

Oracle Argus

Release Notes—What's New



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ORACLE®

Oracle Argus Release Notes—What's New, Release 8.4.1

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Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Diversity and Inclusion](#)
- [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>.

Diversity and Inclusion

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

Related resources

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

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

Access to Oracle Support

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

Cloud customers receive support assistance through Support Cloud

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

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

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

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

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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 2023, Version 2	Revised Axway version in the Technology Stack section.
August 2023, Version 1	Initial version of the release notes.

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What's New

- [Technology Stack](#)
- [Oracle Argus Compatibility Matrix](#)
- [Enhancements to Oracle Argus Safety](#)
- [Enhancements to Oracle Argus Insight](#)
- [Merged Patches](#)
- [Download Oracle Argus 8.4.1](#)
- [Install Oracle Argus 8.4.1](#)
- [Upgrade Oracle Argus database](#)

Technology Stack

The following components have been added to the Oracle Argus 8.4.1 technology stack:

- Oracle Analytics Server 2023
See [what's new in OAS 2023](#).
- Microsoft Windows 2022 server (64-bit)
- Microsoft Visual C++ 2015 to 2022 Redistributable x64
- Microsoft Edge (Chromium based) version 116.0.1938.54 (64-bit)
- Google Chrome version 116.0.5845.97 (64-bit)
- Axway 2.6 UP2023-07
- Documentum 22.1
- IDCS 22.2.61
- IP Works 22.0.8318
- PDF Library 10.0.1
- Right Fax 22.4
- Aspose Cells, Words, PDF 22.10.0

See:

- [Dictionary support](#)

Dictionary support

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

Dictionary	Supported versions
MedDRA Dictionary	26.0 (March 2023) 25.0 (March 2022), 25.1 (September 2022) 24.0 (April 2021), 24.1 (September 2021)
WHO Drug Dictionary (Format: B3 and C3, both English and Chinese)	March 2023 March 2022, September 2022 March 2021, September 2021
J Drug Dictionary	April 2023 April 2022, October 2022 April 2021, October 2021
JFMDA Dictionary	5.0 4.0

Oracle Argus Compatibility Matrix

Application	Compatible Version with this Argus Safety Release
Oracle Argus Analytics	8.4.1
Oracle Argus Insight	8.4.1
Oracle Argus Mart	8.4.1
Oracle Life Sciences Empirica Signal and Oracle Life Sciences Empirica Topics	9.2.2.1

Enhancements to Oracle Argus Safety

The following are the enhancements to Oracle Argus Safety:

- [Regroup system numbering](#)
- [Interoperability with Oracle Safety One Intake](#)
- [Document Management System support](#)
- [Translation capabilities](#)
- [Multilingual dialog enhancements](#)
- [EMA regulation and business rule updates](#)
- [Listedness assessment based on onset date for SUSARs](#)
- [Non-company drug causality assessment for clinical trial cases](#)
- [FDA eMDR regulation updates](#)
- [Selection of countries without ISO A2 codes in user group](#)
- [Former US territories listed in US_STATES code list](#)
- [IMDRF/FDA codes updates - 2022](#)
- [E2B \(R3\) batch export](#)
- [Allow users to specify due date in batch E2B submission](#)

- [Event term to appear instead of internal code in Decoded View](#)
- [Support of null flavor ASKU and NASK values](#)
- [Japan PSR-NUPR updates](#)
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- [SSO re-authentication using OpenID Connect changes](#)
- [Enable application managed idle timeout](#)
- [Oracle Argus re-skinning](#)
- [MedDRA recode log header changes](#)

Regroup system numbering

Summary

Regroup the System Numbering menus

Description

The Case System Numbering and LAM System Numbering menus are grouped under a new menu called System Numbering under System Configuration.

Previously, one audit log category for System Numbering was rendering audits on both Case System Numbering and LAM System Numbering. Now, the audit log categories are segregated for each, allowing to render of audit results for the selected system numbering (either/both).

Interoperability with Oracle Safety One Intake

Summary

Interoperability with Oracle Safety One Intake

Description

Oracle Argus Safety 8.4.1 enables the advanced intake feature through integration with Oracle Safety One Intake. Oracle Safety One Intake is designed to accept the Adverse Event (AE) reports in various file types through UI or API uploads.

It enables you to configure these uploads for identification of the ingested reports. The system uses Optical Character Recognition (OCR) and Artificial Intelligence (AI) predictions on reports that are in PDF, DOC, DOCX, and XML file types to extract information from the reports and automatically process them. It also includes features for manual rectification of extracted attributes when there are processing issues, a monitoring feature for ingested AE reports, and the ability to publish the reports to Oracle Argus Safety where they are converted into cases.

New User Roles in Oracle Argus Safety Console

To access the Oracle Safety One Intake UI, the following roles are introduced in Oracle Argus Safety Console:

1. Intake Processor
2. Intake Designer

Note:

These roles have no significance in Oracle Argus Safety. For more information, see the Oracle Safety One Intake release notes.

New Enabled Module

A new option, Intake, is introduced in the Enabled Modules. For more information, see the *Oracle Safety One Intake release notes*.

New System Numbering in Oracle Argus Safety Console

For the documents uploaded in Oracle Safety One Intake, a unique identifier is assigned. To define the format of this unique identifier a new screen: Intake System Numbering is introduced, which is accessible from `Argus Console > System Configuration > System Numbering > Intake`. For more information, see the *Oracle Safety One Intake release notes*.

New Interchange profile

The Structured and non-structured documents (pdf, docx, txt, etc.) uploaded in Oracle Safety One Intake are processed and converted into E2B R3+ messages (XML) and published to Oracle Argus Safety via REST API. To decode this E2B R3+ message, a new profile: SAFETY ONE ARGUS E2B R3+ TEMPLATE is introduced. This template is activated only when you opt for Oracle Safety One Intake. For more information, see the *Oracle Safety One Intake release notes*.

Note:

The structured documents (E2B (R2) and E2B (R3)) uploaded in Safety One Intake are processed and published to Oracle Argus Safety with their original tags intact. Such structured documents are decoded in Oracle Argus Safety based on the sender and receiver configuration and interchange profile mapping set in the reporting destination code list.

Document Management System support

Summary

Argus Bridge supports Document Management System integration with Argus via API (Enhancements 35332554 and 21548860)

Description

Argus supports Documentum version 22.1 and all use cases supported by Argus Safety also work with Documentum V.22.1. A new section titled **Bridge Configuration**

is added to Console > System Configuration > Webservice. This menu is visible only if you belong to groups with access set to **Enabled** on the Webservice screen in Console > Access Management > Argus > Groups > Menus > Webservice. In addition, the following updates have also been made:

- The Service Settings option has been moved from the Document Management screen to Service Settings;
- A new common profile switch has been added;
- A new Argus Bridge schema has been added.

The Bridge Configuration section contains parameters used to configure the below details for integration with any document management system:

Serviced Assembly section

Parameter name	Description
Service	The options available are document and translation. Select the Document option to configure the document management system.
Class name	The DLL name.
Assembly File	The actual DLL file created for the document management system.
Configuration JSON File	Upload the JSON file. A sample JSON file is provided in the <i>Argus Administration Guide</i> . The following placeholders should be replaced with your required values: {SERVER_URL}, {SERVER_PORT}, {THIRD_PARTY_REPO}, {USERNAME}, {PASSWORD}, {CABINET_ID}.
Service status	This parameter can be set as: <ul style="list-style-type: none"> • Not configured • Configured • Argus Safety API Load Balancer URL is not configured



Note:

These settings are at global level and not enterprise specific.

Service Settings update

The Settings section is moved from Console > System Configuration > Common Profile Switches > Document Management to Console > System Configuration > Webservice > Bridge Configuration.

The following settings are now available:

- The common profile switch label Enable storage of case attachment files in Document Repository and additionally the searching and attaching files already existing in Document Repository to a case is split into two separate parameters, as listed below:
 - Enable searching and attaching files already existing in External Storage to a case parameter. The available settings are **Yes** and **No**.

- Enable storage of case attachment files parameter. The available settings are **Argus** and **External Storage**.
- Enable Storage of ICSR reports in Document Repository option is renamed as Enable storage of ICSR reports. The available settings are **Argus** and **External Storage**.
- Enable storage of submitted periodic reports in Document Repository option is renamed as Enable storage of submitted periodic reports. The available settings are **Argus** and **External Storage**.
- Enable storage of submitted expedited reports in Document Repository option is renamed as Enable storage of submitted expedited reports. The available settings are **Argus** and **External Storage**.

 **Note:**

These settings are at enterprise level.

New common profile switch

A new common profile switch has been added in `Console > System Configuration > Common Profile Switches > Network Settings > Argus Safety API Load Balancer URL`.

 **Note:**

This profile switch is available in the default enterprise. It is set at the global level and not specific to the enterprise.

If a Load Balancer setup exists, then provide the Load Balancer URL. Otherwise, you should provide the web server URL.

New Argus Bridge schema

A new schema entitled *ARGUS_BRIDGE* has been added to manage bridge configurations and to store the BLOB file attachments. Storage of case attachments and of reports is managed thus:

- When the **Enable storage of case attachment files** parameter is set to **Argus**, the data is stored only in Argus Bridge for new attachments in legacy cases or for new cases. This is available for the following tables: *CASE_NOTES_ATTACH*, *CASE_NOTES_E2B_ATTACH*, *LAM_NOTES_ATTACHMENT*.

 **Note:**

For existing attachments of legacy cases, the attachments would continue to be stored in the *CASE%* tables. Due to this framework, the size of *ARGUS_APP* is expected to decrease gradually because large sized attachments are now stored in the *ARGUS_BRIDGE* schema.

- When the **Enable storage of case attachment files** parameter is set to **External Storage** for the *CASE_NOTES_ATTACH*, *CASE_NOTES_E2B_ATTACH*,

LAM_NOTES_ATTACHMENT tables, the data is stored only in the Document management system.

In the exceptional cases where the application is unable to send the file to the document management system, then Argus temporarily stores the actual file in *ARGUS_BRIDGE*. The application would retry to move the attachment from Argus Bridge to the document management system based on the *SERVICE.PROFILE.MAX_RETRY_COUNT* table. The default retry value is three times. If the application retries as per the *MAX_RETRY_COUNT* table and it is not able to push the attachment to document management system, then the attachment is retained in *ARGUS_BRIDGE*.

The *SERVICE_PROFILE.MAX_RETRY_COUNT_REFRESH_INTERVAL* table is used to evaluate the frequency of trying to move the attachment. The default value is set to eight hours.

- When the parameter for ICSR/Expedited/Periodic reports is set to **Argus**, the data is stored only in *CMN_REG_REPORTS*.
- When the parameter for ICSR/Expedited/Periodic reports is set to **External Storage**, the data is stored in *CMN_REG_REPORTS* due to regulatory needs and also in the document management system.

 **Note:**

The reference is still maintained in *ARGUS_BRIDGE*.

For exceptional scenarios, the application follows the same method as storage of case attachment files.

A migration script is executed while upgrading to 8.4.1. This migration script is to ensure that files stored in Documentum prior to the Argus 8.4.1 upgrade are synced up with *ARGUS_BRIDGE*.

Translation capabilities

Summary

Support for Integration with Translation Services to translate text in the multilingual dialog supported fields

Description

Oracle Argus Safety is enhanced to support integration with the OCI translation service along with the other 3rd party translation services to translate the text from English to non-English and vice-versa for the Multilingual dialog fields. The following enhancements have been made to achieve this:

- Argus Console changes
 - For integration with translation services from different vendors, the translation adapter can be configured from Console > System Configuration > Webservice > Bridge Configuration > Service Assembly section after selecting **Translation** in the Service drop-down.
 - New enterprise-level switch, Enable Translation Service, is added under the Bridge Configuration > Service Settings section to enable or disable the translation feature.

 **Note:**

This switch appears when you select Translation in the Service drop-down.

- Code list changes
 - A new `Trans_Lang_Code` attribute is added to the Language Code list that can be accessed from `Console > Flexible Data Re-categorization > Flexible Re-categorization > Languages`.
 - This attribute contains the language codes to be used by the translation service.
 - Language codes for the OCI translation service are added to this attribute as part of the factory data. However, if you are using any other translation service, then you can update these codes to match with the codes supported by the translation service provider.
- Multilingual dialog changes
 - If translation is enabled, then the Translate button appears in all the multilingual dialog supported fields to translate text from English to non-English and vice-versa.
 - This option is available to Oracle Argus Safety Japan users as well in the multilingual dialog to translate text from English to Japanese.
 - For Japanese to English translation, Oracle Argus Safety Japan users can use the English version of the multilingual dialog from the split screen view.

 **Note:**

See the next section for more enhancements on the multilingual dialog irrespective of the translation capabilities.

Multilingual dialog enhancements

Summary

Multilingual dialog enhancements for easier review

Description

The multilingual dialog user interface has been enhanced for easier review for global as well as Japanese users as follows:

- Global Multilingual Dialog Box
 - The layout has been changed such that the English and other language text boxes now appear adjacent to each other.
 - English flag and foreign language icons are removed.
 - Global users can now view Japanese text by selecting the Japanese option from the language drop-down.
 - Japanese data entry is enabled for the global user for the following fields:

- * Abbreviated Narrative
- * Case Comment
- * Company Comment
- * Evaluation in light of similar events in the past
- * Narrative
- Inclusion of Translate button (only when translation is enabled) for translation from English to Non-English and vice-versa.
- Japanese Multilingual Dialog box
 - The layout has been changed such that the Japanese and other language text boxes (including English) appear adjacent to each other.
 - English flag, Japanese flag, and foreign language icons are removed.
 - Inclusion of Translate button (only when translation is enabled) for translation from English to Japanese.

EMA regulation and business rule updates

Summary

EMA regulation and business rule updates

Description

EU ICSR IG rev 2 business rule updates

E2B(R3) profile has been enhanced for post marketing and clinical ICSRs as per the business rules published by EU ICSR IG Business Rules and EV Human Business Rules.

- The business rules for date and time states that No date/time value should exceed the current CET time plus 12 hours. Failure of the validation of the date format generates an error. Conformance rules in Oracle Argus, validates the dates based on UK GMT, and hence to comply with the business rules, all date-time validations in the EMA(R3) profile have been modified from UK GMT to CET.
- As per the latest EU Clinical Trial Regulation, released on 31-Jan-2022, the Study Registration Number[C.5.1.r.1] must have a valid EudraCT number or unique EU trial number [Format: YYYY-5NNNNNXX- VV] when the data element Study Registration Country (ICH E2B(R3) C.5.1.r.2) contains the value EU.

Oracle Argus Safety enables you to add the EU trial number in the study configuration.

Export mappings are updated to enable transmitting EU Trial number in the STUDYREGNUMB[C.5.1.r.1] element, and conformance rules are provided to validate data present in the STUDYREGNUMB[C.5.1.r.1] element for the correct format.

DRUGDOSAGETEXT[G.k.4.r.8] for vaccines mapping change as per the EMA guidelines (Enhancement 34451821)

In Oracle Argus, DRUGDOSAGETEXT[G.k.4.r.8] was populated with the concatenation of dose and dose units separated by a space for vaccine products. As per the regulatory requirement from EMA, details of the dose that resulted in the adverse reaction are required in the DRUGDOSAGETEXT[G.k.4.r.8] element.

Export mappings for DRUGDOSAGETEXT[G.k.4.r.8] in EMA E2B(R3) profile has been updated to send free text present in dose description instead of dose and dose units information. Drug and drug-device combination products work on the similar logic.

DRUGSTARTPERIOD[G.k.9.i.3.1a] to not populate for event without onset latency information (Bug 34766412)

In Oracle Argus, the DRUGSTARTPERIOD[G.k.9.i.3.1a] and DRUGSTARTPERIODUNIT[G.k.9.i.3.1ab] elements were mapped to onset from the first dose and onset from the last dose respectively in the product event details. In the absence of data in these fields, the data was being populated from the corresponding fields present at the product level. Deriving the data from product level is not compliant with the EMA regulations.

Hence, the DRUGSTARTPERIOD [G.k.9.i.3.1a] and DRUGSTARTPERIODUNIT[G.k.9.i.3.1ab] elements have been directly mapped to the fields in product event details.

Negative ACK received from EMA due to negative value in E2B(R3) field TESTRESULT[F.r.3.2] (Bug 33752952)

EMA does not accept negative values in the TESTRESULT[F.r.3.2] element, but there may be test results that have negative values. The export mapping logic for the TESTRESULT[F.r.3.2] element has been modified to populate negative values in the TESTRESULTTEXT[F.r.3.4] element with the label: Test Result.

Code system version for OID (Enhancement 28955562)

The HL7 view of E2B(R3) EMA, MFDS, and NMPA reports displayed `codeSystemVersion=1.0` for `codeSystem=2.16.840.1.113883.3.989.2.1.1.23` associated with:

- REPORTTYPE[C.1.3]
- DUPLICATER3[C.1.9]
- NULLIFICATIONREASON[C.1.11.2]

The `codesystemversion` has been changed to `2.0` as per the regulation.

DRUGSTRUCTUREDOSAGENUMB[G.k.4.r.1a] tag to transmit individual dosage (Enhancement 33563052)

The DRUGSTRUCTUREDOSAGENUMB [G.k.4.r.1a] element in EMA E2B(R3) populated the product of dosage regimen dose and frequency. As per the EMA guidelines, each individual dosage must be transmitted independent of the frequency. The export mappings has been modified to transmit only the dosage data.

Allow tradename to be selected for non-interventional study products (Enhancement 20270050)

As per the EMA regulation, for non-interventional studies, the MEDICINALPRODUCT[G.K.2.2/ B.4.k.2.1] element must have trade name of the product. The E2B(R3) and E2B(R2) export mappings for the EMA profile have been revised to transmit trade name in the MEDICINALPRODUCT[G.K.2.2/ B.4.k.2.1] element, derived based on the license for which the report is scheduled. If there are multiple study products in the case, then the trade name for other products are derived based on the license that matches the agency country for which the report is scheduled.

Error when viewing ICSR in the decoded view with date formats CCYYMMDDhhmm+/-ZZzz (Enhancement 33982604)

The decoded view displayed `500 Internal Server`, if the dates present in ICSR were in the `CCYYMMDDhhmm[+/-ZZzz]` and `CCYYMMDDhhmm[+/-ZZ]` format. Oracle Argus has been enhanced to support these date formats during E2B(R3) import along with the existing formats.

For more information, refer to the following eTRM documents:

- *ArgusInterchange841_E2B(R2) Export Mappings.xlsx*
- *ArgusInterchange841_E2B(R3) Export Mappings.xlsx*
- *ArgusInterchange841_E2B(R3) Import Mappings.xlsx*
- *Argus_Safety8.4.1_CaseForm_Console_Updates_Summary.xlsx*

Listedness assessment based on onset date for SUSARs

Summary

Listedness assessment based onset date for SUSARs (Enhancement 33313288 and 31830885)

Description

As per EU clinical trials directive, expectedness assessments for SUSARs are required to be performed using the version of IB/RSI approved for the study, at the time of occurrence (event onset date) of the suspected SAR.

The following changes have been made in the application based on customer feedback on datasheet configuration and EU clinical trial regulations:

Datasheet configuration changes:

- The revision number is now visible in the Datasheet Configuration screen and the ability to capture the revision name of the datasheet, enables business users to view user-friendly information when reviewing case event assessment data.
- The ability to create datasheet revisions is provided without needing to add preferred terms to the datasheet.
- The datasheet revisions dialog is revised to view the revision and its corresponding terms in separate tables for better readability.
- The header rows within the datasheet preferred terms are now frozen when the user scrolls through the terms (Enhancement 26281827).

Study configuration changes:

- For all company study products, an option is provided to fix a datasheet revision for which event assessment can be performed.

 **Caution:**

Oracle recommends not to configure datasheet revisions for open labeled study products within blinded studies, as these products are treated as non-study products in the case form.

- A new dialog is invoked for company products that have active datasheets and users can select one datasheet revision for multiple tradenames associated with the product.

Case form changes:

- The Case Event Assessment screen is enhanced to display the revision name and allow you to hide or unhide the datasheet revision details along with License using expand and collapse button (Enh 31830885).
- Datasheet name is appears as link. On click of this link, the datasheet revision number, name, activation date, and event terms pertaining to the latest datasheet revision are displayed.
- Datasheet revision and Activation dates appears as a link. On click of these links, the datasheet revision number, name, activation date, and event terms pertaining to the datasheet revision that was used for assessment are displayed.
- The above mentioned user interface changes are made in the Local Labeling and Medical Review screens.
- Event assessment for clinical trial cases is done considering the datasheet revision configured in the study and the onset date of the event.
- Upgrade consideration—For the study cases that were created prior to upgrade, if the event assessment is required to be done based on specific datasheet revision, then the following are required:
 - The company products within study configuration must be configured with datasheet revision.
 - Business users must use the **Re-calculate** option in the Event Assessment screen to use appropriate datasheet revision instead of using latest datasheet revision.
- The existing logic of using the latest datasheet revision is used in the following scenario:
 - All products in study cases where the datasheet revisions are not configured.
 - All products in non-study cases and non-company study cases.
 - non-company products and non-study products within study cases where the datasheet revisions are configured.

Non-company drug causality assessment for clinical trial cases

Summary

Causality assessment for non-study non-company products in study cases.

Description

For clinical study cases, some agencies require the E2B reports to have a causality assessment for all suspect products including non-company products that are not part of the study configuration. Suspect non-company products can be a WHO Drug Product, J Drug, or Non-Company product manually added in the case form. Argus is enhanced to support capturing the causality assessment for non-company and non-study products.

Causality data is sent to agencies based on the configuration option provided in the EDI tab in Reporting Destination.

Case form update in study cases

- You can capture causality data for all non-company non-study drugs in the `Events > Event Assessment` tab and in the `Medical Review > Event Assessment` tab. The non-company study drugs are displayed in the Event Assessment screen, as per the existing functionality to capture causality for both WHO drug and J drug.
- License and datasheet details appear blank for the non-company non-study drugs.
- You can capture data in the `Events > Product-Event Details` tab for the non-company products (study/non-study).
- The case level causality is computed based on the study products only irrespective of the company or non-company product.

Note:

Listedness field is not available for the non-company non-study drugs.

Console updates

- A new check box **Transmit Non-Company product Causality for study cases** is added to the `Argus Console > Code Lists > Argus > Reporting Destination > EDI` tab.
- The marking of this checkbox determines if the causality assessment and latency data captured for the non-company non-study product is required to be transmitted to the agency.
- This checkbox does not affect the import functionality, i.e. the causality assessment data is imported to the case irrespective of this parameter setting.
- Case-level causality parameters in the expedited reporting rules do not consider causality data entered for non-company non-study drugs.

Reporting updates

- All E2B(R2) and E2B(R3) report mappings are enhanced to transmit the causality and latency data for the non-company non-study drugs based on the **Transmit Non-Company product Causality for study cases** switch at the agency level.
- Conformance rules for causality elements in the E2B(R3) report are revised to consider the **Transmit Non-Company product Causality for study cases** switch.

- Import mapping logic for all profiles is enhanced to consider the causality for the non-company products.
- There is no impact on the periodic reports due to causality data entered in non-company non-study products.

Update consideration

- In the study cases that were created prior to upgrade, any non-study, non-company product added will appear in the Event Assessment screen with blank causality assessment and must be updated manually.
- The new **Transmit Non-Company product Causality for study cases** agency level checkbox is unchecked by default for the existing agencies configured in the system prior to upgrade.

For more details refer to the following mapping documents:

- *ArgusInterchange841_E2B (R2) 2.1 Export Mappings.xlsx*
- *ArgusInterchange841_E2B (R2) 2.2 Export Mappings.xlsx*
- *ArgusInterchange841_E2B (R2) Import Mappings.xlsx*
- *ArgusInterchange841_E2B (R3) Export Mappings.xlsx*
- *ArgusInterchange841_PMDA E2B (R3) Export Import Mappings.xlsx*
- *ArgusInterchange841_E2B (R3) Import Mappings.xlsx*

FDA eMDR regulation updates

Summary

FDA eMDR enhancements 2022 (Enhancement 34749011)

Description

CDRH has published revised guidance for eMDR in August 2022, which is effective from March 2023.

The following changes have been made in the application based on the regulation updates:

- The size of the FDA Exemption number field in `Case Form > Product Information > Device information` is increased from 7 to 10.
- The country name for MACEDONIA, THE FORMER YUGOSLAV REPUBLIC OF within the Country code list is changed to NORTH MACEDONIA as per the ISO specification.
- The data length of the element EXEMPTIONNO is extended from 7 to 10 in eMDR profile.
- The DESCRIPTION DESCRIPTION_J data in CFG_M2 for the following elements in eMDR profile is changed from MACEDONIA, THE FORMER YUGOSLAV REPUBLIC OF to MACEDONIA as per GENC3 standards that is applicable for eMDR report.
 - FMFRCOUNTRY[F14]
 - MFRCONTACTCOUNTRYCODE[G1]

- MFRCOUNTRY[D3]
- REPORTERCOUNTRYR3[E1]
- The data element number for UFCONTACTEMAIL is changed from [F3] to [F4].
- The following new validations are provided in the eMDR profile:
 - UFCONTACTEMAIL[F4]
 - MFRCONTACTEMAILADDRESS [G1]
 - FDAPATIENTCODES [F10 Part 1]
 - FDADEVICECODES [F10 Part 2]
 - MFRPATIENTCODE[H6]
 - MFRDEVICECODE[H6]
- The validation on the TYPEOFDEVICENAME[D2] element is removed from the eMDR profile.
- The validation for the TYPEOFREPORTABLEEVENT[H1] element is revised to be applicable only for the initial report (Enhancement 29681544).

Selection of countries without ISO A2 codes in user group

Summary

Unable to select country KOSOVO (Country ID 273) in `User Groups > Listedness Determination` (Enhancement 34311494)

Description

In prior releases, the countries with an ISO A2 code were displayed in the `Listedness Determination Countries` field of the `User Group Configuration` screen. There are a few values in the `Countries` code list that does not have ISO A2 code but have GENC3 codes and listedness assessment could not be made for these countries.

The system has been updated to list the countries in the `Listedness Determination Countries` field that has either ISO A2 code or GENC3 codes.

Former US territories listed in US_STATES code list

Summary

Former U.S. Territories listed in `US_STATES` code list (Enhancement 33817061)

Description

The `US_STATES` flexible code list has the list of states that belong to the United States of America.

The following values which are no longer part of the US territory have been deleted from the `US_STATES` flexible code list:

- Marshall Islands
- Federated States of Micronesia
- Palau

IMDRF/FDA codes updates - 2022

Summary

Updates to CFG_FDA_IMDRF_CODES and allowed value repository based on the new Annexures released by IMDRF and FDA (Enhancement 34794391)

Description

The CFG_FDA_IMDRF_CODES repository has been enhanced to include the IMDRF maintenance updates released on March 2022:

Annex A

Added terms: A0105, A0106, A020603, A050406, A050407, A050705, A050901, A090814, A210106

Modified terms: A020601, A0504, A050401, A050402, A110201, A2302

Annex B

Added term: B24

Modified term: B05

Annex C

Added terms: C1010, C1011

Annex D

Added terms: D1108, D19

Annex E

Added terms: E012208, E012209, E0140, E0141, E0142, E0143, E014301, E014302, E0207, E0208, E0311, E0312, E0313, E050102, E0519, E0753, E083804, E083903, E0845, E0846, E0847, E0848, E0849, E0850, E0851, E0852, E0853, E0907, E0908, E090801, E090802, E0909, E0910, E1034, E1035, E1108, E1109, E120203, E120204, E120205, E120206, E120207, E120208, E120209, E1418, E1520, E1636, E1637, E1638, E1639, E1640, E1641, E171602, E171603, E1724, E1725, E1726, E1805, E2121, E2122, E2123, E2205, E2206, E2207, E233802

Modified terms: E0309, E0506, E2337, E082901, E1025, E120501, E1618, E1621, E1625, E180102, E2103

Annex F

Added terms: F1006, F1007

Annex G

Added term: G07003

The Allowed Value repository (CFG_M2 table) for eVAERS and FDA 2.2 DTD profile has been updated. For details on the new and updated values in CFG_FDA_IMDRF_CODES and CFG_M2 tables, see *Argus_Safety8.4.1_CaseForm_Console_Updates_Summary.xlsx*.

E2B (R3) batch export

Summary

Allow multiple E2B (R3) reports in a single transmission file (Enhancement 29719798)

Description

Batch export has been enabled for E2B (R3) reports: ICH, EMA, PMDA, MFDS, and NMPA. To configure the maximum number of ICSRs to be included in a single XML file, use `Console > Reporting destination > EDI > Maximum # of reports to include` in the `msg` parameter.

When multiple E2B (R3) reports are selected for manual or auto transmit, system checks the **Maximum # of reports to include in the msg** value and automatically creates the XML with multiple ICSRs based on this parameter value. While creating this batch file, the parameters `Console > Reporting destination > EDI > Allowed report size (in MB)` and `Allowed attachment file size per attachment (in MB)` are respected.



Note:

Different report types, like initial, follow-up, amendments, and others are clubbed in separate batch files for processing.

The application already supports the import of batch ICSR, creation of batch ACK, and import of batch ACK for E2B (R3) profiles.

To enable searching for the E2B (R3) reports included in a single XML file, new field **Local Message #** has been added as a search criteria in the `Worklist > Bulk ICSR Transmit > Reports` screen.

Allow users to specify due date in batch E2B submission

Summary

Batch E2B submission to allow the user to specify the due date (Enhancement 27031907)

Description

Oracle Argus Safety allows users to schedule reports in bulk for a set of cases from the `Case Actions > Case Open` dialog, **Batch** button.

A new section, **Due Date**, has been added to this screen. This screen enables you to select the parameters for report due date calculation whenever the **Save with case, mark as Submitted** is selected for final reports.

Event term to appear instead of internal code in Decoded View

Summary

E2B (R3) decoded view update for Reaction(s)/Event(s) Assessed field (Enhancement 27674227)

Description

For EVENTUNIVERSALLYUNIQUEID[G.k.9.i.1] Reaction(s) / Event(s) Assessedelement, the E2B (R3) reports decoded view displays the event term within brackets, like the event term being displayed within brackets for REACTIONMEDDRALLT[E.i.2.1b] Reaction / Event (MedDRA code) . When an Oracle Argus Safety Japan user opens the decoded view from the J split screen, the Japanese term is displayed.

Support of null flavor ASKU and NASK values

Summary

Null flavor ASKU and NASK values to be supported for Gender[D.5] and Parent Gender[D.10.6] for ICH, MFDS, and NMPA profiles (Enhancement 33655830)

Description

For ICH, MFDS, and NMPA profiles, the null flavors MSK, UNK, ASKU, and NASK are now supported for the Patient Gender[D.5] and Parent Gender[D.10.6] elements. For more details, see *E2B(R3) mapping document*.

Japan PSR-NUPR updates

Summary

Japan PSR-NUPR form Remark column updates (Enhancement 34083743)

Description

Improved print options have been added for the Remark column data from the Japan PSR-NUPR report.

In the case listing table which is used for internal reviews, populate the Remark column with all available data for trade name, formulation, strength and drug code. That is, populate the column as per the **Product details printing format in the P S R NUPR - Word format** profile switch, when set to Option 1 - Print Trade Name, Formulation, Strength, Drug code as available.

When profile switch is set to **Print Trade Name unknown when Formulation or Strength not available**,

- Print the data for Japanese marketed licenses in the format - *Trade Name (J)* (Drug Code (J)).
- For any of the following conditions, print the data as 販売名不明 (Drug Code (J)).
 - If Trade Name (J) includes 不明
 - If either Strength or Unit has no value
 - If Formulation value is blank or set to “不明” (Unknown)
 - If Strength and Unit has no value and Formulation is blank /不明

Seiyakukyo Line Listing report updates

Summary

Seiyakukyo Line Listing Report updates

Description

Updates to the report configuration

Seiyakukyo Line Listing (SLL) report, also called JPMA (Japan Pharmaceutical Manufacturers Association) report is enhanced to generate based on the study product along with the existing functionality of generating based on the clinical compound number. The report configuration lists the available study products - auto-populated with Study ID, and Product Name of all products configured in the `Console > Study Configuration` from all study arms including the WHO drugs and J drugs. You can select any study product to generate the SLL report.

In the **Regular (Clinical) and Domestic Study Cases** section of the line listing report, the cases are included based on submitted expedited or E2B reports that have Sponsor Study Number[C.5.3] (a comparison made only if C.5.3 element is populated in the E2B report) and Drug block[G.k] with Medicinal Product Name[G.k.2.2] that matches with the selected study product in the SLL configuration.

In the **Foreign Ichihen Study Cases** section of the line listing report, the cases are included based on cases that have study and study product that matches with the selected study product in the SLL configuration.

Updates to the report output

- A new column **Product Name** is printed.
- The following fields are available for user selection for inclusion in the SLL report when generated in CSV format:
 - Initial Receipt Date (J)
 - Aware date
 - Other References
 - Patient ID
 - Indication PT Term
 - Description as Reported
 - Seriousness Criteria
 - LLT Code
 - PT Code
 - SOC Code
- A new summary table is printed with a list of unlisted and serious adverse events as per the prescribed format by JPMA. Printing of this summary table is optional and is configurable.
Refer to the *Japanese Seiyakukyo Line Listing Report mapping document* for details.

Interchange service configuration enhancements

Summary

Interchange service configuration enhancements

Description

Interchange service configuration

Service Configuration option is provided in `Argus Console > System Configuration > Interchange`. You can access this menu option only when you have permissions to the ESM admin user role. Client-server based ESM Configuration Tool that was used to configure Oracle Argus Interchange server has been de-supported and removed from the installer.

Deployment of Oracle Argus Interchange servers on multiple machines connecting to the same database is being supported in the release. The configuration made in the Service Configuration screen is used by all the Oracle Argus Interchange servers connected to the same database.

Database name is captured as an attribute in the `Argus.ini` file during fresh installation and upgrade of the Interchange server. Interchange servers installed on multiple machines can process transmit and receive requests. Administrator can adjust the permissions of transmit or receive requests to be active on specific Interchange servers. You must restart the Interchange server for these configuration updates to take effect.

Log file path of the Oracle Argus Interchange service is not provided for Interchange Service Configuration. The Interchange Service activities are logged in the `ESM_OWNER.INTERCHANGE_ACTIVITY_LOGS` table, instead of the physical log files. Contents of the log table can be periodically purged. Enablement of the purge feature for `INTERCHANGE_ACTIVITY_LOGS` table, frequency of purge, number of records to be purged are controlled through the `ARGUS_APP.CFG_ARGUS_TABLE_PURGE` table.

Interchange service support for multiple databases has been removed. It is now required to have separate deployments of the Oracle Argus Interchange server for individual databases, such as test, validation, and production database.

Refer to *Oracle Argus Interchange User's Guide* for details on the following concepts :

- Parameters provided in Interchange service configuration.
- Parameters that were present in ESM configuration tool but are deprecated in the Web based option.

Changes to AG Services

- Log file path parameter in AG services has been removed from the AG service configuration.
- Log file path is set at the time of installation and configuration is stored in `Argus.ini` file.

Auto Accept E2B Reports

Summary

Enhancements to ICSR Accept process in Oracle Argus Safety

Description

Improved performance of the Accept process

The **Auto Accept E2B Reports** AG process is single threaded. When Argus Interchange Service processes large load [E2B Import from IN folder], the AG service process becomes a bottleneck on completing auto case accept.

Argus safety has been enhanced to allow configuring multiple **Auto Accept E2B Reports** AG process, in-order to improve performance of the Accept process.

- Argus administrators can configure multiple **Auto Accept E2B Reports** AG process using a unique Argus Service user and task **Auto Accept E2B Reports**.
- You can enable or disable the individual process as per the current configuration functionality.
- By default, two Auto Accept AG process are configured as part of the OOTB factory data using the unique Argus Service user.
 - First, the existing process **Auto Accept E2B Reports** has been renamed as **Auto Accept E2B Reports 1**. AG Service Username: AG Auto Accept E2B 1, and UserID : oagsvc_auto_acpt_e2b_1 are automatically created and associated.
 - Second, a new AG Service process has been added as **Auto Accept E2B Reports 2**, while the UserID: **oagsvc_auto_acpt_e2b_2** is automatically created and associated with this new AG service.

Note:

If you upgrade, but restore your older Argus Service .ini file, then this new process will not be available, but can be configured, if necessary.

Manual Accept processed by the background service

Processing of the ICSR reports is enhanced such that you no longer need to wait for the accept process to complete a report before accepting the next report.

In the ICSR Pending screen, the following actions are queued and handled by the background AG Service **Auto Accept E2B Reports** for processing:

- Initial, follow-up, and nullification reports that are manually accepted via the context menu
- Bulk Accept ICSR
- Duplicate Search
- Selective acceptance
- Difference report

- When you click the **Accept ICSR** for a single or multiple reports, the reports are automatically pushed to the background services for case creation. Status of the report is depicted by icons when processing. Click on the icons to view status details and errors, if any.
- When the report is accepted and the case is created, the report moves to the processed screen.
The user information who accepted the report is captured in the ICSR Processed screen, Routing Comments, and Audit Log of the case. For manually accepted reports, the user name of the user appears, and for auto-accepted reports, the user name appears as System.
- You can manually accept the reports that failed due to errors.
- The **Auto Accept E2B Reports 1** and **Auto Accept E2B Reports 2** AG Services (and others, if configured) run in parallel and handle all reports acceptance that come from auto accept as well as manual accept. The reports in AG Service queue is processed in first-in-first-out order.
- The number of reports being processed for a single cycle for a single AG process configured are determined by the new global profile switch: **Number of reports to be processed by a single Auto Accept AG Process**. You can access this profile switch from Argus Console > Common Profile Switch > Background Services.
 - Default value of this profile switch is 10, and allows value from 1-999.
 - When you enter zero, any non-numeric value, or negative value, appropriate error message appears.
- New filters are added in the ICSR Pending screen as:
 - Queue Status (キューステータス)—Allows the user to filter reports based on the status.
 - Message/Batch Number (メッセージ / バッチ番号)—Facilitates the user to retrieve reports belonging to the same batch number during bulk import. If no value is selected, all batch numbers are selected.

Enabled re-try to accept reports

The **Auto Accept E2B Reports** AG process did not re-try a request, if it failed due to some business validation. Users were forced to accept such reports manually.

A new common profile, **Number of retries to be done for an unsuccessful report to be picked for reprocessing by Auto Accept AG Process**, has been added under Argus Console > Common Profile Switch > Background Services, to set number of times a report re-tries auto accept process before marking them as failed. Default value of this profile switch is 3, and allows value from 1-999.

The time interval for re-processing is determined by another new profile switch, below new profile switch **Number of minutes to wait for a unsuccessful report to be picked for reprocessing by Auto Accept AG Process**, under Argus Console > Common Profile Switch > Background Services. Default value of this profile switch is 60, and allows value from 1-999.

For these profile switched, if you enter zero, any non-numeric value, or negative value, appropriate error message appears.

Import failed ICSR

Currently, when Oracle Argus Interchange import of an E2B report fails, the failed E2B report or acknowledgement file does not appear in the ICSR Pending screen, and is archived and logged in the Interchange import log.

These report may go unnoticed and without a trace. To address this issue, a new screen **ICSR Failed Imports** accessible from `Utilities > ICSR > ICSR Failed Imports` has been added to display the list of failed reports.

You can download these failed files for review from this screen. To view details of the failure, an error link is provided.

This screen is available to the users with access to the **ICSR Failed Imports** menu. The screen is dependent on the enterprise that the user has logged in, and displays the reports that belong to the same enterprise only.

This screen is available to Oracle Argus Safety Japan users as well.

Updates to views on flexible code list tables

Summary

Context based LM tables in mapping (Enhancement 33470471)

Description

Queries pertaining to the views based on flexible code list had context setting depending on the agency, such as, NMPA and MFDS to pick up the appropriate attribute for the corresponding E2B(R3) report generation. These queries required updates for newer profiles to be include the corresponding attributes.

The following View queries have been enhanced to make them independent of the agency:

View Name	Impacted Area
V\$LM_CASE_CLASSIFICATION	<ul style="list-style-type: none"> • All E2B(R3) Profiles - ICH, EMA, PMDA, MFDS, NMPA, and eVAERS <ul style="list-style-type: none"> – OBSERVESTUDYTYPE[C.5.4] • All E2B(R2) Profiles - ICH, EMA, FDA (2.1/2.2), and PMDA <ul style="list-style-type: none"> – OBSERVESTUDYTYPE[A.2.3.3] • NMPA E2B(R3) <ul style="list-style-type: none"> – REPORTSOURCE [C.1.CN.1] – REPORTCATEGORY[C.1.CN.2] • MFDS E2B(R3) <ul style="list-style-type: none"> – OTHERSTUDIESTYPE [C.5.4.KR.1]

View Name	Impacted Area
V\$LM_CAUSALITY	<ul style="list-style-type: none"> • EMA R2B(R3) <ul style="list-style-type: none"> – DRUGASSESSMENTSOURCE [G.k.9.i.2.r.1] – EUDRUGASSESSMENTSOURCE[G.k.9.i.2.r.1.EU.1] – EUDRUGASSESSMENTMETHOD[G.k.9.i.2.r.2.EU.1] – DRUGRESULT[G.k.9.i.2.r.3] – EUDRUGRESULT[G.k.9.i.2.r.3.EU.1] • PMDA(R3) / PMDA(R2) <ul style="list-style-type: none"> – DRUGRESULT[G.k.9.i.2.r.3] • NMPA <ul style="list-style-type: none"> – DRUGASSESSMENTSOURCE [G.k.9.i.2.r.1] – DRUGRESULT[G.k.9.i.2.r.3] – CNSOURCEOFASSESS[G.k.9.i.2.r.CN.1] – CNRESULTASSESS[G.k.9.i.2.r.CN.2] • MFDS <ul style="list-style-type: none"> – DRUGASSESSMENTSOURCE [G.k.9.i.2.r.1] – KRCTRESULTOFASSESSMENT[G.k.9.i.2.r.3.KR.2] – KRMETHODOFASSESSMENT[G.k.9.i.2.r.2.KR.1] – WHOUMCRESLTOFASSESSMENT[G.k.9.i.2.r.3.KR.] • PMDA_DEVICE <ul style="list-style-type: none"> – F8_HEALTHDAMAGE_DETAIL – REPORTCLASS – F10_HEALTHDAMAGE_DETAIL – F10_DESCRIPTIONOFDEVICEPROBLEM – F8_DESCRIPTIONOFDEVICEPROBLEM
V\$LM_DEV_PHASE/ V\$LM_DEV_PHASE_DLP	<ul style="list-style-type: none"> • PMDA E2B(R3) <ul style="list-style-type: none"> – MHLWPHASEOFSTUDIES[J2.13.r.3] • PMDA E2B(R2) <ul style="list-style-type: none"> – MHLWPHASEOFSTUDIES[J.12.i.2]
V\$LM_ETHNIC_GROUP	<ul style="list-style-type: none"> • eVAERS <ul style="list-style-type: none"> – PATIENTETHNICITYGROUP[FDA.D.12] • NMPA E2B(R3) <ul style="list-style-type: none"> – PATIENTMINORITY[D.CN.1] • eMDR <ul style="list-style-type: none"> – PATIENTETHNICITYGROUP[A5.a]
V\$LM_ETHNICITY/ V\$LM_ETHNICITY_DLP	<ul style="list-style-type: none"> • NMPA E2B(R3) <ul style="list-style-type: none"> – PATIENTTRACE[D.CN.2]
V\$LM_MEDIA_TYPE/ V\$LM_MEDIA_TYPE_DLP	<ul style="list-style-type: none"> • All E2B(R3) Profiles - ICH, EMA, PMDA, MFDS, NMPA, and eVAERS <ul style="list-style-type: none"> – INCLUDEDOCUMENT[C.1.6.1.r.2] – LITINCLUDEDOCUMENT[C.4.r.2] • PMDA Device <ul style="list-style-type: none"> – MEDIATYPE

View Name	Impacted Area
V\$LM_MILITARY_STATUS	<ul style="list-style-type: none"> eVAERS <ul style="list-style-type: none"> PATMILSTATUS [FDA.D.14]
V\$LM_REPORTER_TYPE	<ul style="list-style-type: none"> MFDS E2B(R3) <ul style="list-style-type: none"> QUALIFICATIONR3[C.2.r.4]
V\$LM_RISK_CATEGORY_OTC	<ul style="list-style-type: none"> PMDA(R3) <ul style="list-style-type: none"> MHLWRISKCATEGORYOFOTCDRUGS [J2.5.k] PMDA(R2) <ul style="list-style-type: none"> MHLWRISKCATEGORYOFOTCDRUGS [J2.5.k]
V\$LM_ROUTE_ACQUIRE_OTC	<ul style="list-style-type: none"> PMDA(R3) <ul style="list-style-type: none"> MHLWROUTEFORACQUIRINGOTCDRUGS[J2.6.k]
V\$LM_SPECIALIZED_PROD_CATEGORY	<ul style="list-style-type: none"> eVAERS <ul style="list-style-type: none"> SPPRODCATEGORY [FDA.G.k.10.1]
V\$LM_RPT_CATEGORY/ V\$LM_RPT_CATEGORY_DLP	<ul style="list-style-type: none"> PMDA(R3) <ul style="list-style-type: none"> MHLWADMICSRCASENUMCLASSR3 [J2.1a] PMDA(R2) <ul style="list-style-type: none"> MHLWADMICSRCASENUMCLASS[J.4a]

Proxy setup updates

Summary

Proxy details to be stored at global level rather than enterprise level (Enhancement 33279155)

Description

The application has been enhanced to store proxy details at a global level rather than at the enterprise level. The following changes have been made:

- Proxy details that are accessed from Argus Console > Common Profile Switches > Network Settings > Proxy Details, are stored in the CMN_PROFILE_GLOBAL table instead of the CMN_PROFILE_ENTERPRISE table.
- An upgrade script migrates proxy data from the default enterprise of the CMN_PROFILE_ENTERPRISE table to the CMN_PROFILE_GLOBAL table.
- Proxy data stored in all other enterprises except the default enterprise are deleted.
- The following proxy details have been moved to the GLOBAL table from the ENTERPRISE table:
 - PROXY_AUTO_DETECT
 - PROXY_TYPE
 - PROXY_HOST
 - PROXY_PROTOCOL
 - PROXY_PORT
 - PROXY_USER PROXY_PASSWORD

After upgrade, these parameters are visible only in the DEFAULT enterprise:

- The following proxy parameters are be visible in all enterprises, and are specific to each enterprise:
 - Use Proxy settings for ESM DTD Validation
 - Use Proxy settings for SMTP/S
- During Oracle Argus upgrade, if no value was configured in the proxy parameters for the DEFAULT enterprise, then after upgrade, the respective parameters remain blank in the DEFAULT enterprise.

SSO re-authentication using OpenID Connect changes

Summary

Argus Suite to support SSO re-authentication using OpenID Connect (Bug 35162623)

Description

OpenID Connect standard allows third-party applications to verify the identity of the end-user and to obtain basic user profile information using tokens.

Listed below are the changes made to Single Sign-on (SSO) Common profile switches to support re-authentication based on the Open ID connect standard. OpenID Connect is provided as another option under Re-authentication mode along with Oracle Access Manager (OAM).

When you select **OpenID Connect**, the following configuration parameters are enabled for configuration:

- Authority URL
- Authorization Endpoint
- Token Endpoint
- Redirect URI
- Client ID
- Client Secret

When you select **Oracle Access Manager**, the current fields related to IDM configuration are enabled as per existing functionality.

Ported from

8.2.3.4

Enable application managed idle timeout

Summary

Application Managed Session time out (Enhancement 34954700)

Description

A new global-level common profile switch entitled **Enable Application Managed Idle timeout** is provided in Single Sign On node. The new parameter is applicable for both OAM and Open ID Connect options used as re-authentication mode.

Irrespective of the status of the **Enable Application Managed Idle timeout** parameter, the Oracle Argus Safety and Oracle Argus Insight applications are timed-out when the idle time exceeds the time limit specified in the **Session expiration time in minutes** switch.

When the **Application managed idle timeout** is enabled and timed-out of the applications, the user is redirected to the URL that is configured in the Sign-On Logout URL section, and subsequent log in requires to re-enter the user credentials.

When the **Application managed idle timeout** is not enabled but timed-out of the applications, if the time-out has not happened at the authentication server level (IDM/IDCS), then subsequent log in to the applications in the same browser session, does not require to re-enter the user credentials.

Ported from

8.2.3.4

Oracle Argus re-skinning

Summary

Oracle Argus re-skinning

Description

The appearance of Oracle Argus Safety has been enhanced as follows:

- The color theme is based on the Redwood Light theme.
- These changes have been applied through the CSS.
- Images and Quick Launch icons have been replaced to match the theme.
- The following modules have been re-skinned:
 - Oracle Argus Safety Web application (both English and Japan)
 - Global Portal
 - Local Affiliate
 - Login Page
 - Oracle Argus Safety Console
 - Oracle Argus Insight
- Standard dialog boxes shared between the Oracle Argus Safety Web interface, Oracle Argus Safety Console, and Oracle Argus Insight have the Redwood light theme.



Note:

This change applies to the Oracle Argus Safety Web interface only.

MedDRA recode log header changes

Summary

MedDRA recode log header changes (Bugs 34377933, 21088370 and 16849014)

Description

The Argus MedDRA recode logs are enhanced to provide details of the recode screen selections in the header for you to comprehend and analyze the log.

You can select the header columns that appear in the recode log header, such as Enterprise(s) name, User who initiates the recode, Recode Mode, Target MedDRA Version, and other. When multiple enterprises are selected, corresponding target dictionaries are also displayed in the log.

Enhancements to Oracle Argus Insight

Summary

Common Domain URL for Oracle Argus Safety and Oracle Argus Insight, and remove session dependency from Oracle Argus Insight

Description

The application has been enhanced to use a common domain that hosts both Oracle Argus Safety and Oracle Argus Insight.

You can install Oracle Argus Safety and Oracle Argus Insight on a single port in IIS as a virtual directory, similar to Oracle Argus Safety Console and other modules of Oracle Argus Safety.

Moreover, Oracle Argus Insight has been enhanced to make a round robin session through load balancer, instead of the sticky session. In the round robin session, session data is fetched from a centralized location, and user sessions are identified through cookies.

Merged Patches

The bug fixes from the following patches are merged with Oracle Argus 8.4.1:

- 8.2.1.11
- 8.2.3.3
- 8.2.3.4
- 8.4.0.1

Download Oracle Argus 8.4.1

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.
 - a. Argus Safety/Insight—**35714781**
 - b. Argus Mart—**35714823**
 - c. Argus Analytics—**35714833**
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 8.4.1 Installer.

Install Oracle Argus 8.4.1

To install Oracle Argus Safety and Oracle Argus Insight, see the *Oracle Argus Safety and Oracle Argus Insight 8.4.1 Installation Guide*.

To install Oracle Argus Mart, see the *Oracle Argus Mart 8.4.1 Installation Guide*.

To install Oracle Argus Analytics, see the *Oracle Argus Analytics 8.4.1 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 8.4.1](#)
- [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 8.2.1.11
 - 8.2.2 to 8.2.2.2
 - 8.2.3
 - 8.2.3.001

- 8.2.3.1 to 8.2.3.4
- 8.4
- 8.4.0.1
- Oracle Argus Insight
 - 8.1 to 8.4.1 including merged patches
- Oracle Argus Mart
 - 8.1 to 8.4.1 including merged patches
- Oracle Argus Analytics
 - 8.1 to 8.4.1 including merged patches

Upgrade Oracle Argus Safety from 8.1.x to 8.4.1

See the *Oracle Argus Safety and Oracle Argus Insight 8.4.1 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 8.4.1 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 8.4.1 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 8.4.1 Installation Guide, Section Oracle Argus Safety Database Upgrade*.

5. Upgrade Oracle Argus Safety from 8.1.x to 8.4.1
6. Validate the Oracle Argus Safety and DLP Schema, refer to the *Oracle Argus Safety and Oracle Argus Insight 8.4.1 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.