

# Oracle Argus

## Release Notes—What's New



Release 8.4

F51789-02

February 2023

The Oracle logo, consisting of a solid red square with the word "ORACLE" in white, uppercase, sans-serif font centered within it.

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Oracle Argus Release Notes—What's New, Release 8.4

F51789-02

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# Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Related resources](#)
- [Access to Oracle Support](#)
- [Revision History](#)

## 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>.

## Related resources

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

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

## Access to Oracle Support

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You can also call our 24x7 help desk. For information, visit <http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html> or visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

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## Revision History

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<b>Date, Version</b>	<b>Description</b>
February 2023, Version 2	Revised description in the <a href="#">Logic update for G.k.2.2 and J2.11</a> section.
September 2022, Version 1	Original version of the release notes.

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# 1

## What's New

- [Technology Stack](#)
- [Oracle Argus Compatibility Matrix](#)
- [Enhancements to Oracle Argus Safety](#)
- [Merged Patches](#)
- [Download Oracle Argus 8.4](#)
- [Install Oracle Argus 8.4](#)
- [Upgrade Oracle Argus database](#)

## Technology Stack

The following components have been added to the Oracle Argus 8.4 technology stack:

- Microsoft Windows 2019 server (64-bit)
- Microsoft Windows 11 client
- Oracle Identity Management (IDM) version 12.2.1.4 + latest bundle patches
- Oracle Analytics Server (OAS) version 6.4
- Oracle Analytics Publisher (Standalone) version 6.4
- Oracle Data Integrator (ODI) version 12.2.1.4
- Oracle B2B 12.2.1.4
- Axway B2Bi 2.6 UP2022-05
- Google Chrome - Version 94.0.4606.71 (64-bit)
- Microsoft Edge (Chromium based) - 94.0.992.37 (64-bit)

See:

- [Dictionary support](#)

## Dictionary support

The following table lists the supported dictionary versions for this release:

Dictionary	Supported versions
MedDRA Dictionary	25.0 (March 2022), 25.1 (September 2022) 24.0 (April 2021), 24.1 (September 2021) 23.0 (April 2020), 23.1 (September 2020) 22.0 (March 2019), 22.1 (September 2019)

Dictionary	Supported versions
WHO Drug Dictionary (Format: B3 and C3, both English and Chinese)	March 2022, September 2022 March 2021, September 2021 March 2020, September 2020 March 2019, September 2019
J Drug Dictionary	April 2022 April 2021, October 2021 April 2020, October 2020 April 2019, October 2019

## Oracle Argus Compatibility Matrix

Application	Compatible Version with this Argus Safety Release
Oracle Argus Analytics	8.4
Oracle Argus Insight	8.4
Oracle Argus Mart	8.4
Oracle Health Sciences Empirica Signal and Oracle Health Sciences Empirica Topics	9.2.1

## Enhancements to Oracle Argus Safety

The following are the enhancements to Oracle Argus Safety:

- [PMDA E2B\(R3\) and Paper Form updates](#)
- [PMDA Device XML reporting and Paper Form updates](#)
- [Italian states codes enhancement](#)
- [MFDS E2B\(R3\) updates](#)
- [NMPA E2B\(R3\) updates](#)
- [RECEIPTDATE \[A.1.7b\] update in E2B\(R2\)](#)
- [Seiyakukyo Line Listing report enhancement](#)
- [Message Type and Clinical Reference Type codelists enhancements](#)
- [CFG\\_FDA\\_IMDRF\\_CODES repository updates](#)
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- [Support for Modern Authentication](#)
- [Option to skip the interchange process individually](#)
- [Incremental ETL new options to disable the dictionary tables population](#)
- [Override License Evaluation and Similar Events functions](#)
- [Logic update for G.k.2.2 and J2.11](#)

## PMDA E2B(R3) and Paper Form updates

### Summary

PMDA E2B(R3) and Paper Form updates

### Description

PMDA published the updated guidance for investigational reporting on Aug 31, 2020.

Based on the updated guidance, Oracle Argus Safety has been enhanced as follows:

### Case Form updates

- In Study cases, you can capture listedness data for all non-company study drugs on the Events > Event Assessment tab. The non-company study drugs displayed in the Event Assessment screen are as per the existing functionality to capture causality for both WHO drug and J drug.
- In Study cases, the non-company study drugs are displayed in the PMDA tab and Comments subtab. All the applicable fields on the PMDA tab, Drug Information section and Comments subtab are applicable for the non-company study drugs as well.

### Console updates

- A new field, Medicinal Product Name, has been added to the Argus Console > Business Configurations > License screen. This is a Japan specific field and is used to transmit the investigational products for the DC or DD reporting category in G.k.2.2. This configuration could be used in specific use cases as per the PMDA guidance if:
  - The drug has multiple CCNs (Clinical Compound Numbers).
  - It is used for different studies due to a different route of administration.
  - The active ingredient is approved in JP.
  - It is a foreign CT report.
- A new drop-down field, Test Drug Type, has been added to the Argus Console > Studies Configuration > J data entry with the following values: Blank, Main Test Drug, Test Drug, Other than Test Drug. This field can be used to configure the type of drug as required for PMDA reporting by using this configuration in the advanced condition SQL queries for reporting rules.
- The Allow multiple reports for Investigational Drugs check box on the Argus Console > Code Lists > Argus > Reporting Destination > EDI tab has been renamed to Allow multiple reports for Investigational Drugs (Clinical Trial). The reporting categories applicable to this check box are DA, DB, DC, DD. This option needs to be unchecked as per the updated guidance for investigational reporting.
- A new check box, Allow multiple reports for Investigational Drugs (Research and Measure), has been added on the Argus Console > Code Lists > Argus > Reporting Destination > EDI tab. The Reporting categories applicable to this check box are DE, DF,

DG. This option needs to be checked so that multiple reports are scheduled based on drug for cases reportable to PMDA.

### Reporting updates

- The Allow WHO Drug reporting check box in the Argus Console > Code Lists > Argus > Reporting Destination has been renamed to Allow WHO Drug / J Drug reporting. Select this option for PMDA agency and it automatically schedules reports for WHO drug or J drug in a study case if it becomes reportable.
- The Argus Console > Business Configuration > Studies > Study Reporting section has been enhanced to automatically schedule reports for the Japan reporting rules configured in this section when the PMDA agency has the **Allow WHO Drug / J Drug reporting** option set.
- The PMDA E2B(R3) report has been enhanced to support the updated guidance. For more information, refer to the *ArgusInterchange84\_PMDA E2B (R3) Export Import Mappings.xlsx* mapping document.
- The PMDA E2B(R3) paper report has been enhanced to support the updated template (dated March 31, 2022) published by PMDA. For more information, refer to the *PMDA E2B R3 Form - Mapping.xlsx* mapping document.

### Other updates

The following minor PMDA guidance updates, which are already handled by knowledge articles, are incorporated:

- ER 27983031 - D.9.4.r.1b validation error when generating PMDA E2B R3 report
- ER 28580229 - Update conformance rules for J2.5.k and J2.6.k when J2.4.k = 5 (not applicable)
- ER 27234225 - Show all data of PMDA E2B R3 G.k.4.r.4
- ER 28291094 - PMDA R3 guidance updates – Codelists
- ER 28107639 - Updates to allowed values for Dose, Strength, Lab test units
- ER 29428415 - Validations for PMDA E2B(R3) elements to be added that does not allow Future date
- ER 29454686 - PMDA R3 validation for element C.5.2 [studyname] to be triggered in specific scenario
- ER 31477598 - Transmit only Primary reporter country (C.2.r.3) for PMDA R3 Research and Measure reports
- ER 29621135 - For investigational unapproved license, do not transmit G.k.3.1/ G.k.3.2

## PMDA Device XML reporting and Paper Form updates

### Summary

PMDA Device XML reporting and Paper Form updates

### Description

MHLW published the revised paper format and new XML format for Medical Device reports. PMDA published the regulatory guidance that included various documents like Data element checklist, Check rules and XML reference.

Oracle Argus Safety has been enhanced to support scheduling, generating, tracking, transmitting, and submitting PMDA Device XML reports, according to the PMDA guidance. The PMDA Device XML has been implemented as a new report while the existing PMDA Device Form 8 and Form 10 paper reports have been updated as per the revised template.

Oracle Argus Safety has been enhanced to enable the PMDA Device XML report:

- New fields have been added in Case Form and Console.
- The existing fields length has been increased.
- Codelist values have been updated.
- New standard and flexible codelists have been added.
- New repository has been added to load and maintain the JMDN (Japanese Medical Device Nomenclature) data and the JFMDA (Japan Federation of Medical Devices Associations (JFMDA) codes.

### **Case Form changes**

New fields have been added to capture the additional device-related data to support PMDA device reporting.

The following fields are added in Case Form:

- Case Form > Events section
  - Clinical Sign > Suspicion or Risk
- Case Form > Products > Device section
  - Device Problem code > Listedness, Causality, Suspicion or Risk
  - Health Impact Information > Listedness, Causality, Suspicion or Risk
- Case Form > Products > Device > PMDA Device Information section (these are specific to Japanese users)
  - PMDA Control Number
  - Nullification Reason
  - Nullification Reason Details
  - Completion Status
  - Reason for Incompletion
  - Future Response
  - Corrective Action Category
  - Usage continuing
- Case Form > Products > Device > Device Information section
  - Device Comments
  - Device Outcome
  - Device Outcome details
- JFMDA codes  
PMDA has published the JFMDA codes for device information mapped to IMDRF codes. New field JFMDA code has been added to the following sections in Case Form: Patient Problem, Clinical Sign, Device Problem Information, Device Component, Evaluation /

Investigation Code Information for Method/Type, Result/Findings and Conclusion sub sections.

### **Console Changes**

The Existing Device Reporting Category codelist is updated for the revised values.

The Device Classification and the Device Outcome new codelists have been added.

The Device Generic Name, the JMDN code and the Terminology code new fields have been added to Business Configuration > Products and Licenses > Product > J Data Entry screen.

### **PMDA Medical Device Defect Glossary**

The PMDA Device report mandates the use of JMDN codes for Device and of JFMDA Codes for Device Problem, Patient Problem, Device Component and Type of Investigation, Investigation Findings, Investigation Conclusion. New tables have been introduced to the repository to store the JMDN and the JFMDA codes and they are used to code the case. The new repository stores JFMDA codes along with IMDRF codes mapped for all annexures (A to G).

### **Interchange mapping**

The following message profile template for PMDA Device XML has been added:

- PMDA-DEVICE MESSAGE TEMPLATE

### **Scheduling, generating and transmitting reports**

#### **1. XML report**

The new PMDA Device XML report can be manually or automatically scheduled for the agency configured with the PMDA Device message template.

Based on the Device Reporting category selected for the case, either Form 8 XML or Form 10 XML are generated and transmitted. The PMDA Device XML tracking and submission are similar to E2B reports.

The EDI gateway can be configured to transmit PMDA Device XML to agency or partners and to import the acknowledgment.

The existing PMDA device paper forms do not affect the PMDA device XML reporting sequence.

The PMDA Device Viewer allows you to preview the report using various views:

- XML view
- Decode view
- Paper view

#### **2. Paper report**

When you generate PMDA Device Forms, the report is generated as per the revised Form 8 and Form 10 template published by PMDA. All other reports processing remains the same for Form 8 and Form 10. The Form 10 nullification template is as the Form 10 nullification template published by PMDA.

#### **3. Validation**

During the PMDA Device XML report generation, the application generates a validation report with the validation errors details. The validation report is also available when you click the **Draft** button from the toolbar and in the ICSR check report.

For changes to the Case Form and the Argus Console fields, refer to *Argus\_Safety8.4\_CaseForm\_Console\_Updates\_Summary.xls*.

For Interchange mapping changes, refer to *PMDA Device Mapping document for Form 8 and Form 10.xlsx* and the *PMDA Device Best Practices* document.

## Italian states codes enhancement

### Summary

Argus to support Italian State codes (Enhancement 32771615)

### Description

The EU Individual Case Safety Report (ICSR) Implementation Guide Rev 2 states that for ICSRs with Italy as the Primary Reporter country, REPORTERSTATE [C.2.r.2.5] must be populated with a valid Italian state or province code.

The new ITALIAN\_STATES flexible codelist has been added to Flexible Data Re-Categorization to store the Italian states and the corresponding codes.

The EMA E2B(R3) Export and Import mappings have been enhanced to send/receive the Italian states codes for the element REPORTERSTATE [C.2.r.2.5]. A new Conformance rule has been provided for the REPORTERSTATE [C.2.r.2.5] element to check the presence of a valid state name if the Primary Reporter country is Italy.

For more information, refer to the following eTRM documents:

- *ArgusInterchange84\_E2B (R3) Export Mappings.xlsx*
- *ArgusInterchange84\_E2B (R3) Import Mappings.xlsx*
- *Argus\_Safety8.4\_CaseForm\_Console\_Updates\_Summary.xlsx*

## MFDS E2B(R3) updates

### Summary

MFDS E2B(R3) IG and Business Rules - Revisions after May 2021 (Enhancements 33560277, 33635071)

### Description

The MFDS E2B(R3) profile has been enhanced to include the following updates:

- The business rules published on Aug 04, 2021 and Sep 15, 2021
- The implementation guide published on Jul 7, 2021

The Clinical Reference Type standard and flexible codelists are enhanced to add the CT Plan Number value that is used to transmit the Sponsor Study Number.

For an updated list of mappings and validations for MFDS E2B(R3), refer to *eTRM ArgusInterchange84\_E2B (R3) Export Mappings.xlsx*.

## NMPA E2B(R3) updates

### Summary

NMPA E2B(R3) updates as per agency feedback (Enhancement 33787017)

### Description

The CNLISTEDNESS [G.k.9.i.CN.1] mapping has been updated to calculate listedness based on:

- The China license for domestic cases
- All countries licenses for foreign cases

For more details, refer to *ArgusInterchange84\_E2B (R3) Export Mappings*.

## RECEIPTDATE [A.1.7b] update in E2B(R2)

### Summary

Receipt date not updated as per the latest date in E2B(R2) nullification reports (Enhancement 18524838)

### Description

The RECEIPTDATE [A.1.7b] mapping has been updated to use the latest significant follow-up date instead of the date from the previous submitted report when you generate nullification reports.

For an updated list of mappings, refer to the following eTRM documents:

- *ArgusInterchange84\_E2B(R2) 2.1 Export Mappings.xlsx* – for ICH E2B(R2), EMA E2B(R2), FDA E2B(R2) 2.1
- *ArgusInterchange84\_E2B(R2) 2.2 Export Mappings.xlsx* – for FDA E2B(R2) 2.2
- *ArgusInterchange84\_PMDA E2B(R2) Export Import Mappings.xlsx* – for PMDA E2B(R2)

## Seiyakukyo Line Listing report enhancement

### Summary

Handling of deleted events in Seiyakukyo Line Listing report (Enhancement 27891604)

### Description

The Seiyakukyo Line Listing report has been enhanced to print the event data from the submitted E2B report, even if they are deleted from the case after submitting the E2B report.

For more information, refer to the *Japanese Seiyakukyo Line Listing Report* mapping document.

## Message Type and Clinical Reference Type codelists enhancements

### Summary

Codelist updates for Health Canada and EMA (Enhancement 31456510)

### Description

#### Message Type codelist

The following message types used for Health Canada Agency (TPMO) have been added to the Message Type standard codelist:

- sapicrs: Expedite ICSRs as per the guidance for the Special Access Programme.
- camricrs: Expedite ICSRs as per the guidance for Canada's Access to Medicines Regime.
- cticrs: Expedite ICSRs from interventional clinical trials.

### Clinical Reference Type codelist

The Clinical Reference Type codelist has been updated with the EU Trial Number value required to report studies that are registered under the EU Clinical Trial Regulation.

For more information, refer to *Argus\_Safety8.4\_CaseForm\_Console\_Updates\_Summary.xls*.

## CFG\_FDA\_IMDRF\_CODES repository updates

### Summary

Updates to CFG\_FDA\_IMDRF\_CODES repository based on the new Annexures released by IMDRF and FDA (Enhancement 31498878)

### Description

The CFG\_FDA\_IMDRF\_CODES repository has been enhanced to include the IMDRF Maintenance updates released on March 5, 2021:

- Annex A: Modified 2 terms (A0908, A15).
- Annex B: Added 1 new term (B23) and modified 1 term (B16).
- Annex C: Added 1 new term (C23) and modified 1 term (C19).
- Annex D: Added 4 new terms (D0107, D0108, D1501, D18) and modified 3 terms (D10, D1107, D12).
- Annex E: Added 2 new terms (E2120, E2342) and modified 23 terms (E0105, E010904, E0115, E0135, E0304, E0508, E0710, E0749, E082901, E0835, E0843, E1101, E1305, E1409, E1412, E1625, E1904, E1905, E2106, E2119, E231201, E231501, E2336).
- Annex F: Modified 5 terms (F14, F2204, F2305, F25, F26).
- Annex G: Added one term (G07002) and modified 9 terms (G02011, G0201501, G02020, G03006, G0405202, G04095, G04130, G0600102, G0600601).

## Date of LMP enhancement

### Summary

No validation error when entering Date of LMP (Enhancement 30158944)

### Description

When the date entered in the **Onset Date/Time** field on the **Events** tab was prior to the **Date of LMP** field value on the **Patient** tab, the application returned an error message.

The Date of LMP value is now retained and no validation error is displayed when the entered Date of LMP is a later date than the Onset Date/Time value.

## Amendments/Follow-ups section enhancement

### Summary

Increase maximum number of follow-ups (Enhancements 33778883, 20249749)

### **Description**

#### **Case Form updates**

The Amendments / Follow-ups section on the Case Form General tab has been enhanced to allow you to submit up to 500 entries.

#### **Report updates**

The SAFETYREPORTVERSION data length has been extended from 2 to 3 digits for the following factory R2 profiles:

- ICH-ICSR V2.1 MESSAGE TEMPLATE
- ICH-ICSR V2.1 MESSAGE TEMPLATE – EMA
- ICH-ICSR V2.1 MESSAGE TEMPLATE – FDA
- ICH-ICSR V2.2 MESSAGE TEMPLATE – FDA

For the detailed data length changes, refer to the following eTRM documents:

- *ArgusInterchange84\_E2B (R2) 2.1 Export Mappings.xls*
- *ArgusInterchange84\_E2B (R2) 2.2 Export Mappings.xls*
- *ArgusInterchange84\_E2B (R2) Import Mappings.xls*

## Dictionary Loader/Recoding Self Service

### **Summary**

Support Dictionary Loading self-service interface for MedDRA, WHODrug, J-Drug dictionaries, and MedDRA Recode

### **Description**

Two new menu items have been added to Argus Console > Tools > Dictionary Management:

- Dictionary Loader
- MedDRA Recode

The new options can be used as an alternative to the Dictionary Management Client/Server tool.

For CRO setup, the utility is accessible to the users that belong to a default enterprise and a group with Menu access.

The Dictionary Loader option supports loading the below Dictionary Types. The Dictionary Type new codelist includes the following values:

- MedDRA
- MedDRA J
- WHODrug Global (Formats B2/B3; C/C3)
- WHODrug Chinese (Formats B3; C3)
- J-Drug



The Dictionary Loader utility provides the option to load a new dictionary or overwrite a dictionary as per the existing functionality as the Dictionary Management Client/Server tool. To load the dictionary, you need to:

- Upload the dictionary files in ZIP format from local desktop.
- Upload the MDB file for the Dictionary [MedDRA, WHO Drug or J Drug dictionaries].
- Select the dictionary type.
- Select the dictionary version and other mandatory information to initiate the loading process.

After initiating the load, the application automatically creates the dictionary schema and the user based on the selected Dictionary Type and Version. On the Dictionary Loader interface, you can view the terms loading status and progress. After the successful completion or failure of the load, you can download the log files. An email is also sent to one or more users configured in the Dictionary Loader interface.

The application performs a rollback if there is any failure during loading, and the status is displayed in the Dictionary Loader interface.

The dictionary loading happens in the background, meaning that the user who initiated the loading can navigate to other screens and resume other tasks. The application allows loading one dictionary at a time. Other dictionaries can be loaded subsequently after completing the prior load. Similarly, the dictionaries loading and recoding cannot be done in parallel and they need to be sequentially executed.

 **Note:**

The MDB files are provided along with the Argus installation and they contain the list of dictionary versions along with the queries to load the data into the database. Periodically, Oracle releases MDB files with newer versions and the customers can download and use them by referring to My Oracle Support and can find more details in *Argus Safety Administration Guide*. The MDB file is required to be loaded only once per dictionary type. A subsequent upload is required only when the dictionary version number shown in the utility is not reflecting the latest dictionary that is required to be loaded.

The MedDRA Recode functionality is used to recode the already coded MedDRA terms to the MedDRA dictionary version configured in System Configuration.

The new interface from Argus Console is similar to the existing recode option in the Dictionary Management Client/Server tool.

In a CRO setup, the MedDRA Recoding tool only recodes the items that match the selected enterprises and the selected MedDRA version to recode. You can recode:

- Current terms only
- Non-Current terms only
- Update dictionary version

Recoding can be done in View Only or Update mode. In View Only mode, cases are not updated or recoded, but a log is made available with the potential cases that are impacted. The View only mode allows the users to select the target version on the MedDRA Recode window without changing the dictionary version in System Management (Common Profile Switches). In Update mode, the cases are actually recoded and audit logged. The Target

dictionary is the dictionary version that is selected in Argus Console > Common Profile Switch for each enterprise. You can download the logs from the MedDRA Recode interface after recoding in either mode.

The supported log files are the same as in the Dictionary Management Client/Server tool.

The recoding logic remains the same.

For more details on Dictionary Loading and Recoding features, refer to *Argus Safety Administration Guide*.

## System Maintenance mode

### Summary

Enhancement request for maintenance mode (Enhancement 29700457)

### Description

Argus Safety has been enhanced to allow administrators to set the operational mode for the Argus Safety application as System Live or System down for Maintenance through a new common profile switch, System Maintenance, added in Argus Console > System Configuration > System Management (Common Profile Switches).

#### System Live mode

This is the default option. In this mode, all users can log in and perform normal operations based on the assigned roles and privileges.

#### System down for Maintenance mode

In this mode, only users with a global admin role can log in to Argus. They can perform the following functions:

- Access the Argus Console.
- Initiate MedDRA Recoding.
- Open Case Forms and work on them.

Users without a global admin role receive the following system message when they try to log in into Argus Safety, Argus Safety Japan, Argus Insight or Argus LAM: `System is currently down for maintenance. Please contact your system administrator for more information. This message is logged in the following logs, when the system is in Maintenance mode for every cycle of that service:`

- ESM Log
- AG Service Log
- Windows Log for Dictionary Loading

When the enterprise creation is in progress, the user cannot activate the Maintenance mode and gets the following message: `Enterprise creation is in progress. Please try again later.`

When the system is down for maintenance, the following services and jobs are not available for the global admin or for any other users:

- Interchange services [E2B Transmit, E2B Import]

- Argus Safety Services - AG services
- Argus Safety Windows Service
- EOSU
- Auto Archiving
- Duplicate Search
- OOTB Database Jobs [Includes PDP Job and Auto Archive Job], Extensibility Jobs



**Note:**

Whenever the application has to go live after a maintenance, only global admin users can select the **System Live** option.

The following services and jobs are available when the system is in Maintenance mode:

- MedDRA Recoding
- Relsys Insight Windows Service
- ETLs (the current running ETL continues and a new ETL can be initiated)
- Global home page

## WHODrug Dictionary Chinese support

### Summary

WHODrug Dictionary Chinese support in Argus (Enhancement 32144414)

### Description

#### Updates to Dictionary Loading tool

The Dictionary Loading tool has been enhanced to support loading the WHODrug Chinese dictionary in B3 and C3 formats. The options to load or overwrite is similar to loading the WHODrug Global dictionary.

#### Updates to Drug Coding window

A new common profile switch has been added to set the Chinese dictionary version to be used. Once the Chinese dictionary is set, the Drug Coding window can be used to search for Trade Name, Ingredient, Formulation and Country based on Chinese terms. The records in the Drug Coding window display the Chinese data in round brackets along with the English data for Trade Name, Formulation, Sales Country, ATC Description, MAH and Ingredients columns, where the Chinese equivalent data are available. If the Chinese dictionary is not set in the common profile switch, then the Drug Coding window continues to work for English term search and selection.

#### Updates to Product tab

On selecting **WHO Drug** from the Drug Coding window, the application auto populates the Chinese trade name and the Chinese generic name in the Product Name and the Generic Name fields on the Product tab in the Multi-language window for the Chinese language. These are used for the NMPA E2B(R3) report.

## WHODrug Global dictionary updates

### Summary

Changes to the WHODrug Global files from the March 2022 version onwards (Enhancement 33657654)

### Description

Starting with March 2022, the WHODrug Global files underwent 3 changes:

- Substance Length field expansion
- Country codes and names updates
- Casing standardization in the WHODrug Global C3 format

Oracle Argus has been enhanced to successfully import the WHODrug files.

### Substance Length field expansion

The Substance Name field in WHODrug Global has been extended, that is:

- In the B3 format (BNA.csv/txt), the Substance Name field has been extended from 45 to 250 characters.
- In the C3 format (SUN.csv/txt), the Substance Name field has been extended from 110 to 250 characters.

### Country codes and names updates

Country codes and names have been updated according to the ISO 3166-1 standards.

### Casing standardization in the WHODrug Global C3 format

UMC unifies the drug names casing in C3 format. This modification effectively standardizes the appearance of drug names bearing the same drug code (all drug names with the same drug code have the same casing).



#### Note:

There is no impact to the Case Form as the Substance Name already supports 250 characters. Argus Insight and Argus Mart tables and views have been updated to support the Substance Name length to 250 characters.

## Web service SOAP protocol for MFDS

### Summary

Need to establish gateway setup to MFDS Korea trading partner (Enhancement 33325092)

### Description

The MFDS Korean authority published the implementation guide for web service based on the E2B XML files submission to the authority. The authority has

implemented a web service system for XML files exchange between the MAH and MFDS system using the standard communication protocol (SOAP protocol).

You can leverage this feature, thereby eliminate the EDI gateway systems need, like Axway B2Bi/Oracle B2B, to exchange files with the MFDS authority.

### Console changes

A new menu option, MFDS, has been provided under Argus Console > System Configuration > Interchange Webservice to configure the web service related to the parameters.

The webservices configuration settings are populated with pre-configured data, except for user ID and auth key that are required to be updated by customers.

A new method, Webservice, has been added in the Argus Console > Code Lists > Argus > Reporting destination codelist > EDI tab > Method field, and the administrator can select the corresponding configured web service.

### Interchange service changes

A new process has been introduced to post the E2B XML files to the MFDS web service. The generated E2B report is placed in the OUT folder based on the existing functionality. The new process picks the files for the agency configured for the web service, posts the request to the MFDS web service and updates the response.

In turn, the service also polls the queue for pending acknowledgments, requests the MFDS web service for acknowledgment file and writes back the acknowledgment file returned by the web service into the IN folder for the Interchange service to read and update the case.

## Support for Modern Authentication

### Summary

Modern Authentication of Microsoft Exchange compatibility with Argus SMTP (Enhancement 33983220)

### Description

Modern Authentication is a combination of authentication and authorization methods. It is more secure than the Basic Authentication method, which relied only on a user name and password.

The method is based on ADAL (Active Directory Authentication Library) and OAuth 2.0. An application does not store the users credentials, but the authentication is done with tokens provided while registering.

In this release, Oracle Argus has been enhanced to support only Microsoft Office 365 to send emails based on Modern Authentication.



### Note:

As a pre-requisite, Argus application needs to be registered in Azure AD to obtain required credentials, like Client ID and Client Secret to send emails.

### Console updates

The Modern Authentication option is added in the Argus Console > System Configuration > SMTP Configuration > Authentication drop-down field. When this option is selected, the SMTP Password field is disabled and the Modern Authentication Configuration section is enabled for you to configure Client ID, Client secret and Tenant ID.

### Email transmission

The Oracle Argus services and Oracle Argus Insight ETL service have been enhanced to send email notifications using the Modern Authentication method.

## Option to skip the interchange process individually

### Summary

Option at agency level to skip interchange process individually (Enhancement 33350871)

### Description

There is a need to suppress ACK transmission when authorities like EMA do not accept acknowledgment. Certain agencies do not send back MDN, and during the data refresh of the production data on the lower environment, the ICSR transmission on lower environment needs to be suppressed.

This enhancement allows you to suppress ICSR transmission, skip MDN polling and suppress ACK transmissions individually for each reporting destination by selecting the corresponding check box in the EDI tab:

Check box	Description
Suppress ICSR transmission	When selected for an agency, the report is generated and marked for transmission as per the existing functionality. However, during transmission, the Interchange service process does not pick the report for transmission, that is, the physical file is not created.
Suppress ACK transmission	When selected for an agency, the Interchange service skips the generation and the transmission of physical ACK file and the transmission for the imported case for this destination.
Skip MDN polling	When selected for an agency, the Interchange service skips polling the MDN status from EDI gateway.

A new check box, Only show not suppressed transmissions, has been added in Worklist > Bulk ICSR Transmit screen to display only the not suppressed transmission reports, by default. You can uncheck this option to view all reports.

A new check box, Show only reports with ACK suppression, has been added in Reports > Processed ICSR Report screen to display the suppressed ACK transmission reports. You can view all reports, by default.

## Incremental ETL new options to disable the dictionary tables population

### Summary

Incremental ETL should have an option to disable the population of Dictionary Tables (Enhancement 33685973)

### Description

The Oracle Argus Mart Initial ETL populates the dictionary tables from Oracle Argus Safety. However, the Incremental ETL is used to populate the dictionary tables from Oracle Argus Safety during every run. Since the dictionary data do not change, there is no need to populate the dictionary tables during every run.

The following common profile switches have been added under Argus Console > System Configuration > System Management (Common profile switch) > Argus Mart:

- Populate MedDRA Dictionary during Incremental ETL
- Populate WHO Drug Dictionary during Incremental ETL

### Populate MedDRA Dictionary during Incremental ETL

When the **Do not populate MedDRA and MedDRA J tables** option is selected, the Incremental ETL does not populate the MedDRA dictionary tables in Argus Mart.

When the **Populate MedDRA and MedDRA J Tables** option is selected (default), the Incremental ETL populates the WHO Drug dictionary tables in Argus Mart.

### Populate WHO Drug Dictionary during Incremental ETL

When the **Do not populate WHO Drug tables** option is selected, the Incremental ETL does not populate the WHO Drug Dictionary tables in Argus Mart.

When the **Populate WHO Drug tables** option is selected (default), the Incremental ETL populates the WHO Drug Dictionary tables in Argus Mart.

## Override License Evaluation and Similar Events functions

### Summary

Override License evaluation and Similar events functions (Enhancement 32868082)

### Description

The following common profile switches are introduced so that if configured, the functions would not be overridden with the default function during Oracle Argus upgrade. The updates made in these functions would be retained as they are:

- Override License Evaluation Function (Note: Default function shall be used if left BLANK): the default value is F\_EVAL\_PROD\_LIC.
- Override Similar Events Function (Note: Default function shall be used if left BLANK): the default value is SF\_IND\_SIMILAR\_EVENTS.

## Logic update for G.k.2.2 and J2.11

### Summary

Logic for G.k.2.2 and J2.11 as per the new PMDA E2B(R3) investigational reporting (34397868)

### Description

PMDA published notifications for new investigational reporting. The mandatory date for submitting investigational reports as per the updated notification is 01-Sep-2022.

Mapping for MHLWADMICSRREPORTTIMESEVENT [J2.11] and MEDICINALPRODUCT [G.k.2.2] elements for PMDA E2B(R3) profile has been enhanced as below:

- MHLWADMICSRREPORTTIMESEVENT[J2.11]  
When the PMDA E2B(R3) report is generated with reporting category DA, DB, DC, or DD, Listedness is transmitted in J2.11 for each product-event combination.
- MEDICINALPRODUCT[G.k.2.2]  
When the PMDA E2B(R3) report is generated for a foreign case with investigational products, the mapping logic works as below:
  - If J2.1a = DC or DD,
    - \* If data is entered in Console > Medicinal Product Name, then transmit that value.
    - \* Or, transmit the same value as for the domestic marketed company product scenario.
  - If J2.1a <> DC or DD,
    - \* Transmit the same value as in the domestic marketed company product scenario.
  - If the drug codes do not exist in both above scenarios, then transmit the Clinical Compound Number. If the drug codes exists, transmit the English Product Name.

#### Ported from

8.2.3.2

## Merged Patches

The bug fixes from the following patches are merged with Oracle Argus 8.4:

- 8.2.1.9
- 8.2.1.10
- 8.2.3.2

#### Note:

The 33624116 bug from 8.2.1.9 patch has been merged. The rest of the 8.2.1.9 patch scope was already merged in 8.2.3.1.

## Download Oracle Argus 8.4

Execute the following steps to download the patch from Oracle Software Delivery Cloud (OSDC):

1. Log in to OSDC (<https://edelivery.oracle.com>) using your credentials.
2. From the **Search by** drop-down list, select **All**.



3. Enter Oracle Argus Standard Edition or Oracle Argus Enterprise Edition, as applicable.
4. To choose the relevant platform, click **Select Platform**, and click **Select**.
5. To add to your download queue, click **Continue**.
6. On the Download Queue page, select the relevant release and click **Continue** to download.

## Install Oracle Argus 8.4

To install Oracle Argus Safety and Oracle Argus Insight, see the *Oracle Argus Safety and Oracle Argus Insight 8.4 Installation Guide*.

### Note:

Oracle Argus Insight installation process has been moved from Schema Creation Tool to Liquibase for silent installation. The Schema Creation Tool (short cut from the Start Menu under Oracle Installation) has also been removed. You must use Liquibase for fresh schema creation or upgrade.

To install Oracle Argus Mart, see the *Oracle Argus Mart 8.4 Installation Guide*.

To install Oracle Argus Analytics, see the *Oracle Argus Analytics 8.4 Installation Guide*.

## Upgrade Oracle Argus database

See the respective Oracle Argus product installation guides for this release.

To upgrade Oracle Argus Safety, see:

- [Database upgrade version](#)
- [Upgrade Oracle Argus Safety from 8.1.x to 8.4](#)
- [Upgrade Oracle Argus Safety from 7.x to 8.0 and 8.0.0.x to 8.1](#)

## Database upgrade version

You can upgrade the database from either of the following versions:

- Oracle Argus Safety
  - 8.1
  - 8.1.1
  - 8.1.2
  - 8.1.2.1 to 8.1.2.6
  - 8.1.3 to 8.1.3.2
  - 8.2
  - 8.2.0.1 to 8.2.0.8
  - 8.2.1 to 8.2.1.10

- 8.2.2 to 8.2.2.2
- 8.2.3
- 8.2.3.001
- 8.2.3.1
- 8.2.3.2
- Oracle Argus Insight
  - 8.1 to 8.4 including merged patches
- Oracle Argus Mart
  - 8.1 to 8.4 including merged patches
- Oracle Argus Analytics
  - 8.1 to 8.4 including merged patches

## Upgrade Oracle Argus Safety from 8.1.x to 8.4

See the *Oracle Argus Safety and Oracle Argus Insight 8.4 Installation Guide*.

## Upgrade Oracle Argus Safety from 7.x to 8.0 and 8.0.0.x to 8.1

1. From Oracle Argus 8.0 Schema Creation Tool, validate the Oracle Argus Safety and DLP Schema (if DLP is currently installed), using the file `VLDN_80.CTL` located at `.\Oracle\Argus\DBInstaller\SchemaValidation`.
2. Verify the validation log file and make sure that there are no errors, missing and invalid objects.
3. Install the recommended Java version on the server from where the following steps will be executed.

Refer to the *Oracle Argus Safety and Oracle Argus Insight 8.4 Installation Guide, Section Oracle Components*.

4. From Oracle Argus Safety 8.9.9.003 patch (patch ID: 30398730), use one of the following upgrade folders and paste it on the server where Oracle Client is installed.
  - To upgrade from 7.x to 8.0, use `.\Argus_Database_Upgrade\1-Upgrade_from_7x_to_80`.
  - To upgrade to 8.0.0.x to 8.1, use `.\Argus_Database_Upgrade\2-Upgrade_from_800x_to_81`.

When copied, update the `dbinstaller.properties` file as mentioned below:

- **ArgusSecurekey** location
- **TDE** attribute (if required) with the required connection details.
- All the user details present in the properties file.
- Parameters as specified for the Oracle Argus Safety Database setup. For more details, refer to the *Oracle Argus Safety and Oracle Argus Insight 8.4 Installation Guide, Section Oracle Argus Safety Database Upgrade*.

Alternatively, to upgrade Oracle Argus Safety from the user interface, go to the 2-Upgrade\_from\_800x\_to\_81\dbinstaller folder, open the command prompt, and run the dbinstallerUI.bat file as an administrator.

For more details to upgrade from the user interface and for silent upgrade (using the dbinstaller.bat file), refer to the *Oracle Argus Safety and Oracle Argus Insight 8.4 Installation Guide, Section Oracle Argus Safety Database Upgrade*.

5. Upgrade Oracle Argus Safety from 8.1.x to 8.4
6. Validate the Oracle Argus Safety and DLP Schema, refer to the *Oracle Argus Safety and Oracle Argus Insight 8.4 Installation Guide, Section Validate Oracle Argus Safety Database*.
7. Verify the validation log file and make sure that there are no errors, missing and invalid objects. Ignore any extra objects in validation due to dlp\_case\_rev\_master\_bkp and tmp\_dcrm\_upd\_data, these objects are related to dlp\_case\_rev\_master correction script.