr>
<td>StCePt</td>
<td>Study, Center, Patient</td>
</tr>
<tr>
<td>StCnCeInPt</td>
<td>Study, Country name, Center, Investigator, Patient</td>
</tr>
<tr>
<td>StCnCePt</td>
<td>Study, Country name, Center, Patient</td>
</tr>
<tr>
<td>StCoCeInPt</td>
<td>Study, Country ISO code, Center, Investigator, Patient</td>
</tr>
<tr>
<td>StCoCePt</td>
<td>Study, Country ISO code, Center, Patient</td>
</tr>
<tr>
<td>StInPt</td>
<td>Study, Investigator, Patient</td>
</tr>
</tbody>
</table>

- **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 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.
This chapter discusses the BI Publisher based PMDA (R3) Paper forms architecture.

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

The PMDA (R3) Paper forms utilize the BI 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 BI Publisher.

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

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Functionality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety Server</td>
<td>The server where 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.</td>
</tr>
</tbody>
</table>
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.

The server where (R3) Paper report templates are located and executed. Report output is pushed back to Argus once generated using Web APIs.

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 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.

<table>
<thead>
<tr>
<th>Component</th>
<th>Functionality</th>
</tr>
</thead>
<tbody>
<tr>
<td>AG Service</td>
<td>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.</td>
</tr>
<tr>
<td>BI Publisher Server</td>
<td>The server where (R3) Paper report templates are located and executed. Report output is pushed back to Argus once generated using Web APIs.</td>
</tr>
<tr>
<td>Safety DB Server</td>
<td>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 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.</td>
</tr>
</tbody>
</table>
8.1 PMDA E2B (R3) Paper Report - DB Architecture

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

8.1.1 DB Objects

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

For report generation, this schema holds:

- Tables
- Packages
- Java objects

8.1.2 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_EXP_ 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>
<thead>
<tr>
<th>Table Name</th>
<th>Type</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>GTT_RPT_EXPD_XML</td>
<td>Global Temp</td>
<td>Stores the E2B XML data from the SAFETYREPORT table in ESM Schema owner.</td>
</tr>
<tr>
<td>GTT_RPT_EXPD_XML_LAB</td>
<td>Global Temp</td>
<td>Extracted lab tests data from the XML is stored in this table. Data pertains to a single case for a user in a session.</td>
</tr>
</tbody>
</table>
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 Argus Safety, refer to the *Argus Flexible Reporting Data Model.xls*.

### 8.1.3 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.

### 8.1.4 Packages

The BI Publisher Owner schema holds the following package types:

- Utility Package
- 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**

<table>
<thead>
<tr>
<th>Procedure/Function</th>
<th>Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>f_get_biprep_path</td>
<td>Obtains the BIP report path from configured flexible code lists.</td>
</tr>
<tr>
<td>f_get_codelist_code</td>
<td>Obtains the Code list CODE from the CODE_LIST_DETAIL_DISCRETE table.</td>
</tr>
<tr>
<td>p_get_expd_rpt_params</td>
<td>Obtains the records from the CFG_RPT_AGG_PARAMS table for the PMDA (R3) Paper report template (Default template id is 11).</td>
</tr>
<tr>
<td>f_get_rpt_ctr</td>
<td>Obtains the count from the RPT_SAVED_MSG table for the report to be generated.</td>
</tr>
<tr>
<td>f_get_rpt_catg</td>
<td>Obtains the Code list Display Value from CODE_LIST_DETAIL_DISCRETE table.</td>
</tr>
<tr>
<td>f_get_rpt_catg</td>
<td>Function to get the Reporting Category from CMN_REG_REPORTS.</td>
</tr>
<tr>
<td>f_get_ja_date</td>
<td>Function to convert varchar date column in lab matrix to Japanese date format.</td>
</tr>
<tr>
<td>p_get_blinded_text</td>
<td>Procedure to get the blinded text and blinded text element for B.4.k.2.2.</td>
</tr>
</tbody>
</table>

**PKG_EXPD_RPT - Data Load Package**

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

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

### 8.1.5 Argus Application Schema

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

<table>
<thead>
<tr>
<th>Table Name</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFG_RPT_AGG_PARAMS</td>
<td>Contains the parameters passed for each report, segregates the parameters that are part of the report header, and selects the default values.</td>
</tr>
<tr>
<td>SAFETY_ERR_LOG</td>
<td>Stores errors, warnings, and debugs that occur during execution. Pushes errors into the Argus Safety error log.</td>
</tr>
</tbody>
</table>

### 8.1.6 ACCESS GRANTS to BI 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
9.1 BI 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 BI Publisher guides for more information.

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

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

9.2 PMDA (R3) Data Model

The BI Publisher data model comprises:

- 9.2.2. Event triggers
- 9.2.3. Parameters

9.2.1 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.

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

### 9.2.2 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.

### 9.2.3 Parameters

Parameters are part of the data model. The graphic below displays the parameters of the PMDA (R3) Paper report.
This data model contains only Text type parameters.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PN_REPORT_FORM_ID</td>
<td>This is the report form ID passed from the Argus UI to the BIP report. OOTB values are:</td>
</tr>
<tr>
<td></td>
<td>81: Marketed Form (1,2)</td>
</tr>
<tr>
<td></td>
<td>82: Marketed Form (3,4)</td>
</tr>
<tr>
<td></td>
<td>83: Marketed Form (5,6)</td>
</tr>
<tr>
<td></td>
<td>84: Investigational Form (1,2)</td>
</tr>
<tr>
<td></td>
<td>85: Investigational Form (3,4)</td>
</tr>
<tr>
<td></td>
<td>86: Investigational Form (5,6)</td>
</tr>
<tr>
<td>PN_PRINT_AS</td>
<td>The watermark text is printed based on this parameter. For final report, no watermark is printed. The default value is Draft.</td>
</tr>
<tr>
<td>PV_MKT_INV</td>
<td>The parameter is either M for Marketed or I for Investigational.</td>
</tr>
<tr>
<td>PN_J10_BLIND</td>
<td>J10 element must be updated if the PN_J10_BLIND is 1, irrespective of the Blinded flag.</td>
</tr>
<tr>
<td>PN_PRT_UNBLIND</td>
<td>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.</td>
</tr>
<tr>
<td>PN_IMP_(R3)</td>
<td>This parameter is used to identify whether the report is to be generated through case import.</td>
</tr>
<tr>
<td></td>
<td>0 - Regular cases</td>
</tr>
<tr>
<td></td>
<td>1 - E2B Imported cases, but case is pending for save</td>
</tr>
<tr>
<td>PN_RPT_FAXHEADER</td>
<td>Header value for FAX obtained from the profile configuration.</td>
</tr>
<tr>
<td>PV_RPT_CATG</td>
<td>Report Category value used in deriving the PMDA Report title.</td>
</tr>
<tr>
<td>PN_REG_REPORT_ID</td>
<td>This is a system parameter and should not be changed.</td>
</tr>
<tr>
<td>PN_REPORT_ID</td>
<td>This is a system parameter and should not be changed.</td>
</tr>
</tbody>
</table>

All these parameters are passed from the Argus 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 BI Publisher. It can only be executed from Argus Safety.

9.3 PMDA (R3) Paper Report templates

There are 3 RTF templates for PMDA (R3).

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

9.3.1 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.

<table>
<thead>
<tr>
<th>Column</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CODE</td>
<td>This is auto generated.</td>
</tr>
<tr>
<td>RPT_TYPE</td>
<td>0 = Expedited, 1 = Periodic.</td>
</tr>
<tr>
<td>FORMCATEGORY</td>
<td>This column is used to identify the category of report forms e.g. for all</td>
</tr>
<tr>
<td></td>
<td>PMDA forms, it is 1; otherwise 0.</td>
</tr>
<tr>
<td>REPPATH</td>
<td>The report path of the BI Publisher.</td>
</tr>
<tr>
<td>BIPREPTYP</td>
<td>Report template value to be matched with CFG_RPT_AGG_PARAMS. Default value is 11.</td>
</tr>
<tr>
<td>-------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>

The remaining columns are currently not used.
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.

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

### 10.1 Database Layer

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

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

PMDA paper reports have fixed report format and style. However, they can be customized from the BIP perspective.
10.2 Extending the BI 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 TestnameNull IS NOT NULL THEN ' (' || TestnameNull || ')' 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_WMARCH

```
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;

Q_WMARCH  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.

10.3 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 mhlwadmicsrremarks1 has been modified.

2. Make sure the correct Profile is selected for your agency.
3. Create a case with the remarks entered.

4. Before profile modifications, the `mhlwadmics remarks` element does not have the `remarks1` column.
5. After executing the report with correct agency, the remarks column is updated in the XML.

10.4 Configuring Blinding for PMDA (R3)

10.4.1 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 DRUGAUTHORIZATIONHOLDER.

By updating the \textit{cfg\_e2b} table, the \textit{Blind in PMDA AE Paper Report} checkbox is enabled.

Execute the following update statements by logging in as an ARGUS\_APP user.

Execute the statements for a particular (R3) profile.

\begin{verbatim}
UPDATE cfg\_e2b
  SET blind\_pmda\_ae\_paper\_rpt = 1
WHERE profile = 'AAR\_PMDA\_R3\_PROFILE' and dtd\_element = 'DRUGAUTHORIZATIONHOLDER';
\end{verbatim}

\begin{verbatim}
UPDATE cfg\_e2b
  SET is\_blind\_pmda\_dtd\_element = 1
WHERE profile = 'AAR\_PMDA\_R3\_PROFILE' and dtd\_element = 'DRUGAUTHORIZATIONHOLDER';
\end{verbatim}

Once updated from the profile, the checkbox is enabled.

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

Scenario 2:

As displayed in cmn_profile, the blinded value is printed.

XML generated after checkbox checked:

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

Actual Report
Oracle® Argus Safety Flexible Reporting Extensibility Guide
This appendix lists the probable issues you may encounter while installing, configuring, customizing, and adding a report to the BI Publisher.

A.1 BIP Icon not Displayed Against Corresponding BIP Specific Fields in the Periodic Reporting Configuration

Alternately, BIP Aggregate Reporting does not show up under Reporting in Common Profile switches.

- **Cause**
  BI Publisher Periodic reports are not enabled.

- **Solution**
  On the Argus Console, navigate to System Configuration > Enabled Modules. Make sure that BIP Aggregate Reporting is checked.

*Figure A–1  BIP Aggregate Reporting Enabled*

- **Cause**
  The page level cache is not refreshed.

- **Solution**
BI Publisher Periodic report does not Execute from Argus UI

A.2 BI Publisher Periodic report does not Execute from Argus UI

The BI Publisher Periodic reports do not run when invoked from the Argus UI. The status of the report remains Pending on the Background Reports screen.

- **Cause**
  
The BIP Common user ID or password entered for the BIP Aggregate Reporting Common Profile Switch is wrong or empty.

- **Solution**
  
  Make sure there is a user ID present in the BIP Aggregate Reporting common profile switches. Verify that the user ID and password present in this switch can login to the BI Publisher. Also, make sure that the user ID has complete access to all reports.

- **Cause**
  
  In Linux/Unix the report path is case sensitive. The Report path in the REPORT_TEMPLATE is empty or has an incorrect path.

- **Solution**
  
  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.

**Figure A-2 Verify Report Template Path**

![Verify Report Template Path](image)

- **Cause**
  
  The endpoint address present in the AGProc.config file is incorrect.

- **Solution**
  
  Confirm the following:
  - The endpoint address is present.
ORA-01427: single-row sub-query returns more than one row
ORA-06512: at "<bip_owner>.PKG_AGG_RPT" for p_updclinicaldrugrole procedure

- It points to the BI Publisher Server (including the port number).
- No unnecessary space is present in the URL.
- Services are properly mentioned—SecurityService is mapped against SecurityService, and ScheduleService is mapped against SchedulingService.

- **Cause**
  The Oracle DataAccess version present in the AGProc.config file is incorrect.

- **Solution**
  Refer to the Install guide and make sure the correct entry is provided.

- **Cause**
  Missing Argus UI user in the BI Publisher.

- **Solution**
  Make sure that the Argus UI user exists and is allowed to login and run the required reports.

### A.3 Database Connection Errors

- **Cause**
  The BI Publisher report cannot utilize the JDBC provided.

- **Solution**
  Make sure the JDBC connection name is in lowercase. (asbip)

**Note:** Sometimes, customer may have configured each service associated to one exe files. In such scenarios, the AG _Proc config related to Peridic Reporting should be modified.

### A.4 BI Publisher Scheduled Report Output does not Show up

- **Make sure:**
  - The report is scheduled and not open if run from the BI Publisher Console.
  - The database job used for copying the report output is running correctly.
  - The database link AS_TO_BIPREP is valid

### A.5 ORA-01427: single-row sub-query returns more than one row
ORA-06512: at "<bip_owner>.PKG_AGG_RPT" for p_updclinicaldrugrole procedure

- **Cause**
  The issue has been caused due to the study configuration having duplicated attributes.

- **Make sure:**
  - To check the study configuration and ensure that it does not have any duplicates.
## A.6 Troubleshooting PMDA (R3) Paper Forms

<table>
<thead>
<tr>
<th>Sl No</th>
<th>Issue</th>
<th>Cause</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Missing or invalid junk characters instead of Japanese characters</td>
<td>Japanese fonts are not installed in the BI Publisher Server</td>
<td>Follow Argus Safety Install Guide section 13.2.1 Installing and Configuring East Asian Fonts</td>
</tr>
</tbody>
</table>
| 2     | 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 Detail: ResourceProvider is null | The catalog privileges are not set properly.                    | Follow Argus Safety Install Guide section 13.3.3.2 Managing Folder Privileges |
| 3     | 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. |

### Additional Troubleshooting Details:

- **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.

- **The endpoint address present in the web.config file is incorrect**
  - Confirm the following:
    - The endpoint address is present
    - It points to the BI Publisher Server (including the port number).
    - No unnecessary space is present in the URL.
  - Services are properly mentioned: SecurityService is mapped against SecurityService, and ScheduleService is mapped against SchedulingService and ReportService is mapped against ReportService.

- **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.
<table>
<thead>
<tr>
<th>SL No</th>
<th>Issue</th>
<th>Cause</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>BIP Icons are not displayed against corresponding BIP specific fields/tabs in the Argus UI - Periodic Reporting Configuration</td>
<td>BI Publisher Periodic reports are not enabled in the Argus Console The page level cache is not refreshed</td>
<td>In the Argus Console, navigate to System Configuration &gt; Enabled Modules. Make sure that BIP Aggregate Reporting is checked Restart the IIS server</td>
</tr>
<tr>
<td></td>
<td>BI Publisher Periodic report does not Execute from Argus UI and the status of the reports remains in &quot;Pending&quot; status in the Report Generation Screen</td>
<td>The BIP Common user ID or password entered for the BIP Aggregate Reporting Common Profile Switch is wrong or empty</td>
<td>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.</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>The Report path in the REPORT_TEMPLATE is empty or has an incorrect path</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The endpoint address present in the AGProc.config file is incorrect</td>
<td>Confirm the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The Oracle Data Access version present in the AGProc.config file is incorrect</td>
<td>Refer to the Install guide and make sure the correct entry is provided.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Missing Argus UI user in the BI Publisher</td>
<td>Make sure that the Argus UI user exists and is allowed to login and run the required reports from BI Publisher console</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The BIP Report fails with error: Report data size exceeds the maximum limit (&lt;n&gt; bytes). Stopped processing</td>
<td>The report exceeds the maximum data size specified for report generation</td>
<td>Log in to Oracle BI Publisher - <a href="http://hostname:port/xmlpserver/">http://hostname:port/xmlpserver/</a></td>
</tr>
<tr>
<td></td>
<td>The BI Publisher report cannot utilize the JDBC provided</td>
<td>The BI Publisher report is unable to connect to the database</td>
<td>Make sure the JDBC connection name is in lowercase (asbip)</td>
</tr>
<tr>
<td></td>
<td>Invalid or missing Report Output Pusher job</td>
<td>Invalid database link AS_TO_BIPREP</td>
<td>Make sure that the Report Output Pusher is running without any failure</td>
</tr>
<tr>
<td></td>
<td>Unscheduled Reports</td>
<td>The reports are not scheduled in the BI Publisher, but being run (using the &quot;open&quot; option)</td>
<td>Verify whether the database link AS_TO_BIPREP is valid and pointing to the proper DEV_BIPLATFORM metadata repository database</td>
</tr>
<tr>
<td></td>
<td>Description</td>
<td>Solution</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>----------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Error, ORA-01427: single-row sub-query returns more than one row ORA-06512: at &quot;.PKG_AGG_RPT&quot; for p_updclinicaldrugrole procedure</td>
<td>Check the study configuration and ensure that it does not have any duplicates</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Error, ORA-20005: object statistics are locked (stattype = ALL) &gt;&gt; Error while copying case series - 1, USER_NAME - &lt;logged in user&gt;</td>
<td>Required tables are locked. exec dbms_stats.unlock_table_stats('BIP_OWNER', 'GTT_RPT_AGG_UNIQ_CASES');</td>
<td></td>
</tr>
</tbody>
</table>