Oracle Argus
Release Notes—What's New

Release 8.2.2

F32458-05

November 2020

ORACLE®

Oracle Argus Release Notes—What's New, Release 8.2.2

F32458-05

Contents

Preface

1   What's New

Preface

This preface contains the following sections:

- Documentation accessibility
- Related resources
- Access to Oracle Support
  To receive support assistance, determine whether your organization is a cloud or on-premises customer. If you're not sure, use Support Cloud.
- 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

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

Cloud customers receive support assistance through Support Cloud

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

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

- English interface of Oracle Health Sciences Customer Support Portal (https://hsgbu.custhelp.com/)
- Japanese interface of Oracle Health Sciences Customer Support Portal (https://hsgbu-jp.custhelp.com/)

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.

On-premises customers receive support assistance through My Oracle Support

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

Revision History

Date, Version	Description
November 2020, Version 4	Revised 8.9.9.002 version to 8.9.9.003 with patch ID in the Upgrade Oracle Argus Safety from 7.x to 8.0 and 8.0.0.x to 8.1 section.
October 2020, Version 3	Revised Axway B2Bi version number in the Technology Stack section and added a note in the Install Oracle Argus 8.2.2section.
August 2020, Version 2	Added links to the Reference documents section.
July 2020, Version 1	Original version of the release notes.

1

What's New

In this guide:

Technology Stack

The following components have been added to the Oracle Argus 8.2.2 technology stack:

- Oracle Database 19c
- Oracle Client 19c
- Oracle RAC 19c
- Axway B2Bi 2.6 Service Pack 1 Patch 1

Also, see:

- Dictionary support

Dictionary support

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

Dictionary	Supported versions
MedDRA Dictionary (English and Japanese)	23.0 (April 2020) 22.1 (Sep 2019), 22.0 (Mar 2019) 21.1 (Sep 2018), 21.0 (Mar 2018)
WHO Drug Dictionary (Format: B3 and C3)	Mar 2020 Sep 2019 and Mar 2019 Sep 2018, Mar 2018
J Drug Dictionary	Apr 2020 Oct 2019 and Apr 2019 Oct 2018 and Apr 2018 Apr 2017

Oracle Argus Compatibility Matrix

Application	Compatible Version with this Argus Safety Release
Oracle Argus Insight	8.2.2
Oracle Argus Mart	8.2.2
Oracle Argus Analytics	8.2.1
Oracle Health Sciences Empirica Signal and Oracle Health Sciences Empirica Topics	9.0 and 9.1

> **Note:**
>
> The Oracle Argus Safety 8.9.9.89 patch has been merged with this release, hence, you do not need to install it separately.

Enhancements to Oracle Argus Safety

The following are the enhancements to Oracle Argus Safety:

- South Korea MFDS E2B (R3) Export
- Support for EC Manufacturer Incident Report (MIR)
- CDER E2B(R2) Combination Products
- CDER E2B(R2) Similar Device Combination Products
- CBER eVAERS changes
- CDRH eMDR changes
- Other enhancements to Oracle Argus Safety
- Reference documents

South Korea MFDS E2B (R3) Export

The Ministry of Food and Drug Safety (MFDS), formerly known as the Korea Food & Drug Administration published the Regional implementation guide for E2B (R3) reporting in January 2019 and the Business Rules document in January 2020. The implementation guide defines 14 KR specific E2B (R3) regional data elements, and local guidance business rules regarding submissions of E2B (R3) to the MFDS for South Korea.

The application has been enhanced with the capability to schedule, generate, transmit, track, and submit E2B (R3) reports in accordance with the MFDS E2B (R3) Implementation guide, Business rules, and ICSR Reference instance published by MFDS.

The following is the list of changes made in the application for supporting MFDS E2B (R3):

- Case Form changes
- Console changes
- WHO Drug codes
- Interchange mapping
- Generating, tracking, and transmitting reports
- Validation and attachments

Case Form changes

Below are the new Case Form fields introduced to capture the MFDS Product Code and MFDS Ingredient Code for Patient/Parent Historical drugs and Suspect/Concomitant drugs. These are required for generating MFDS E2B (R3) reports for post-marketed domestic cases.

- Patient > MFDS Product Code
- Parent > MFDS Product Code
- Product > MFDS Product Code
- Substance Information > MFDS Ingredient Code

Below are the new Case Form fields introduced to capture the WHO Medicinal Product Code for Patient/Parent Historical drugs. These are required for generating MFDS E2B (R3) reports for post-marketed foreign cases.

- Patient > WHO Medicinal Product ID
- Parent > WHO Medicinal Product ID

Console changes

The Standard and Flexible codelists have been updated, with additional factory data for generating MFDS E2B (R3) reports:

- Console > Codelist > Reporting Destination Type
- Console > Codelist > Case Classification
- Console > Codelist > Clinical Reference Type
- Console > Codelist > Flexible re-categorization > REPORTER_TYPE
- Console > Codelist > Flexible re-categorization > REPORTING_DESTINATION_TYPE
- Console > Codelist > Flexible re-categorization > CASE_CLASSIFICATION
- Console > Codelist > Flexible re-categorization > CLINICAL_REFERENCE_TYPES
- Console > Codelist > Flexible re-categorization > CAUSALITY_CATEGORY
- Console > Codelist > Flexible re-categorization > LANGUAGES
  -> Korean language (Kor) has been added so that the PRIMARYSRCREACTREPORTEDLANG [E.i.1.1b] and CASESUMMARYLANG [H.5.r.1b] elements can transmitted with Korean data.

WHO Drug codes

According to MFDS guidelines, the WHO Medicinal Product ID in the WHODrug Global C3 format must be transmitted in KR regional elements for foreign ICSRs.

A new common profile switch is introduced to support transmitting WHO dictionary version and WHO Medicinal Product ID in the KR regional elements. It is under Console > Common profile switch > Reporting > E2B > Regional Drugs Dictionary. The mapping logic is designed so that regardless of the format the company uses for case processing (B3 or C3), the MFDS E2B (R3) report is generated by fetching the WHO Medicinal Product ID using this profile switch.

Interchange mapping

A new message profile template (ICH-ICSR V3.0 MESSAGE TEMPLATE – MFDS) is introduced for MFDS, with default mappings for export and conformance rules, according to MFDS guidelines.

A new acknowledgement profile template (ICH-ICSR V3.0 ACKNOWLEDGEMENT TEMPLATE – ICH) is introduced, to be used for receiving acknowledgement from MFDS.

Generating, tracking, and transmitting reports

The MFDS E2B (R3) report is generated in the HL7 format, with appropriate comments embedded in the XML, for easy identification of data elements. The ICSR Viewer for the report supports three views:

- XML view
- HL7 view
- Decoded view

You can send and track reports under Worklist > Bulk ICSR Transmit and Utilities > ICSR > ICSR Transmit Status.

Validation and attachments

The MFDS E2B (R3) profile is provided with validation rules as a part of factory data. The rules are based on the Conformance rules defined by MFDS regulations. During E2B (R3) report generation, case data is validated against the rules using ICSR Validation. The list of failed validations is displayed in the ICSR Validation report.

Attachment types supported for MFDS E2B (R3) is provided as part of factory data in newly introduced common profile switch Reporting > E2B > File attachments allowed for MFDS E2B(R3) Profile.

Support for EC Manufacturer Incident Report (MIR)

The European Commission (EC) has released the Manufacturer Incident Report (MIR) version 7.2 in September 2019. The national competent authorities accept the new MIR PDF and XML report, and manufacturers continue to follow the existing MIR processing workflow. The MIR PDF or XML is required to be submitted by manufacturers to notified bodies.

Oracle Argus Safety has been enhanced to support scheduling, generating, tracking, transmitting, and submitting MIR PDF or XML reports, according to MEDDEV guidance. MIR is implemented as a new report in Oracle Argus Safety, and it supports both PDF and XML formats.

Oracle Argus Safety has been enhanced to enable the MIR report in Oracle Argus Safety: new fields have been introduced, the length of existing fields has been increased, codelist values have been updated, new flexible codelists have been added, and new fields have been added to the Reporting Destination configuration.

For more information, see:

- Case Form changes
- Console changes
- New common repository for IMDRF and FDA Codes
- Configuration-related updates
- Interchange mapping
- Generating, tracking, and transmitting reports
- Validation

Case Form changes

New fields have been added to capture additional device-related data to support MIR reporting:

- Product > Device
- Product > Device > EU/CA Device

To help you perform coding using FDA codes and IMDRF codes at the same time, the Patient Problem and Device Problem Information and Evaluation / Investigation Code Information sections in the M/W Info dialog box have been moved to Product > Device.

IMDRF codes fields have been added to the Patient Problem and Device Problem Information and Evaluation / Investigation Code Information sections. The lookup dialog boxes in these sections now display the FDA codes along with IMDRF codes.

A new button under the Device tab allows you to access similar incidents:

- Product > Device tab > Similar Incidents

The Similar Incidents dialog box allows you to capture details of the similar incidents required to be submitted as part of the MIR Report. The identification and computation of count of similar incidents is performed outside the Oracle Argus system, and fields to capture the results are provided in the Similar Incidents dialog box.

Console changes

To support MIR reporting, existing codelists have been updated, and a new flexible codelist has been added.

- **Updated codelists:** Reference Type, Clinical Reference Types, Occupations, and Medical Device Info.
- **New codelist:** Risk Class Type.

New common repository for IMDRF and FDA Codes

The MIR report mandates the use of IMDRF Codes for Device Problem, Evaluation / Investigation, Clinical Signs, and Health Impact information. The CFG_FDA_IMDRF_CODES repository allows you to store the IMDRF codes for Device Problem, Evaluation / Investigation, Clinical Signs, and Health Impact information used for coding in the case. The new repository stores FDA codes along with IMDRF codes for Device Problem and Evaluation / Investigation information.

The CFG_MEDWATCH_CODES FDA codes repository used in previous versions of Argus is now obsolete.

Configuration-related updates

The application now supports specific MIR configuration.

- DEVICE_SUBCOMPONENTS has been updated with new attributes, to store the IMDRF Code and Definition.

- The Authorized Representative field has been added to the Product Configuration screen, and this field derives data from the manufacturer codelist.

- Under License Configuration, new fields are provided, such as Risk Class Type, Nomenclature Text, Medical Device Terminology, Basic UDI-DI, Notified Body ID Number, and Certificate Number of Notified Body.

- Under Reporting Destination Configuration, the Agency Information tab has been updated with a new Contact Type as Authorized Representative.

- The EDI tab has been updated with an MIR Report Type field. This allows you to configure either the MIR XML report or the MIR PDF report to be transmitted.

Interchange mapping

As part of the MIR implementation, the new EC MIR MESSAGE TEMPLATE profile is now available, with default export mappings.

Generating, tracking, and transmitting reports

The new MIR report form is now available. MIR reports can be scheduled or generated manually or automatically. The MIR viewer allows you to preview the report and to switch between XML and PDF modes.

When the final MIR report is generated, it can be transmitted manually or automatically via AG services. MIR reports are transmitted to the configured agency by email only, and the report is sent in XML or PDF format based on the reporting destination configuration. You can track transmission of MIR reports in the Bulk Reporting screen, and you can view submitted reports under Worklist > Bulk Transmit.

Validation

During MIR report generation, the application generates a validation report with the details of validation errors. MIR validations are not carried out against the native Argus Interchange validation framework. Instead, the case data is validated against the XSDs provided by the European Commission.

After successful transmission, MIR reports can be marked as submitted manually in the Bulk Reporting screen or the Report Details dialog box of the individual report.

CDER E2B(R2) Combination Products

FDA published final guidance for Industry for Post Marketing Safety reporting for Combination Products in July 2019.

Oracle Argus Safety 8.2.2 provides features to configure and process cases with the combination products and report to FDA as per the latest regulations.

The following are the list of changes made in the release:

- Console updates
- Case Form updates
- Interchange mapping updates
- Report updates
- Upgrade considerations

Console updates

The COMBO_PRODUCT_RELATIONSHIP flexible re-categorization codelist is provided that enables you to define PMOA and constituent products using the following columns:

- PMOA_PROD_NAME
- PMOA_LIC_NUMBER
- PMOA_COUNTRY
- CONS_PROD_NAME
- CONS_LIC_NUMBER
- CONS_COUNTRY

Case Classification codelist is provided with a new factory data - Combination Product. The Combination Product value is used to identify a case as a combination product case and data entry users are required to select this value in Case Form > General tab > Case Classification.

Case Form updates

The new Case Form table CASE_PMOA_CONS_RELATION is provided in the back-end to store details of the combination products present in the case.

When you enter the primary mode of action product and constituent products, and set Case Classification as **Combination Product**, the application populates data in this table that matches the products against the products available in the COMBO_PRODUCT_RELATIONSHIP flexible codelist. The entries in the CASE_PMOA_CONS_RELATION table are used by export mappings to populate device specific data in the FDA E2B(R2) 2.2 DTD report.

Interchange mapping updates

The new ICH-ICSR V2.2 MESSAGE TEMPLATE - FDA profile is provided with the default export mappings. You can use the new profile to submit reports for both combination and non-combination products.

Export mappings for FDA E2B(R2) 2.2 DTD profile are derived using FDA E2B(R2) 2.1 DTD profile. However, the following updates are made to the FDA E2B(R2) 2.2 DTD profile:

- New elements are provided with export mappings and allowed values.
- Changes to the mapping logic for the existing elements in E2B(R2) 2.1 DTD profile.

Import Mappings are not provided for the FDA E2B(R2) 2.2 DTD profile in this release.

Report updates

E2B report form generates report using the FDA E2B(R2) 2.2 DTD profile. The following features are common to the FDA E2B(R2) 2.2 DTD profile and the existing FDA E2B(R2) 2.1 DTD profile:

- ICSR viewer
- ICSR check
- ICSR length check
- ICSR transmission
- Mark as submitted
- ICSR acknowledgement receipt
- ICSR attachments
- Time-out

The MedWatch and CIOMS view displays only the elements that are available for the FDA E2B 2.1 DTD profile.

PSUR and CTPR periodic reports send ICSRs using the FDA E2B(R2) 2.2 DTD profile, if you select the corresponding reporting destination in the Report Selection screen.

Reports submitted using the FDA E2B(R2) 2.2 DTD profile are considered in the following sections of NDA:

- Line listing of 15-day reports submitted.
- Cases sent to FDA under a different NDA.
- Listing of Nullified 15 day Alert Cases Submitted during the Reporting period.

Upgrade considerations

Oracle Argus Safety 8.9.9.89 was released in September 2019 to provide capabilities to perform Combination Product reporting for Post Marketed products.

Oracle Argus Safety 8.2.2 incorporates the features implemented in 8.9.9.89 along with similar device reporting feature and minor improvements as described below.

The following features provided in Oracle Argus Safety 8.9.9.89 are obsolete:

- The OOTB Post Save function FN_OOTB_POSTSAVE used to populate Combination Product data in CASE_PMOA_CONS_RELATION table

- The following Common Profile Switches that were added in 8.9.9.89 release to specify customer specific Post Save function are removed in this release:

    – Custom Post Save Routine Name

    – Execute Custom Post Save Routine

If any customer specific Post Save function name was specified in these switches, then it is moved back to an existing switch Case Form Configuration > Custom routine after commit.

CDER E2B(R2) Similar Device Combination Products

FDA published revised technical specification in February 2020 covering guidance on Similar device reporting.

As per this guideline, if a reportable malfunction occured using device constituent parts of combination products marketed outside the U.S, then the Combination Product applicant is required to submit Malfunction reports to FDA if the following conditions are met:

- there is a similar device that is part of Combination Product constituent in a U.S. marketed combination product and

- the malfunction is likely to occur in the U.S.marketed combination product

The following are the list of changes made in the release:

- Case Form updates
- Interchange mapping updates

Case Form updates

A new field **Similar Device** is provided in the Case Form > Products > Device > Product Information section.

The label for radio button option **Treatment** has been changed to **Treatment / Other** as this option is set for similar device product.

Similar device products are identified during case save by checking if the case has the following information and the entries are populated into CASE_PMOA_CONS_RELATION table:

- Case Classification is Combination Product.

- Case has a PMOA Product and Constituent Product that matches with the configuration made in COMBO_PRODUCT_RELATIONSHIP.

- PMOA product present in the case that matches with flexible codelist has the following data:

    – Product is licensed in the United States.

    – Product type is Treatment/Other.

    – Drug Not administered is marked as checked.

- Constituent Product present in Case that matches with flexible codelist has the following data:

  – Product type is Treatment/Other

  – Drug Not administered is marked as checked.

  – Similar Device is marked as checked.

Interchange mapping updates

The Export Mappings for the following elements in FDA E2B(R2) 2.2 profile considers the similar device combination products:

- DRUG [B.4]

- DRUGCHARACTERIZATION [B.4.k.1]

- DRUGAUTHORIZATIONNUMB [B.4.k.4.1]

- DRUGAUTHORIZATIONCOUNTRY [B.4.k.4.2]

- DRUGAUTHORIZATIONHOLDER [B.4.k.4.3]

CBER eVAERS changes

In this section:

- eVAERS regulation updates

- Changed UCUM code for decade to 10.a for Unit fields (Enhancement 30967739)

- Changed mapping for HOSPITALNAME, HOSPITALCITY, and HOSPITALSTATE (Enhancement 28896618)

- Changed DTD_LENGTH for ACTIVESUBSTANCENAME (Enhancement 28138723)

eVAERS regulation updates

In May 2019 and June 2020, the FDA published revised technical specifications to accommodate the submission of Postmarketing Safety Reporting for Combination Products.

> **Note:**
>
> Regulations from June 2020 are partially implemented due to late availability. Remaining regulation updates will be available in the future release.

The following are the list of changes made in the application to be compliant with the latest regulations.

- The new field **Pregnant at time of Vaccination** is available under Case Form > Patient Tab > Patient Details.

- Factory data changes have been made to the following codelists and flexible codelists:

- – Console > Codelist > Routes of Administration

- – Console > Codelist > Anatomical Location

- – Console > Codelist > Flexible re-categorization > Route

- – Console > Codelist > Flexible re-categorization > Location

- • Null flavor set assignments have been changed for the following case form elements under Console > System Configuration > Field Properties:

  - – Patient Title

  - – Patient Middle Name

  - – Patient Last Name

  - – Patient Address 1

  - – Patient City

  - – Patient State

- • Element numbers are provided for all the existing FDA regional elements and for the new elements in eVAERS profile. The element numbers are displayed in the decoded view of the ICSR viewer and as inline comments in the XML file.

- • The following changes have been made to the eVAERS profile:

  - – New elements have been added.

  - – Elements related to the Parent have been deleted.

  - – Mapping logic has changed for elements.

  - – Conformance rules have changed for elements.

  - – Data length has changed for elements.

  - – Data element descriptions have changed for elements.

  - – Allowed null flavors have changed for elements.

  - – Allowed values have changed for elements.

Changed UCUM code for decade to 10.a for Unit fields (Enhancement 30967739)

The mappings and allowed values for the following eVAERS elements have been revised to send the Decade value with the UCUM code 10.a instead of {decade}:

- • PATIENTONSETAGEUNITR3 [D.2.2b]

- • PATIENTAGEATVACCINATIONUNIT [FDA.D.2.1b]

- • PARENTAGEUNITR3 [D.10.2.2b]

- • PASTVACCINEAGEONSETUNIT [FDA.D.8.r.8b]

- • PARENTAGEUNITATVACCINATION [FDA.D.10.2.2.1b]

- • TESTUNIT [F.r.3.3]

Changed mapping for HOSPITALNAME, HOSPITALCITY, and HOSPITALSTATE (Enhancement 28896618)

When you check the **Hospitalized** and **Event Caused Hospitalization** checkboxes in the Events tab, and the Hospital Name, City, State fields are left blank in case form, then regardless of whether the Reporter Country is US or Non US, Null Flavor NI is transmitted in the HOSPITALNAME [FDA.E.i.3.2c.1b], HOSPITALSTATE [FDA.E.i.3.2c.1d] and HOSPITALCITY [FDA.E.i.3.2c.1c] elements.

Changed DTD_LENGTH for ACTIVESUBSTANCENAME (Enhancement 28138723)

The data length for ACTIVESUBSTANCENAME [G.k.2.3.r.1] is changed to 250 AN in eVAERS profile.

CDRH eMDR changes

Based on the updates to the CDRH regulations, the following changes have been made to Case Form, Argus Console, and eMDR Profile.

- The GTYPEOFREPORT [G7] element is now repeatable within the GREPORTTYPE [G7] node. Mappings and allowed values for this element have been revised to distinguish between the Thirty Day report and Initial report.

- The Concept Codes for the DECHALLENGE [C9] and RECHALLENGE [C10] elements have been updated to C86045 and C54055, respectively.

- The list of allowed values for the LOCATIONEVENTOCCUR [F12] element has been updated according to the latest regulations. Mapping changes have been made to the LOCATIONEVENTOCCUR [F12] and LOCATIONEVENTOCCURTEXT [F12] elements.

- The list of allowed values for the APPROXDEVICEAGETEXT [F9] element has been updated to include the Week unit. The Age Unit codelist and DEVICE_AGE_UNIT flexible codelist have been updated to enable the Week unit to appear under Case Form > Product > Device > Device Age field.

- The list of allowed values for the following elements has been updated according to the latest regulations:

  – FDAPATIENTCODE [F10]

  – MFRPATIENTCODE [H6]

- Mapping for UDINUMBER [D4] has been updated to populate data based on the new UDI-DI field added to the Device tab. If this data is missing, data is populated based on existing logic, using the Unique Device Identifier field in the Device tab.

- Data Length for the following eMDR elements has changed according to the latest guidelines:

  – MFRCONTACTFACILITY [G1]

  – CONCOMPRODUCTNAME [D11]

- The Email Address field has been added to Case Form > Analysis > MedWatch Info > F. For Use by User Facility/Importer (Devices Only). The

UFCONTACTEMAIL [F3] element has been added to the eMDR Profile to populate data from the User Facility's Email Address field.

- Mapping for USAGEOFDEVICE [H8] has been updated to send appropriate NCI codes if the Unknown value is selected in the Usage of Device field.

For changes to the Case Form fields and Argus Console fields, see *Oracle Argus Safety8.2.2 CaseForm_Console_Updates_Summary* sheet.

For mapping changes, see *eMDR (R2) Export Mappings* sheet.

Other enhancements to Oracle Argus Safety

In this section:

- Nullification report to mask the reporter and patient data in E2B(R3) (Enhancement 30729108)
- Draft Report button updates (Enhancement 26335541)
- Removed common profile switch - Perform E2B Check on Case Save
- Updated EMA R3 Profile conformance rule to apply reporter country EU (Enhancement 29820228)
- Updated ACK.B.r.5 Date of ICSR message creation (Enhancement 29999426)
- Health Canada Device Reporting Form changes
- Updated auto expectedness assessment
- Oracle Argus Service configuration changes
- Removed password configuration for Oracle Argus Safety Service users
- Removed E2B PDP job, Bulk Transmit E2B and Bulk Transmit Fax processes
- SMTP configuration changes
- Documentation updates

Nullification report to mask the reporter and patient data in E2B(R3) (Enhancement 30729108)

When the Nullification report is generated for any E2B(R3) submitted report, then the Patient and Reporter details were not being masked in the report output. This happened when the previous submitted report for which nullification is being generated was auto-scheduled with reporting rule or manually scheduled with **Protect Confidentiality** set in the scheduling window.

This is because the nullification report is generated based on the latest case data. However, E2B(R2) reports did not has this issue as it was a copy of the previous submitted report.

The E2B(R3) Nullification report has been enhanced to print **MSK** for the patient and reporter elements as per the mapping logic for that element if the previous submitted E2B(R3) report (for which Nullification report is being created) was created with **Protect Confidentiality** set.This enhancement is applicable for all E2B(R3) profiles – ICH, EMA, PMDA, eVAERS, MFDS.

Draft Report button updates (Enhancement 26335541)

Draft report generation on click of the **Draft Report** button from the toolbar has been enhanced to allow you to select destination and product along with the Report Form.

When you click the **Draft Report** button, the View Draft screen is displayed with blank selection in the drop-downs for Report Form, Destination and Product.

- Report Form drop-down: You can select any report, as all the expedited reports are listed.

- Destination drop-down: Displays the list of Reporting Destination configured in Argus Console similar to the list of destination displayed from Case Form > Regulatory Reports > Schedule New Report window > Destination.

- Product drop-down: When Report Form and Destination are selected, the Product drop-down automatically displays the matching product name based on the Report Form and Destination as per the below logic:

  – For the Drug Report Forms, the left most Suspect product having Drug license that matches the agency country is auto selected.

  – For the Device Report Forms, the left most Suspect product having Device license that matches the agency country is auto selected.

  – For the Vaccine Report Forms, then left most Suspect product having Vaccine license that matches the agency country is auto selected.

  – When there is no Product with license that matches the License type and agency country found in the case, then left most suspect product is auto selected.

License with the earliest award date of the selected product that matches the agency country is used for report generation. For PMDA E2B/Paper reports, the first available license of the selected product from PMDA tab > License record where Reporting Category is used for report generation.

The following common profile switches are removed from Argus Console as the draft report generation has the flexibility to specify agency:

- Reporting > eMDR > Default Reporting Destination for draft eMDR generation

- Reporting > eVAERS > Default Reporting Destination for draft eVAERS generation

- Argus J > Default name of Regulatory Agency for Draft Expedited PMDA Reports

The following screens are enhanced with the feature to view draft report that allows selection of report form, destination, and product:

- Medical Review

- Coding Review

- Worklist > Local Labeling > View Default Report

- Local Affiliate > Local Labeling > View Default Report

- Local Affiliate > Local Labeling > Medical Review > View Draft

Removed common profile switch - Perform E2B Check on Case Save

As a performance improvement measure, the common profile switch Reporting > E2B > Perform E2B Check on Case Save is deprecated. The application now generates the ICSR Check report only when you click the **ICSR Check** button from the tool bar. You can no longer generate the ICSR check report on every case save.

Updated EMA R3 Profile conformance rule to apply reporter country EU (Enhancement 29820228)

The conformance rules for EMA E2B(R3) are updated for REPORTERCOUNTRYR3 [C.2.r.3] element to display the validation error, if any of the Reporter Country (not only the Primary Reporter) is entered as EU (European Union).

Updated ACK.B.r.5 Date of ICSR message creation (Enhancement 29999426)

The following changes are made to the acknowledgement file generated for the EMA E2B(R3) and PMDA E2B(R3) reports:

- Inline comment for MESSAGEDATER3 [ACK.M.4] in ACK file is corrected to show the correct element name and number.
- REPORTMESSAGEDATE [ACK.B.r.5] is populated with correct code and codesystem data in the ACK file.

Health Canada Device Reporting Form changes

Health Canada Medical Device Report template has be updated with the following changes:

- In the footer, removed word Canada that appeared after MedEffect TM.
- In the footer, the publication details are changed from HC Pub.: 110180 (October 2011) to Canada HC Pub.: 110180 (April 2018).
- URL printed in the privacy notice statement is updated as per the template published by Health Canada.

Updated auto expectedness assessment

As per EU Clinical Trial Directive (EU CT'3) guidelines, the expectedness assessment must be performed using the datasheet version applicable at the time of occurrence of the event. To comply with this guideline, the **Revision #** and **Active on date** (datasheet activation date) fields are now provided in Case Form that enables you to view the datasheet revision number used for **Listedness** determination.

When the event expectedness is assessed based on a datasheet, the **Revision #** and **Active on date** fields are displayed in the following screens:

- Case Form > Events > Event assessment > Data sheet
- Case Form > Events > Event Assessment >Data sheet link > Datasheet Labeled Term popup
- Case Form > Case Actions > Medical Review > Medical Review tab > Event Assessment > Data sheet

- Case Form > Worklist > Local Labeling > Pending and Historical tab > Data sheet
- Local Affiliate > Local Labeling > Pending and Historical tab > Data sheet

Oracle Argus Service configuration changes

Oracle Argus Safety Services deployed on fresh install is provided with default service users and processes.

The following critical processes are marked as enabled in the Oracle Argus Safety Service user interface. You can enable the remaining non-critical processes manually.

- Batch Report Generation
- Batch Report Generation Worker 1
- Batch Report Generation Worker 2
- Batch Periodic Reports 1
- Batch Periodic Reports 2
- Bulk Report Transmit Email
- Priority
- Priority Assessment
- Queue Management
- Report Scheduling 1
- Report Scheduling 2
- Report Scheduling Check 1
- Report Scheduling Check 2
- Audit Log Update
- General Email

Removed password configuration for Oracle Argus Safety Service users

Argus Console users that are marked as Service users no longer require password. The **Password** field for the service user has been removed. In an upgraded environment, for the existing service users, the application ignores the password present in the INI file.

The password data capture for the service users has been removed from the AG Service configuration tool. The Case Intake and Literature screens no longer require service user password in the configuration file.

Removed E2B PDP job, Bulk Transmit E2B and Bulk Transmit Fax processes

- **E2B PDP job:**
  As the batch generation process handles E2B reports, the following has been removed:
  - PDP job for E2B report generation.
  - The Configuration screen in the AG Service configuration tool to configure DB load timings.

– The **System Resource Usage** button.

- **Bulk Transmit E2B process:**
  When the E2B report was transmitted from the bulk reporting screen, the Bulk Transmit E2B background process marked the E2B report for transmission to be picked-up by the Interchange service.

  Now, when you transmit the report from the Bulk Reporting screen, the report is marked for transmission . In addition, the background reports generation happens only through the Batch Report Generation and Batch Report Generation Worker processes. Hence, the Bulk Transmit E2B process is no longer required and has been removed.

- **Bulk Transmit Fax process:**
  When the fax report was transmitted from the Bulk Reporting screen, the Bulk Transmit Fax background process marked the fax reports for transmission to be picked-up by the Fax process.

  Now, when you transmit the report from the Bulk Reporting screen, the report is marked for transmission. In addition, the background reports generation happens only through the Batch Report Generation and Batch Report Generation Worker processes. Hence, the Bulk Transmit Fax process is no longer required and has been removed.

> **Note:**
>
> You may want to delete Bulk Transmit E2B and Bulk Transmit Fax processes in the Oracle Argus Safety Service user interface, letting these process running will cause extra system resource usage and will not process any work.

SMTP configuration changes

SMTP configuration has been enhanced to avoid blocked emails sent from Oracle Argus cloud due to incorrect or incomplete configurations.

- The layout of SMTP Configuration under Console > System Configuration > SMTP Configuration has been enhanced to group configuration for better readability and understanding.

- A new **Global From Address** mandatory field has been added to accept an email address. When emails are sent from Oracle Argus Safety, the **From address** field for all the emails is set to the **Global From Address**. The former **From Address** field value is now populated in the **Reply To** field to maintain the existing functional behavior.

- The **FQDN** field is now mandatory.

- The Save button has been renamed as **Validate and Save**.

The application attempts to send a test email to the email address configured in the **From Address**. If the email fails, the configuration is not saved. You must enter a valid email address to save the configuration.

The test email takes into account proxy configuration if configured in the proxy settings. The **FQDN** is also validated with a DNS server however if this fails, the configuration is still saved.

Documentation updates

Since the Oracle Argus Safety and Oracle Argus Insight installers were merged into a common source repository and are built as a single unit and package, the installation guides of both the products has also been merged and renamed as the *Oracle Argus Safety and Oracle Argus Insight Installation Guide*.

Reference documents

Go to My Oracle Support (MOS) to access the following Electronic Technical Reference Manuals (eTRMs):

- For more information on new Case Form fields, Console updates, usage of common profile switches, and configurations, see:
    - MIR Case Form Console Updates Summary.xlsx
    - Non-MIR Case Form Console Updates Summary.xlsx

- For more information on export logic, new elements, mapping changes, allowed values, null flavors, conformance rules, data length, element number, and element description changes, see:
    - E2B (R3) Export Mappings.xlsx
    - MIR Export Mappings.xlsx
    - E2B (R2) 2.2 Export Mappings.xlsx

- For ACK import logic, see the E2B (R3) Import Mappings sheet.

> **Note:**
>
> eTRMs are password-protected. Log a Service Request (SR) to obtain the password.

Go to the Oracle Help Center > Argus 8.2.2 Books page to access the following:

- For more information on best practices to be followed for configuration of combination products or similar device combination products, case data entry, or report generation, and see:
    - South Korea MFDS E2B(R3) Best Practices
    - EC Manufacturer Incident Report (MIR) Best Practices
    - For E2B(R2) 2.2 profile, see to the CDER E2B(R2) Combination Product Best Practices
    - CBER eVAERS Combination Product Best Practices

- For more information on the default service user names, see the *Oracle Argus Safety Service Administration Guide.*

Enhancements to Oracle Argus Mart

The following are the enhancements to Oracle Argus Mart:

- ETL—Signal Mart (SM) case revision based on granularity configuration (Enhancement 31217258)
- Inclusion of new fields (Enhancement 31232390)

ETL—Signal Mart (SM) case revision based on granularity configuration (Enhancement 31217258)

Oracle Argus Mart ETL created SM revisions for all the locked case revisions in Oracle Argus Safety processed by the ETL. However, not all locked case revisions were relevant for analysis. This caused overhead and ETL took prolonged time to complete. In addition, the granularity or the level of required locked case revisions varied across customers.

Oracle Argus Mart is enhanced to provide a configuration that allows you to decide the level of granularity on locked case revisions required for analysis.

You can now configure the following granularity levels:

- A parameter or key is made available in the Oracle Argus Safety CMN_PROFILE_GLOBAL table to set the granularity level.
- These configuration changes do not impact behavior of the Reporting Mart (RM) table population.
- To specify the granularity of processing SM revisions, a new SM_REVISIONS_GRANULARITY common profile switch configurable from Oracle Argus Safety has been added:

Granularity Level	Description
ALL (Default)	Process all revisions in the ETL range.
ETL	Process latest revision of each case in the ETL range.
DAILY (Recommended)	Process earliest revision and day-wise latest revision of each case in the ETL range.

Inclusion of new fields (Enhancement 31232390)

The following Oracle Argus Mart Signal Mart (SM) tables have been modified as a result of changes in the Oracle Argus Safety tables:

Table	Column	Description
SM_PRODUCT	AUTH_REPRESENTATIVE_VE	Identifies the authorized representative of the product.
SM_PRODUCT	AUTH_REPRESENTATIVE_V2	Store the Japanese value of the authorized representative.
SM_PRODUCT	MFDS_PRODUCT_CODE	Store a 9-digit unique code per product licensed in South Korea.
SM_PRODUCT	MFDS_PRODUCT_CODE_SU	Stores the value as blinded or non-blinded for the study case based on unblinding status.

Table	Column	Description
SM_EVENT_PRODUCT	IMDRF_CODE	Defines clinical sign IMDRF code.
SM_EVENT_PRODUCT	REVISION	Stores revision number of the datasheet used for the event assessment.
SM_INGREDIENTS	MFDS_INGREDIENT_CODE	It is 7-digit unique code per Ingredient assigned by South Korea MFDS.
SM_INGREDIENTS	MFDS_INGREDIENT_CODE_SU	Field is used to store blinded/non-blinded value based on case study.
SM_PAT_HIST	MFDS_PRODUCT_CODE	MFDS Product Code, It is 9-digit unique code per product licensed in South Korea.
SM_PREGNANCY	PREG_AT_VACCINE_VE	Pregnancy at the time of Vaccination 0-No 1-Yes 2-Unknown
SM_PREGNANCY	PREG_AT_VACCINE_V2	Pregnancy at the time of Vaccination Japanese decode values.

Merged Patches

The bug fixes from the following patches are merged with Oracle Argus 8.2.2:

- 8.2.0.6
- 8.9.9.89
- 8.1.3.1
- 8.2.1.2
- 8.2.1.3

Download Oracle Argus 8.2.2

Execute the following steps to download the patch from My Oracle Support (MOS):

1. Open an MOS (https://support.oracle.com) session in a browser.
2. Click the **Patches & Updates** tab.
3. In the **Patch Name** or **Number** field, enter the patch ID:
   - Argus Safety—**31454695**
   - Argus Insight—**31454695**
   - Argus Mart—**31584423**
4. Click **Search**.

5. Click **Download** and save the compressed file to a temporary location on your local system.

6. Locate the downloaded file and extract it to a temporary directory. The file contains the Oracle Argus 8.2.2 Installer.

Install Oracle Argus 8.2.2

To install Oracle Argus Safety and Oracle Argus Insight, see the *Oracle Argus Safety and Oracle Argus Insight 8.2.2 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 8.2.2 Installation Guide*.

Upgrade Oracle Argus Database

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

To upgrade Oracle Argus Safety, see:

- Oracle Argus Safety upgrade version
- Upgrade Oracle Argus Safety from 8.1.x to 8.2.2
- Upgrade Oracle Argus Safety from 7.x to 8.0 and 8.0.0.x to 8.1

Oracle Argus Safety upgrade version

You can upgrade the Oracle Argus Safety database from either of the following versions:

- 8.1
- 8.1.1
- 8.1.2
- 8.1.2.1 to 8.1.2.6
- 8.1.3
- 8.1.3.1
- 8.2
- 8.2.0.1 to 8.2.0.6
- 8.2.1
- 8.2.1.1
- 8.2.1.2

- 8.2.1.3

Upgrade Oracle Argus Safety from 8.1.x to 8.2.2

See the *Oracle Argus Safety and Oracle Argus Insight 8.2.2 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 8.2.2 Installation Guide, Section 1.2.2 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 8.2.2 Installation Guide, Section 13.2 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 8.2.2 Installation Guide, Section 13.2 Oracle Argus Safety Database Upgrade*.

5. Upgrade Oracle Argus Safety from 8.1.x to 8.2.2.

6. Validate the Oracle Argus Safety and DLP Schema, refer to the *Oracle Argus Safety and Oracle Argus Insight 8.2.2 Installation Guide, Section 12.3 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.