Oracle Argus

Release Notes—What's New

Release 8.4.4
G18174-03
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Oracle Argus Release Notes—What's New, Release 8.4.4

G18174-03

Contents

Preface

1 What's New

Preface

This preface contains the following sections:

Documentation accessibility

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

Diversity and Inclusion

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

Related resources

For information about Oracle Argus patches, see My Oracle Support.

All documentation and other supporting materials are available on the Oracle Help Center.

Access to Oracle Support

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

Cloud customers receive support assistance through Support Cloud

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

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

- English interface of Oracle Life Sciences Support Cloud (https://hsgbu.custhelp.com/)

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

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

On-premises customers receive support assistance through My Oracle Support

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

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What's New

Technology Stack

The following component has been updated to the Oracle Argus 8.4.4 technology stack:

- Google Chrome version 131.0.6778.108/109
- Microsoft Edge (Chromium based) version 131.0.2903.86 (official build) (64-bit)
- Axway 2.6 UP 2024-07 GA

See:

- Dictionary support

Dictionary support

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

Dictionary	Supported versions
MedDRA Dictionary	27.0 (March 2024), 27.1 (September 2024) 26.0 (March 2023), 26.1 (September 2023) 25.0 (March 2022), 25.1 (September 2022)
WHO Drug Dictionary (Format: B3 and C3, both English and Chinese)	March 2024, September 2024 March 2023, September 2023 March 2022, September 2022
J Drug Dictionary	April 2024, October 2024 April 2023, October 2023 April 2022, October 2022

Dictionary	Supported versions
JFMDA Dictionary	6.0 5.0

Oracle Argus Compatibility Matrix

Application	Compatible Version with this Argus Safety Release
Oracle Argus Analytics	8.4.4
Oracle Argus Insight	8.4.4
Oracle Argus Mart	8.4.4
Oracle Safety One Intake	25.1
Oracle Life Sciences Empirica Signal and Oracle Life Sciences Empirica Topics	9.2.3

Enhancements to Oracle Argus Safety Cloud Service

The following are the enhancements to Oracle Argus Safety Cloud Service in this release:

- Oracle Safety One Intake updates
- Gen AI Narrative
- OCI domain name update

Oracle Safety One Intake updates

Summary

This release offers Oracle Safety One Intake to enhance intake capabilities, and provides a unified interface for managing adverse event reports

Description

UI updates
A new Safety One Intake tab is added that redirects you to the Safety One Intake module. This module centralizes intake functionalities, offering an improved interface for managing adverse event reports.
The Intake Worklist within Oracle Safety One Intake replaces the traditional ICSR Pending screen, providing additional features such as PII (Personally Identifiable Information) support and case assignment capabilities.

- English E2B(R2) and E2B(R3) reports ingested via the interchange service now appears in the Safety One Intake > Intake Worklist and Monitor List, replacing the Reports > ICSR Pending, Processed & Utilities > ICSR > Failed Imports screens.
- PMDA E2B (R2) and E2B (R3) reports continue to appear in the traditional ICSR Pending and Processed screens.

Additionally, when follow-ups are received for a case, a notification appears in the case form, enabling case processors to take necessary actions. The application allows follow-ups to be

held, if the case is not ready for merging due to submission deadlines or other reasons that is configurable.
Likewise, an indication about such notifications appear on the Worklist New, Worklist Open, and Case Actions Open screens.
A new Intake ID column is added to the Case Form > Follow-up section, displaying the follow-ups merged into the case. You can click this Intake ID to view the individual follow-up information.
For more details, refer to the Safety One Intake Release Notes > Consolidated Intake Processing Workflows.

Console updates
To support intake processing, the following changes are made in Argus Console:

- A new check box, Hold Follow-up Merge during Intake, is added to Argus Console > System Configuration > Workflow > States.
- A new node, Intake Processing, is added to Argus Console > System Configuration > System Management (Common Profile Switches). This node is at the enterprise level.
- To support auto-assignment for both case and intake records, use Argus Console > System Configuration > System Management (Common Profile Switch) > Workflow > Case Routing > Enable Auto opening of the next case/intake record option.
- A new check box, Allow Narrative Processing During Intake, is added to Code List > Argus Code List > Reporting Destination > EDI.

For more details, refer to the Safety One Intake Release Notes > Changes to the Argus Console.

Gen AI Narrative

Summary

Narrative generation using OCI Gen AI service

Description

In this release, Argus Safety introduces a Gen AI-powered narrative generation feature. This feature auto-generates narratives from the structured data available in a case, making this process efficient with highly natural, accurate and complete narratives. Hence, minimal manual user intervention is required. This feature is available for case processing in the Analysis tab as well as for medical reviews in the Medical Review screen of the case form.

Configuration changes
A new profile switch, Enable Narrative Generation using Gen AI, is introduced under Argus Console > System Management (Common Profile Switches) > Case Processing. You can enable or disable the Gen AI feature using this switch.

Case Form changes
A new Generative (AI) button is added for the Narrative field in the case form. This button is available for the Argus Global user. When you click this button, a new dialog appears with the existing narrative text (if any) adjacent to the system generated output using the Gen AI service for comparison. You can substitute the entire existing narrative with the system-generated text by clicking the Replace button, or manually copy specific sections of the system-generated text and paste them into the existing narrative.
This dialog also allows you to provide feedback for the system-generated output, which will help us improve the quality of the Gen AI service.

> **Note:**
>
> The narrative generated using Gen AI is for evaluation purposes only. Hence, it is disabled by default.

When to enable this feature

To make sure the narratives generated via this feature meet your quality standards, Oracle recommends you perform thorough testing and evaluation with your real-world data to assess its performance in the test environment. This will help you understand how the feature works and identify any areas for improvement. You can compare our AI results with your own quality standards.

How it works
Raise a ticket with Oracle Support to get the following information to proceed further with testing and evaluation:

- Guidelines on what to expect.
- Key metrics to measure performance.
- Tips for debugging.
- Model Card details, including the model's intended use, performance, limitations, and AI governance.

What next?
When the results generated via Gen AI are validated and meet your expectations, the product team will work with you on the next steps to deploy this feature for product usage.
We will also provide a formal validation pack when the feature is fully released to make sure it meets all regulations and is based on the real-world performance data. We are committed to working with you to make sure our AI feature generate optimal suggestions.

OCI domain name update

Summary

OCI domain name in Argus URL

Description

The OCI domain name is revised from oracleindustry.com to safetyone.ocs.oraclecloud.com in URLs that are part of Argus Cloud Service offering.

The new OCI domain name is included in URLs of the following application for fresh deployments and upgrades:

- Oracle Argus Safety
- Oracle Safety One Intake
- Oracle Analytics Server
- Oracle Safety One Argus B2B UI
- Axway B2Bi UI
- SFTP

> **Note:**
>
> The OCI domain name changes specified above are applicable for both production and non-production environments.

For upgrade deployments, the new URL details are shared by AMS to customers. Customers are expected to share these details with their end users. Domain name for AS2 and API URL remains the same, oracleindustry.com.

For Fresh deployments, the domain names are as follows:

- Domain name remains the same, oracleindustry.com, for API URL.
- Domain name is updated as safetyone.ocs.oraclecloud.com for GatewayAS2 URL (Axway B2Bi and Oracle Safety One Argus B2B).

Enhancements to Oracle Argus Safety

The following are the enhancements to Oracle Argus Safety in this release:

Case processing updates

Advanced studies—Multiple blinded products support

Summary

Multiple blinded products are supported in the case form (Enhancements 29020500, 33751893, 34736032, and 35962269)

Description

The industry has observed significant changes to the clinical trial design and methodology. In order to accommodate the evolution of clinical research, there is a need to enhance Argus Safety system to support advanced study configuration, case processing, and reporting. In this release, the system is enhanced to support multiple blinded products in the case form.

Study configuration changes

Argus Console > Business Configuration > Studies is updated to allow grouping of blinded treatment products. Configuration of blinded treatment groups is not mandatory and is available for blinded studies only.

A new button, Add blinded treatment groups, is introduced in this screen. When you click this button, a pop-up window appears, where you can configure blinded treatment groups at the study-arm-level. Each Treatment Group name must be unique. One or more blinded study products from the respective study can be associated with the Treatment Group.

When a study product is associated with a treatment group, all blinded products are expected to have an associated treatment group. In case form, you can select treatment groups that are associated with at least one blinded study product.

Treatment groups and respective blinded study products selected in the case form cannot be deleted or turned non-blinded.

Case form changes

Book-in screen

There are no changes to manual or E2B book-in screens in this release. Upon selection of Project ID, Study ID and Study Name, Case Actions > New Case > Product Name and Generic Name populates with the Study Name, as per the existing functionality.

Products tab in blinded state

New options are available in Products tab when blinded treatment groups are configured in study configuration. You must select the blinded treatment group in the new field, Treatment Group, which is mandatory and blank, by default. You can also add and delete blinded treatment group tabs using the right-click menu. Case form supports a maximum number of blinded treatment group tabs equal to the total number configured in the study configuration.

Only blinded treatment groups that are associated with at least one blinded study product in study configuration are available for selection in the case form.

When a treatment group is selected, product name as reported, product name, and generic name are updated to the format <Study Name (Treatment Group)>.

Event assessment tab

The blinded treatment groups are displayed along with study name under the Product column in the Event Assessment tab. Causality and listedness assessment can be captured for each blinded treatment group.

In Argus 8.4.3 release, the ability to assess listedness for each suspect study product in blinded cases based on their own datasheets/licenses was introduced. This is configurable in Argus Console > System Configuration > System Management (Common Profile Switches) > Case Processing > Assessments > Criteria for Event Level Assessment for Blinded Study. This functionality is maintained for each blinded treatment group:

- If **Include datasheet/licenses for the default blinded study product** is selected, then the system behaves as per existing functionality to evaluate and display event assessment only for single blinded product.

> **Note:**
>
> If a primary license is configured in study configuration, then event assessment is performed for the primary license product. If no primary license is configured in study configuration, then the event assessment is performed for any of the blinded product.

- If **Include datasheet/licenses for all the blinded study products** is selected, then the system displays all datasheets and licenses for the blinded study products associated with the blinded treatment group row as per study configuration.

Other
Case form sections and prints display the blinded treatment group(s) in the same format as shown in the Products tab > Product Name to the user based on their access rights including, but not limited to:

- PMDA tab
- Product Event Details tab
- Manual Report Scheduling dialog
- Medical Review
- Coding Review
- Case Summary
- Local labelling
- Medical Summary
- Case Form print

Blinded view
Pre-unblinding, users who do not have access to view or print unblinded information, see all blinded study products present in the case (tabs are blinded), including legacy cases where Treatment Groups were not implemented. The Treatment Group field is visible, if configured. Product name and generic name remain blinded until after the end of study unblinding.
Post-unblinding, users who do not have access to view or print unblinded information, see all study products present in the case (tabs are blinded), including legacy cases where Treatment Groups were not implemented. The Treatment Group field is visible, if configured. Product name and generic name remain blinded until after the end of study unblinding.

Legacy cases and study cases without treatment group configured
If study configuration is not updated to include treatment groups, the new Treatment Group drop-down field is not be available in the case form, and there is no impact on legacy cases and reporting.
If study configuration is updated to include treatment groups, by default, the one existing blinded product tab has a blank Treatment Group drop-down with no additional updates.

Manual unblinding
Manual unblinding in the General tab of the case form is enhanced to allow users to select one or more study products the patient received. This is not a mandatory step.
If treatment groups are configured, this dialog lists all configured treatment groups and respective study products for selection.

If treatment groups are not configured, this dialog lists all products marked as Blinded in study configuration for selection.
The system updates the product tab(s) automatically based on the study products selected in this dialog.
If no study product is selected, users are prompted to select a study product in Products > Study Drug, as per the existing functionality.

> **Note:**
>
> Add Study Drug option on right-click menu remains available after unblinding, as per the existing functionality.

Reporting changes

Paper reports (CIOMS I, CIOMS I Local and MedWatch)
Argus is enhanced to print more than one blinded product when a blinded report is generated for an unblinded case and multiple study products are added.
If the case is blinded and the report is set to view unblinded data, then Product Name includes <Study Name (Treatment Group) (code not broken)> for each Treatment Group.
If the case is blinded and report is set to hide unblinded data, then Product Name includes <Study Name (Treatment Group) (code not broken)> for each Treatment Group. The rest of the study product fields are restricted as per existing behaviour.
If the case is unblinded and report is reviewed to view unblinded data, then Product Name displays the unblinded product, as per the existing behaviour. If the case is unblinded and the report is set to hide unblinded data, then Product Name includes <Study Name (Treatment Group) (code not broken)> for each Treatment Group. The rest of the study product fields are restricted as per the existing behaviour.
For more details, refer to CIOMS I, CIOMS I Local and MedWatch mapping documents.

Expedited report scheduling
Expedited report scheduling considers the existence of multiple treatment groups for report scheduling. You can also schedule report for any of the blinded products in the case.

E2B export (all profiles)
There are no changes in the mapping logic for E2B(R3) reports based on the Treatment Group configuration. Data populated in the MEDICINALPRODUCT[G.k.2.2] element of the Blinded E2B(R3) reports is the data available in the Product Name field that contains <Study Name (Treatment Group)>.
The mapping logic for E2B(R2) reports (ICH, EMA, FDA 2.1, and FDA 2.2) is revised to populate all the blinded products (from the study configuration) based on the Treatment Group selected in the case form.
For more details, refer to the following documents:

- *ArgusInterchange844_E2B (R3) Export Mappings*
- *ArgusInterchange844_E2B (R2) 2.1 Export Mappings.xlsx*
- *ArgusInterchange844_E2B (R2) 2.2 Export Mappings.xlsx*

.

E2B(R3) import
When a study is configured with Treatment Groups, import of ICSRs is as follows:
During initial import:

- Product Name and Generic Name are populated with Study Name.
- Company Drug Code is populated as Study Drug.
- Treatment Group is not populated.
- Dosage and Causality are copied from the respective drug block of ICSR.
- If there are more blinded products in ICSR than configured in the Study, then the excessive blinded products are added as non-study products.

During follow-up import:

- If the treatment groups are selected for blinded products in the case, then the system compares the blinded products in ICSR with the blinded products in the case by matching the primary keys (as present in PK element CSV that can be downloaded from Interchange Mapping screen) associated with the parent element as Drug. Blinded product data from incoming ICSR is updated to the respective blinded products of the case.
- If the blinded product data from incoming ICSR does not match with the primary keys associated with parent element drug, then the blinded product is inserted to the case and data is populated as per the previous point.
- If the number of blinded products present in ICSR exceeds the number of blinded products configured in the study, then the system imports the excess products as non-study products.
- If the treatment groups are not specified for blinded products in the case, then the system includes ICSR in failed report section with an error indicating that the Treatment Groups are not specified for blinded products in the case.

When the study is not configured with Treatment Group, import of ICSR is as follows:

- If the incoming initial ICSR has multiple blinded products with no Treatment Groups, then the blinded products are imported with product name as study name. If there are more blinded products in ICSR than configured in the study, then the excessive blinded products are added as non-study products.
- If the incoming follow-up ICSR has multiple blinded products with no Treatment Groups, then the existing blinded products present in the case are updated. If there are more blinded products in ICSR than configured in the study, then the excessive blinded products are added as non-study products.

PMDA E2B(R2, R3) import
There are no changes to the PMDA E2B(R2, R3) import mappings. The system creates a single blinded product on initial and follow-up ICSR import.

E2B(R2) import
There are no changes to the E2B(R2) import mappings. The system creates a single blinded product on initial and follow-up ICSR import.

Periodic reports
The line listing sections of the following reports prints multiple blinded study drugs as available in the case with blinded information, when it is generated with the Blinded Line listing check box as checked:

- PSUR
- CTPR

- CIOMSLL
- Case listing

Product Name prints the data present in the Product Name field of the Product tab. Therefore, if a Treatment Group is selected for a blinded study product, then the Treatment Group that was populated in the Product Name field within parentheses is printed in these reports.
The blinded column of the summary tabulation of the following reports counts an event only once for cases that have multiple blinded products:

- CTPR (native)
- DSUR (BIP)
- PBRER (native)
- PBRER (BIP)

The cumulative tabulation prints a list event counts pertaining individual blinded products present in the case. However, total of adverse event for this report counts the event once per case.
There is no change on the IND or NDA reports since the product name is not populated in these reports.
There is no change in the CDA report, if the product name is used in the row or column selection.

Argus Unblinding Advanced updates
To perform end of study unblinding (EOSU) from Argus Unblinding Advanced screen, you select the study product(s) that the patient received for each unique treatment code. This selected product(s) is added as study drug in the case after unblinding, as per the existing functionality.
The Argus Unblinding Advanced screen is enhanced to display the treatment group along with the existing study product name list.

- When Treatment Groups are configured:

  After study product(s) selection in the profile and successful execution in update mode, during unblinding of case, the system checks the respective Treatment Group(s) and updates the blinded product tabs in Case Form as per study configuration. The system does not allow duplicate selection of treatment code: Product Name (Treatment Group) combination, as per existing functionality.
- When Treatment Groups are not configured:

  No change in existing functionality.

> **Note:**
>
> Treatment Code in the EOSU profile is not directly related to the Treatment Groups defined in Argus Console. Treatment code in EOSU is derived from the PRD file that is loaded.

Argus Unblinding Lite updates
Argus Unblinding Lite is updated to exclude studies with the Treatment Group configuration and display only Study IDs without treatment groups.
For more details, refer to the *ArgusSafety8.4.4_CaseForm_Console_Updates_Summary.xls*.

Auto assignment and opening of cases

Summary

Auto assignment and opening of cases

Description

In Worklist > New, a new button, Open Next Case, is introduced and is enabled for all users. When you click this button, a next high priority case from the worklist is automatically assigned to you and opened for further processing, as when you manually accept a case. The next high priority case is picked up as per the below order:

1. Cases that are already assigned to the logged-in user.
2. Cases that are already owned by the logged-in user.
3. Cases that are already assigned to the group as the logged-in user.
4. Cases that are unassigned (not assigned to any user, not owned by any user, not accepted by any user).

If there are multiple cases, then the case with highest priority (1, being high priority, and 0/null being lowest priority) in the Worklist > Priority column with the highest number in Days Open is considered for auto assignment and opening.

A new button, Route and Open Next Case, is introduced in Case Form. The next case is auto-assigned and opened, when you click Route and Open Next Case button in the Case Routing window of the case form. If there are no cases available, then the message, No cases available for opening, is displayed.

This feature is enabled by default. To configure this feature, a new common profile switch in Workflow > Enable Auto opening of the next case/intake record with options Yes (default) and No can be used. This switch is available at the enterprise level.

Argus Unblinding Advanced updates

Summary

Argus Unblinding Advanced updates (Enhancements 36621715, 36673888, 36708518, 36615481, and 36752028)

Description

The following Argus Unblinding Advanced features are enhanced:

Capture follow-up receive and Safety receive date for every PRD file
For a precise due date calculation, you can manually set the following two new fields in the End Of Study Unblinding (EOSU) profile:

- File Generated Date—Date when the randomization file was generated in the Clinical system (Follow-Up received Date)
- File Received Date—Date when the randomization file was received by Safety system (Safety Received Date)

It is optional to set these dates. If the dates are not set, the EOSU profile execution date is used.

Ability to download PRD file from EOSU profile
You can download the latest Patient Randomization Data (PRD) file that was loaded in the EOSU Profile.
The existing Download button, which previously downloaded the PRD Loading report, now downloads both the PRD file and the Loading report as a zipped file.

> **Note:**
>
> The PRD files loaded before Argus 8.4.4 upgrade are not downloadable. For these files, the Download button only downloads the .txt loading report.

Allow blank reporting group
You can configure and execute an EOSU Profile without assigning an Expedited Reports Group, even if the option to run reports is selected. In such cases, the responsible group remains blank in the scheduled report.
If the reporting rule includes a Responsible Group, that group is allocated to the report.

Restrict automatic archiving of unblinded cases without reports
For greater flexibility to process the unblinded cases without reporting, the cases are not automatically archived. Unblinded cases with no reports are assigned a workflow state based on the current functionality, but are not archived unless the workflow state is Closed. Cases with workflow state as Closed are archived automatically.

Deprecated Argus Unblinding Client-Server tool
The Argus Unblinding client-server module for End-of-Study Unblinding is deprecated from this release. The existing profiles, setup parameters, and logs will reflect in the Utilities > Unblinding Advanced screen.

Ability to disable Causality as Determined Result auto-population

Summary

Causality as Determined Result auto-population in the Event Assessment tab can be disabled by default (Enhancement 22286968)

Description

The auto-population of Causality as Determined Result based on Causality as Reported Result in the Event Assessment tab of the case form can be disabled by default using a new common profile switch, Disable auto-population of Causality as Determined Result in the Event Assessment tab case form.

This switch is accessible from Console > System Configuration > System Management > Case Processing > Assessments. The default value is set as No to avoid any impact on the current users.

Print enterprise name in Print PDF reports

Summary

Print enterprise name in the Print PDF reports (Enhancement 34286078)

Description

The Print PDF report is enhanced to include the enterprise name in the following PDF reports for the users using the multi-enterprise application.

- Access Management > Users, Groups and Sites
- System Configuration Workflow
- Interchange > Manage Profile and View Audit Log
- Code List > Reporting Destinations
- Business configuration > Products, Licenses, Clinical Studies and Expedited Reporting Rules

Users can manage display of the enterprise name by checking the Display Enterprise Short Name in Report Header option in Argus Console > System Configuration > Common Profile Switches > User Interface. This option is unchecked by default. When enabled, the enterprise name appears in the reporter header next to the time stamp, like:

```
17-Jun-2024 13:14 GMT + 5.5 / <Enterprise Short Name>
```

Inclusion of additional blinded fields in the case

Summary

Inclusion of additional blinded fields in the case form (Enhancement 35969341)

Description

Case blinding feature is enhanced to blind additional fields in a case form for a blinded study case and for users who have checked the Protect from Unblinded Information check box.

Additionally, blinded fields are masked in the print case form reports, if you have checked the Protect from Printing Unblinded Information check box in Argus Console > Users.

The following fields are masked with blinded text in the case form and case form print reports:

- Product > Vaccine > Vaccine Information > Batch / Lot Number
- Product > Product Information > Obtain Drug Country, Drug Authorization Country, Market Authorization Holder, Manufacturer
- Event Assessment > Data Sheet/License column

If the Protect from Unblinded Information check box is unchecked, then the above mentioned fields are displayed with data in the case form for both the blinded study case and unblinded case.

In the MedWatch report, C1[Manufacturer/Compounder Name] mapping is updated to display blinded text when blinded conditions are satisfied. For more information, refer to *ArgusSafety8.4.4_MWPaperReportMappings.xlsx*.

Regulation updates

Ability to generate nullification report for CIOMS I

Summary

Nullification reports can be generated for CIOMS I and CIOMS I Local reports (Enhancement 36501946)

Description

A new switch, Automatically schedule nullification report on case deletion, enables you to automatically generate a nullification report for a previously submitted CIOMS I or CIOMS I Local report upon case deletion. You can enable this switch from Console > Code Lists > Argus > Reporting Destination > Report screen. To avoid any impact on the current users, by default, this check box is unchecked.

Additionally, you can manually generate a nullification report for a previously submitted CIOMS I or CIOMS I Local report by configuring the time frame for the nullification report. This time frame is configured using the existing switch, Time Frame for Manual Nullification, from Console > System Configuration > System Management > Case Processing > Reporting > Scheduling.

The nullification report is scheduled with an aware date consistent with the latest case data corresponding to E2B(R2) element, RECEIPTDATE[A.1.7b], and E2B(R3) element, RECEIPTDATE[C.1.5], and a due date as two days more than the date of scheduling.

The text entered in Action Justification during nullification scheduling is populated in the 7 +13 DESCRIBE REACTION(S) section of the CIOMS I form, at the top of case description, with the prefix, Nullification Reason.

The scheduled CIOMS I or CIOMS I Local nullification report can be accessed from the following screens:

- Reports > Bulk Reporting
- Worklist > Bulk Transmit
- Reports > Compliance > Submitted, once the report is marked as submitted.

FAERS updates

FDA E2B(R3) reports to capture verbatim drug reporting

Summary

Introduction of a new free text field for Verbatim Drug Reporting in Book-In and Case Forms to support FDA E2B(R3) compliance (Enhancement 20308352)

Description

According to the FDA Regional Implementation Guide for E2B(R3), Electronic Transmission of Individual Case Safety Reports for Drug and Biological Products (April 2024 edition), the MEDICINALPRODUCT[G.k.2.2] data element must have the medicinal product name as reported by the primary source.

Book-In screen
During the book-in process, you can enter the verbatim product name in the Product Name as Reported field . This auto-populates the Product Name field, when you move to the next field (tab out). Once the Product Name field is filled, both the Product Name and Product Name as Reported fields can be edited and saved separately. After the product name is entered, either manually or automatically, you can continue to code the product using the existing functionality.
For sponsored trial cases, the Product Name as Reported field auto-populates with the study name based on the selected project/study ID, and then becomes read-only, similar to the Product Name field.

Case Form
The case form displays the Product Name as Reported as entered during initial book-in. If you add a new product directly in the case form, this field remains blank, allowing for free text entry.
In the blinded study cases, this field displays the study name in a read-only format. For open-label studies, it displays the configured drug name. When you add a new study drug, the Product Name as Reported field displays the study name as a read-only text.

Mapping updates
The Product Name as Reported value for products is transmitted in MEDICINALPRODUCT[G.k.2.2] for the FAERS E2B(R3) reports.
If the Product Name as Reported value is not available, then data entered in the Product Name field for products is transmitted as per the ICH guidelines.
For the unblinded studies, the product name used to break the blind for each study product is transmitted.

> **Note:**
>
> Post upgrade, the existing cases are unaffected as the Product Name as Reported field is optional.

FDA E2B(R3) reporting updates for business rules and other enhancements

Summary

Implementation of the latest FDA E2B(R3) reporting updates for business rules and enhancements (Enhancement 36594304)

Description

Argus Safety is enhanced to implement the latest FDA E2B(R3) reports regulations released in January/April/August 2024 in the FDA Regional Implementation Guide for E2B(R3) Electronic Transmission of Individual Case Safety Reports for Drug and Biological Products Business Rules Updates.

The FAERS FDA E2B(R3) profile is modified to incorporate these new rules.

IND report for spontaneous case
As per FDA Scenario #8, the manufacturer must submit a premarket IND safety report for drugs product, where the premarket IND product is niether approved nor marketed in the US, but such product is marketed outside the US, where an adverse event has occurred.
Reports that are scheduled and generated for an IND license from a spontaneous case now includes the INDNUMB[FDA.C.5.5a] and CROSSREPORTEDIND[FDA.C.5.6r] elements.

Post-Marketed report for clinical trial case
Reports that are scheduled and generated for an MKT license from a clinical trial case no longer includes the INDNUMB[FDA.C.5.5a] and CROSSREPORTEDIND[FDA.C.5.6r] elements.

Automatic cross-reported IND population
The IND number of a cross-reported IND is currently transmitted based on the manual configuration in the Study and Additional Information section of the case.
The mapping for the CROSSREPORTEDIND[FDA C.5.6.r] element is enhanced to automatically populate and transmit license numbers belonging to the same product as the cross-reported IND, based on the product-license configuration and study configuration.
The existing mapping logic, which transmits manually configured cross-reported INDs from Study > Clinical Reference and Case Form > Additional Information, is retained. Only Unique values are transmitted in the repeatable elements for CROSSREPORTEDIND[FDA C.5.6.r].
For more information, refer to *ArgusInterchange844_E2B (R3) Export Mappings document*.

New FAERS attribute to support attachments
To support attachment types approved for FDA E2B(R3) reporting, a new FAERS attribute is added in the MediaType flexible code list.

XPath and HL7 changes
To comply with the latest FDA E2B(R3) Core and Regional Data Elements and Business Rules - Version 1.7 (April 2024), the following modifications are made in XPath and HL7:

- New Batch message wrapper
- The Null flavor XSLT for PARENTSEXR3[D.10.6] and PATIENTSEXR3[D.5] include codesystem '1.0.5218', like:

  ```
  <administrativeGenderCode nullFlavor="MSK" codeSystem="1.0.5218"/>
  ```

- Corrected XPATH for DEVICEINFO[G.k.12] that includes <part classCode="PART"> <partProduct classCode="DEV" determinerCode="KIND">.
- Xpath update for DEVICELOTNUMBER[FDA.G.k.12.r.9]. The device lot number is moved within the Device section.
- OPERATOROFDEVICE[G.k.12.r.10] OID is '2.16.840.1.113883.3.989.5.1.2.1.1.6'.
- FOLLOWUPTYPE[G.k.12.r.2.r] OID is '2.16.840.1.113883.3.989.5.1.2.1.1.5'.
- Element number for FDA Specialized Product Category is displayed as FDA.G.k.10.1.

For more details, refer to *ArgusInterchange844_E2B(R3) Export Mappings*.

eMDR updates

Summary

eMDR enhancements 2024 (Enhancement 36920725)

Description

FDA CDRH published revised guidance in August 2024, which is effective from March 2025. Argus Safety is enhanced to comply with the latest guidelines.

Interchange mapping changes
Data element validation
For an initial case, codes are required for the following data elements. If the code is missing, a validation error message is be displayed.
For a follow-up case, the following data elements do not trigger a validation message, when their value is null.

- MFRPATIENTCODE [H6]
- MFRDEVICECODE [H6]
- EVALCODEMETHOD [H6]
- EVALCODERESULT [H6]
- EVALCODECONCLUSION [H6]
- MFRCOMPONENTCODE [H6]
- MFRHEALTHIMPACTCODE [H6]
- FDAPATIENTCODES [F10 Part 1]
- FDADEVICECODES [F10 Part 2]
- FDACOMPONENTCODES[F10 Part 3]
- FDAHEALTHIMPACTCODES[F10 Part 4]

Increased length of the following elements:

- UFREPORTNUMBER [F2]
- UFCONTACTMIDDLENAME [F4]

Revised mapping logic of the following elements:

- REPORTTYPE[B1]
- UDINUMBER[D4]

For more details, refer to *ArgusInterchange844_eMDR (R2) Export Mappings.xlsx*.

Case form changes
In the Case Form > Analysis > MedWatch Info > F. For Use by User Facility/Importer (Devices Only) section, the Contact Person MI field length is increased from 1 to 15.

eVAERS updates

Summary

eVAERS Regulatory updates (Enhancements 33415880, 36173188, and 30838996)

Description

FDA CBER published revised guidelines in December 2023 for eVAERS report submission.

Console changes

- In the Flexible Codelist List Maintenance, a new NCI Code [C53528] labeled Urgent Care Center is added to Vaccinated_AT.
- In the Country flexible code list, a new GENC2 attribute is added and each country is assigned with a GENC2 code.

  You can modify the GENC2 code data for both factory-provided countries and custom countries.

Interchanging mapping changes

Mapping changes for Vaccine Facility section

The eVAERS Report mapping is enhanced, such that, when a report is generated, the VACCINE FACILITY[G.k.4.r.14] and ADMINISTRATION INFORMATION[FDA.E.i.3.4] elements are populated in the Drug(s) Information[G.k] section.

The Vaccine Administration section is transmitted for suspect and non-suspect vaccines, if data is present. If no vaccine facility information is available for vaccines other than the first suspect vaccine, then the Facility block under the Drug(s) Information[G.k] section is not populated for that vaccine in the XML.

Existing E2B generation validation for VACCAT[FDA.G.k.4.r.14.8] is revised to ensure the facility type information is checked for the scheduled suspect vaccine. If the facility type information is missing, then the validation messages are displayed. However, if the facility type information is missing for subsequent vaccines within the same case, then no validation message is displayed.
The following validations are removed as these validations are not triggered with the existing OOTB report mappings:

- VACCFACILITYNAME [FDA.G.k.4.r.14]
- VACCFACILITYADD [FDA.G.k.4.r.14.1a]
- VACCFACILITYCITY [FDA.G.k.4.r.14.2]
- VACCFACILITYSTATE[FDA.G.k.4.r.14.3]
- VACCFACILITYCOUNTRY[FDA.G.k.4.r.14.4]
- VACCFACILITYPOSTCODE[FDA.G.k.4.r.14.5]
- VACCFACILITYTELEPHONE[FDA.G.k.4.r.14.6]
- VACCFACILITYFAX [FDA.G.k.4.r.14.7].

Populate GENC2 country codes in the country data element instead of ISO-3166-1 country codes

The mappings for the following country data elements are updated to send GENC2 codes instead of ISO A2 codes:

- REPORTERCOUNTRYR3[C.2.r.3]
- SENDERCOUNTRYCODE[C.3.4.5]
- STUDYREGCOUNTRY[C.5.1.r.2]
- PATIENTCOUNTRYCODE[FDA.D.1j]
- REACTIONOCCURCOUNTRY[E.i.9]
- OBTAINDRUGCOUNTRY[G.k.2.4]

- DRUGAUTHORIZATIONCOUNTRY[G.k.3.2]
- VACCFACILITYCOUNTRY[FDA.G.k.4.r.14.4]
- MANUFACTURERCOUNTRY[FDA.G.k.12.r.7.1e]

Other eVAERS profile updates
To accept additional characters, like underscore ("_"), space (" "), parentheses ("()"), and hash ("#"), mapping of the following data elements along with validation rule and validation message is updated:

- DOCFILENAME[FDA.C.1.6.1.r.3]
- LITFILENAME[FDA.C.1.6.1.r.3]

The updated list now includes Letters (a–z, A–Z), Digits (0-9), special characters plus ("+"), period ("."), and hyphen ("-").

The allowed value (CFG_M2) check on the DEVICEPROBLEMCODE[FDA.G.k.12.r.3.r] element is removed for the eVAERS profile.

Transmit FDA SPL Code or EDQM in Route of administration (ROA) and Dose formulation (DF)
The mapping for Patient Route of Administration, Parent Route of Administration, and Drug Formulation has been updated.
When the selected code list value does not have NCI Code in Patient Route of Administration, Parent Route of Administration, and Drug Formulation, then a valid EDQM Term ID is populated with version information in the following data elements:

- DRUGROUTEOFADMINTERMIDVER[G.k.4.r.10.2a]
- DRUGPHARMADOSEFORMTERMID[G.k.4.r.9.2b]
- DRUGPARROUTEOFADMINTERMIDVER[G.k.4.r.11.2a]
- DRUGPARROUTEOFADMINTERMID[G.k.4.r.11.2b]
- DRUGROUTEOFADMINTERMID[G.k.4.r.10.2b]
- DRUGPHARMADOSEFORMTERMIDVER[G.k.4.r.9.2a]

When the selected code list value does not have NCI Code or EDQM Term ID (deprecated, rejected, or unmapped EDQM Term ID) in Patient Route of Administration, Parent Route of Administration and Drug Formulation UI, then the selected code list value (free text) is populated in text format in the following data elements:

- DRUGADMINISTRATIONROUTETEXT[G.k.4.r.10.1]
- DRUGPARADMINISTRATIONTEXT[G.k.4.r.11.1]
- DRUGDOSAGEFORM[G.k.4.r.9.1]

For more information, refer to *ArgusInterchange844_E2B (R3) Export Mappings.xlsx*, E2BR3_Mappings Sheet.

Case form changes
When multiple vaccines are available in a case, you can now enter and save specific details for each individual vaccine in the Vaccine Administration section, Vaccine Facility section, and Best Doctor/Health Care Professional Information section.
Legacy cases having vaccines with facility or administration data are updated after upgrade as per the following logic :

- For cases with single suspect vaccine and one or more non-suspect vaccines, vaccine facility or administration detail is associated with the suspect vaccine present in the case. Vaccine facility or administration detail is not associated with the non-suspect vaccine present in the case.
- For cases with suspect and non-suspect vaccines:
  - If there is one suspect vaccine for which eVAERS or VAERS report is scheduled, generated, or submitted, then the vaccine facility or administration detail is associated with that vaccine, and left blank for other suspect and non-suspect vaccines.
  - If there is more than one vaccine for which eVAERS or VAERS report is scheduled, generated, or submitted, then the vaccine facility or administration detail is associated with the vaccines that has vaccine reports, and is left blank for other suspect and non-suspect vaccines.
  - If there are no eVAERS or VAERS report scheduled, generated, or submitted for the case, then the vaccine facility or administration detail is associated with the first suspect vaccine based on the sort order, and not with the non-suspect vaccine present in the case.
- For cases with non-suspect vaccines and no suspect vaccines, the vaccine facility or administration detail is associated with the first vaccine present in the case.

NMPA E2B(R3) updates

Summary

NMPA E2B(R3) updates (Enhancements 36107103, 34907611, and 34783867)

Description

The mapping is updated for the following elements:

- RECEIPTDATER3[C.1.5]—Contains same value as RECEIVEDATER3[C.1.4] Initial receipt date for initial reports.
- REACTIONSTARTDATER3[E.i.4]—Removed dependency on the Protect Confidentiality flag.

For more details, refer to *ArgusInterchange844_E2B(R3)ExportMappings*.

When value of the following elements is less than 1, then the value is formatted with preceding 0 followed by a decimal dot in the ICSR viewer (XML view, Decoded view, and HL7 view), and the outbound XML file.

```
For example, 0.7 and not .7
```

- PATIENTWEIGHT[D.3]
- PARENTWEIGHT[D.10.4]
- TESTRESULT[F.r.3.2]
- LOWTESTRANGE[F.r.4]
- HIGHTESTRANGE[F.r.5]
- STRENGTH[G.k.2.3.r.3a]
- DRUGSTRUCTUREDOSAGENUMB[G.k.4.r.1a]
- DRUGCUMULATIVEDOSAGENUMB[G.k.5a]

MFDS E2B(R3) updates

Summary

MFDS E2B(R3) updates (Enhancements 36373010, 32685700, and 35616714)

Description

The mappings and validations for MFDS E2B(R3) are updated based on the MFDS verification rules published on 17-Oct-2023, 18-Jan-2024, and 24-Jan-2024.

Mappings of the following elements are updated:

- PATIENTBIRTHDATER3[D.2.1]
- PATIENTONSETAGE[D.2.2a]
- GESTATIONPERIOD[D.2.2.1a]
- PATIENTAGEGROUP[D.2.3]

Validations of the following elements is updated:

- Handling future dates:
  - RECEIVEDATER3[C.1.4]
  - RECEIPTDATER3[C.1.5]
- MedDRA currency:
  - PATIENTEPISODENAME[D.7.1.r.1b]
  - PATIENTDRUGINDICATION[D.8.r.6b]
  - PATIENTDRUGREACTION[D.8.r.7b]
  - PATIENTDEATHREPORT[D.9.2.r.1b]
  - PATIENTDETERMINEAUTOPSY[D.9.4.r.1b]
  - PARENTMEDICALEPISODENAME[D.10.7.1.r.1b]
  - PARENTDRUGINDICATION[D.10.8.r.6b]
  - PARENTDRUGREACTION[D.10.8.r.7b]
  - REACTIONMEDDRALLT[E.i.2.1b]
  - TESTNAMELLT[F.r.2.2b]
  - DRUGINDICATIONMEDDRACODE[G.k.7.r.2b]
  - SENDERDIAGNOSISMEDDRACODE[H.3.r.1b]
- Other validations:
  - SENDERCITY[C.3.4.2]
  - SENDERSTATE[C.3.4.3]
  - SENDERPOSTCODE[C.3.4.4]
  - PATIENTMEDICALPRODUCTID[D.8.r.1.KR.1b]
  - PARENTMEDICALPRODUCTID[D.10.8.r.1.KR.1b]
  - DRUGMEDICALPRODUCTID[G.k.2.1.KR.1b]
  - SUBSTANCEID[G.k.2.3.r.1.KR.1b]

For more details, refer to *ArgusInterchange844_E2B(R3) Export Mappings*.

EMA E2B (R3) mapping changes for duration related fields

Summary

Mapping changes for Duration related fields in EMA E2B(R3) (Enhancement 36068402)

Description

The EMA profile mapping is updated to preserve the user-entered date format, when the duration includes single or multiple units. In the EMA E2B(R3) profile, export mappings are modified, so that, when the duration period field has a single unit (e.g., 2 years), the user-entered duration detail is populated in the duration element, and UCUM code is populated in the unit element. When the duration period field have multiple units, then duration is rounded to the left-most value, and the corresponding UCUM code is transmitted.

The following is the list of affected elements:

- DRUGSTARTPERIOD[G.k.9.i.3.1a]
- DRUGSTARTPERIODUNIT[G.k.9.i.3.1b]
- DRUGLASTPERIOD[G.k.9.i.3.2a]
- DRUGLASTPERIODUNIT[G.k.9.i.3.2b]
- REACTIONDURATION[E.i.6a]
- REACTIONDURATIONUNITR3[E.i.6b]
- DRUGTREATMENTDURATION[G.k.4.r.6a]
- DRUGTREATMENTDURATIONUNIT[G.k.4.r.6b]

Refer to *ArgusInterchange844_E2B (R3) Export Mappings.xlsx*.

Renamed French authority name from AFSSAPS to ANSM

Summary

French authority is renamed from AFSSAPS to ANSM (Enhancement 14147795)

Description

French authority name was renamed from Agence française de sécurité sanitaire des produits de santé (AFSSAPS) to Agence nationale de sécurité du medicament or National Agency for Drug Safety (ANSM).

Labels are changed in the case form and console from AFSSaPS to ANSM throughout the application.

Device dictionary updates

- IMDRF updates
- Self-service dictionary loader for Medical Device repository

IMDRF updates

Summary

IMDRF March 2024 updates and display of IMDRF term without dependency on FDA codes (Enhancement 36664477)

Description

IMDRF March 2024 updates
IMDRF released AER Terminology codes Annexures (A-G Annexures) in March 2024, followed by FDA releasing Annexures by for the updated FDA codes in August 2024. These updates are included as part of the factory data in IMDRF repository.
The CFG_FDA_IMDRF_CODES repository is enhanced as below:

- Annex A
  - Added terms: A0107, A020505, A050409, A210107, A2205, and A2206
  - Modified terms: A040102, A050406, A090803, and A090804
- Annex B—No change
- Annex C
  - Added term: C1701
- Annex D
  - Added terms: D1401 and D1402
  - Modified terms: D14 and D0302
- Annex E
  - Added terms: E0144, E050305, E051501, E0521, E0607, E0754, E0755, E0756, E0757, E0758, E0858, E0859, E1036, E1315, E1316, E1317, E161201, E161202, E161604, E161605, E1642, E1643, E1644, E1645, E1646, E1647, E1648, E1649, E1650, E1651, E171501, E1728, E2016, E2125, E2126, E2127, E2128, E2129, E2130, E2337, E2344, E2345, E2346, E2347, E2348, E2349, E2350, and E2351
  - Modified terms: E0106, E0512, E0751, E1626, E1707, E2123, E2108, E0619, E232401, and E232402
  - Retired term: E1026
- Annex F
  - Added terms: F29, F1008, F1910, F2308, and F2601
  - Modified term: F27
- Annex G
  - Added term: G0400501
  - Modified term: G0403001

Display of IMDRF term
Updates are made to Case Form to display IMDRF term based on the IMDRF code instead of the FDA code for the following fields in the Product > Device tab:

- Device Problem Information

- Method/Type
- Result/Findings
- Conclusion

> **Note:**
>
> The FDA code field in the case form remains blank, when devices are coded with terms using the Annexures provided by IMDRF that does not have FDA codes. You must reload the Annexures provided by FDA, and reselect this data from the IMDRF lookup to populate FDA codes.

Self-service dictionary loader for Medical Device repository

Self-service dictionary loader for Medical Device repository of IMDRF and JFMDA (Enhancement 36796475)

Description

The self service dictionary loading from Argus Console > Tools > Dictionary Management > Dictionary Loader is enhanced to support loading of IMDRF and JFMDA dictionaries.

> **Note:**
>
> You can load IMDRF and JFMDA dictionaries only from Argus Console. These dictionaries cannot be loaded from the Client-Server dictionary management tool.

IMDRF dictionary
For IMDRF dictionary, zip the Annexure A to Annexure G files for loading into Argus. The loading of files is supported with FDA code columns (FDA Code and NCIt Code), or without FDA code columns. To identify the obsolete records, the Status column in the Annexure files containing the value Retired/Not selectable is used. All other changes between the old and new IMDRF dictionaries are identified by comparing the data in the Argus and selected Annexure files used for loading.
Once the IMDRF dictionary is loaded, the latest dictionary data is used for coding devices in the following sections:

- Product > Device > Health Impact Information
- Product > Device > Evaluation / Investigation Code Information
  - Evaluation Coding – Method / Type
  - Evaluation Coding – Result / Findings
  - Evaluation Coding – Conclusion
- Product > Device > Device Component Information
- Product > Device > Medical Device Problem Coding
- Event > Clinical Sign Coding

If the case form contains IMDRF code and term that became obsolete in the latest dictionary, then the same is indicated by a red cross icon against the corresponding record, when the

case is opened after loading the latest dictionary. For obsolete records, only the IMDRF code is displayed and the IMDRF term is blank thereby indicating that it needs recoding.

Device sub-components in Annexure G
Annexure G that was loaded into Code Lists > Flexible Data Re-Categorization > DEVICE_SUBCOMONENTS are moved to the standard IMDRF dictionary table, CFG_FDA_IMDRF_CODES. This is to maintain consistency in all Annexures A to G. The custom records added in the Device Subcomponents flexible code list continue to exist. It is recommended to clean up custom records from the Device Subcomponents flexible codelist, and use standard dictionary codes and terms for coding the device component information.

JFMDA dictionary
For JFMDA dictionary, zip the Terminology Codelist XML file published by PMDA loading into Argus. Once the JFMDA dictionary is loaded, the latest dictionary data is used for coding devices in the following sections:

- Product > Device > Health Impact Information
- Product > Device > Evaluation / Investigation Code Information
  - Evaluation Coding – Method / Type
  - Evaluation Coding – Result / Findings
  - Evaluation Coding – Conclusion
- Product > Device > Device Component Information
- Product > Device > Medical Device Problem Coding
- Event > Clinical Sign Coding

JFMDA version 6.0 onwards contains currency flag with values Y or N. If the case form contains JFMDA code and term that is updated with currency as N in the latest dictionary, then the same is indicated by a red cross icon against the corresponding record, when the case is opened after loading the latest dictionary. For such records, only the JFMDA code is displayed and the JFMDA term is blank thereby indicating that it needs recoding.

WHODrug updates

WHODrug Dictionary updates

Summary

WHODrug Dictionary updates (Enhancement 36669591)

Description

September 2023 changes—Introduction of new file, Version for E2B
When loading WHODrug Dictionary (Format C3, English or Chinese) from Argus Console > Dictionary Loader self service option, a new file, Version.txt (for English) or Version.csv (for Chinese), is loaded in the sub-folder, version_for_e2b_*mon_day_yyyy*, within the WHODrug dictionary.

Data from the Version file is stored in the CFG_DICTIONARIES.VERSION_E2B table while loading the format C3 dictionary into Argus, and is used for transmitting WHO Medicinal Product ID and WHODrug Version number based on the E2B(R3) configuration.

September2024 changes—Introduction of relative strengths
When loading WHODrug Dictionary (Format C3, English or Chinese) from Argus Console > Dictionary Loader self service option, a new file, Unit Relative.txt (for English) or Unit Relative.csv (for Chinese) is loaded in the sub-folder, unit_relative_*mon_day_yyyy*, within the WHODrug dictionary.
The following updates are made to the Drug Coding screen:

- For every WHODrug record, individual strength of each ingredient is displayed in the Drug Coding screen in the Ingredients field.
- For every WHODrug record, the combined relative strength of WHODrug for all ingredients is displayed in the Drug Coding screen in the Strength column.

> **Note:**
>
> WHODrug dictionary updates are not supported in the Client-Server dictionary management tool.

WHODrug MPID - E2B(R3) updates

Summary

Transmit WHO Medicinal Product ID (MPID) in E2B(R3) reports (Enhancements 36697225 and 36634110)

Description

To ensure precise identification and tracking of medicinal products, LATAM countries like Mexico (COFEPRIS), Colombia (INVIMA), and Argentina (ANMAT) require WHO Medicinal Product ID (MPID) in the E2B(R3) reports.

The ICH E2B(R3) and EMA E2B(R3) factory profiles are enhanced to include the transmission and validation of WHO Medicinal Product ID (MPID) for each drug, as well as for any historical drugs taken by the patient or their parent.

To transmit WHO MPID and its version in the following elements, enable the Transmit WHO Medicinal Product ID option from the Argus Console > Reporting Destination > Reports tab.

- PATPASTDRUGMPIDVERSION [D.8.r.2a]
- PATPASTDRUGMEDICINALPRODID [D.8.r.2b]
- PARPASTDRUGMPIDVERSION [D.10.8.r.2a]
- PARPASTDRUGMEDICINALPRODID [D.10.8.r.2b]
- DRUGMPIDVERSION [G.k.2.1.1a]
- DRUGMEDICINALPRODID [G.k.2.1.1b]

If a case contains a WHO Drug code in B3 format, but the dictionary is configured in C3 format in the Common Profile Switch > Reporting > E2B > Regional Drugs Dictionary, then WHO MPID is automatically derived from the regional drugs dictionary.

Validations also ensure that WHO MPID used for the drug is current and available in the active WHODRUG C3 dictionary or configured regional dictionary.

In the E2B(R3) report, WHODrug MPID uses the code system OID 2.16.840.1.113883.6.294.

The E2B(R3) import for EMA and ICH remains unaffected as WHO MPID is updated in the case based on the product configuration in Argus Console.

Efficiencies

ETL Dashboard and user's local time zone updates

Summary

Support for ETL Dashboard on Oracle Autonomous Database (Enhancement 36850159)

Support for user's local time zone(Enhancement 36664533)

Description

ETL Status dashboard now displays start and end time of the ETL process in local time zone of the user, rather than GMT time zone of the server. To reflect the local time zone, the Start Date (GMT) and End Date (GMT) column headers are renamed as Start Date and End Date, respectively.

ETL Dashboard is now supported on Oracle Autonomous database.

Smart duplicate search

Summary

Smart Duplicate Search enhancements (Enhancements 36649918, 36576147, 36570653, 20308352, and 36895090)

Description

The Smart Duplicate Search feature in enhanced as below:

- You can configure PII security for the Match Score Card screen from Argus Console > Group Access. Such that, when a user does not have access to the patient and reporter information in group configuration in Argus Console, then data under the Selected Record column and Score will not appear for the fields on which restriction is applied in the Match Score Card screen.
- If site security is applied and there are restrictions on a site based on group access in Argus Console, then fields with access restrictions will not appear in the Duplicate Search grid.
- Inclusion of the Product Name as Reported field in Smart Duplicate Search.
- Related fields (like Event and Onset date/time) to be considered as single entity for Smart Duplicate Search. That is, if Event Verbatim (Description as Reported) and Onset date/time in the search criteria matches with the values from the same event from a case, then the score of such case will be higher in comparison to another case record, where Description

as Reported matches to one event while Onset Date/Time matches to Onset Date/Time for another event.

File scan to detect malicious files

Summary

File scan to detect malicious files

Description

An option to scan files uploaded in Argus is introduced by integrating any file scan system with Argus. Configure any custom file scan adapter from Argus Console > System Configuration > Webservice > Bridge Configuration > Service dropdown > File Scan, similar to document management service or translation service.

To support file scan for the Argus Cloud users, the Service Assembly section parameters, like assembly file name, class name, and configuration JSON file are automatically populated using Oracle SFS (Shared File Services). This file scan feature is configured by checking the Enable File Scan check box at enterprise level.

> **Note:**
>
> To use the file scan integration, you must configure the Common Profile Switches > Network Settings > Argus Safety API Load Balancer URL (with port 8091). This is similar to the pre-configuration required for using any of the integration like Document Management System or Translation service.

File scan once configured performs scanning of the files while uploading files into Argus Safety from the following sections. If any file is found to be malicious or if you try to open the file while scanning is in progress, an appropriate error message is displayed.

- Bookin > Attachments and References
- LAM Event > Local Info > Notes and Attachments
- Case Form
  - Additional Information > Notes and Attachments
  - Activities > Contact Log for Letter attachment
  - Patient > Lab Data > Import (only applicable for J user)
- Reports > Periodic Reports
  - Any J periodic report > Generate Final > Checkout > Update any data > Checkin (same the Checkout button changes to Checkin)
  - PSUR/CTPR > Report configuration > Template (only when Dossier is enabled)
  - PSUR/CTPR > View Argus Dossier > Additional Content > Add (only when Dossier is enabled)
- Worklist
  - Contacts > Click the Letter icon > Click YES to save the modified letter > Attach letter for case
  - Letters > Click the Letter icon > Click YES to save the modified letter > Attach letter for case

- Advanced Condition > Case Series > Import
- Utilities > Argus Unblinding > Unblinding Advanced > Randomization Data File load
- Console
  - Codelist > Letter Configuration
  - Codelist > Reporting Destination > Email Text Body
  - Codelist > Event Groups > Import
  - Interchange > Manage Profile > EMA R3/PMDA R3 > Follow-up Receive > PK Element Configuration
  - Tools > Dictionary Management > EDQM > Dictionary File
- EMA E2B(R3) and PMDA E2B(R3) XML file import having attachments

File scan is asynchronous in the following screens. You can upload file(s) and continue working while file scan continues in the background.

- Bookin > Attachments and References
- Case Form > Additional Information > Notes and Attachments

> **Note:**
>
> File scan is not performed while loading dictionaries like WHODrug, MedDRA, J Drug, IMDRF, and JFMDA. File scan is applicable only for attachments directly added in the application. Hence, features like Worklist > Intake, Worklist > J Literature Intake are not applicable because the data is read from these files and populated into Argus. These files are not uploaded into Argus.

For more information, refer to the *Oracle Argus Safety Administrator Guide*.

Retain log of emails sent from Argus

Summary

Retain a log of emails sent from Oracle Argus (Enhancement 37264766)

Description

When an email is sent from Oracle Argus using the General Email AG service, the records are deleted from the RPT_TRANSMIT_EMAIL and RPT_TRANSMIT_EMAIL_ATTACH tables upon successful email generation.

This feature is enhanced, such that, the records in the RPT_TRANSMIT_EMAIL and RPT_TRANSMIT_EMAIL_ATTACH tables are retained for a default of 30 days. You can configure this value by inserting a new record in the CMN_PROFILE table, where `SECTION = SYSTEM and KEY = MAXDAYS_RETAIN_EMAILHISTORY`.

> **Note:**
>
> Oracle recommends that you do not change this value, as increasing this to a high number could lead to performance issues in sending emails.

There is no change in the UI. Only data tables have been changed.

AI/ML features

- Smart event encoding

Smart event encoding

Summary

Event auto-encoding using AI/ML in Argus Safety (Enhancement 36147492)

Description

In this release, Argus Safety introduces the Smart Encoder, an AI/ML-powered feature that enhances the auto-coding process for medical events. The Smart Encoder uses advanced language processing and pattern recognition to accurately interpret medical event descriptions, even with variations in terminology, spelling, or phrasing.

A new profile switch, Smart - Event Encoding, is introduced under Argus Console > System Management (Common Profile Switches) > Case Form Configuration > Modify Case Form Configuration > Auto-Encoding, Dictionary & Central Encoding. This switch enables you to set a customizable threshold for the auto-coding process. The Smart Encoder output is linked to a confidence level; when this confidence meets or exceeds the threshold, the system automatically codes the event with the correct MedDRA term.

For matches that do not meet the threshold, the Smart Encoder offers a selection of suggested terms for the case processors to choose from. If multiple matches are found with top confidence, a *blue i* icon appears for you to review the entry, allowing any necessary adjustments to the coded term.

To enable Smart Event - Encoding, you must upload the Smart Event Encoding Model. The smart encoder relies on MedDRA terminology to accurately code verbatim. After each MedDRA release, a new Smart Event Encoding Model will be provided and made available for download in the zip format. For more information, see:

- Oracle Argus Safety Administration Guide
- Oracle Argus Cloud Service Administration Guide

To upload the Smart Event Encoding Model, a new dictionary type option, Smart - Event Encoder Dataset, is added in the self-service dictionary loader. Oracle recommends to apply the latest Smart Event Encoding Model to ensure optimal coding accuracy.

> **Note:**
>
> The smart MedDRA term search using the Smart Event Encoding feature is for evaluation purpose only. Hence, it is disabled by default.

When to enable this feature

To make sure the search results generated via this feature meet your quality standards, Oracle recommends you perform thorough testing and evaluation with your real-world data to assess its performance in the test environment. This will help you understand how the feature works and identify any areas for improvement. You can compare our AI results with your own quality standards.

How it works
Raise a ticket with Oracle Support to get the following information to proceed further with testing and evaluation:

- Guidelines on what to expect.
- Key metrics to measure performance.
- Tips for debugging.
- Model Card details, including the model's intended use, performance, limitations, and AI governance.

What next?
When the search results generated via Smart Event Encoder are validated and meet your expectations, the product team will work with you on the next steps to deploy this feature for product usage.
We will also provide a formal validation pack when the feature is fully released to make sure it meets all regulations and is based on the real-world performance data. We are committed to working with you to make sure our AI feature generate optimal suggestions.

Enhancements to Oracle Argus Interchange

The following are the enhancements to Oracle Argus Interchange:

Flexibility to process time stamp in acknowledgments

Summary

Flexibility to process time stamp in acknowledgments (Enhancements 33857559 and 36343082)

Description

A new drop down, Local time zone to process Date/Timestamp values of Ack, is added in Argus Console > Code Lists > Argus > Reporting Destination > EDI tab.

This drop down lists all the time zones, where values are similar to Common Profile Switch > Database > Database Server OS Timezone.

When an E2B(R3) acknowledgment file is imported, and if the value in the MESSAGEDATER3[ACK.M.4] element does not contain offset +/-ZZzz,

Or

When a PMDA Device ACK file is imported, and if the value in the ACKCREATEDATE[ACK.6] element does not contain offset,

Then user configured offset is applied to the MESSAGEDATER3[ACK.M.4] element, ACKCREATEDATE[ACK.6] element, and the application considers the value as per the time zone set in the parameter.

Configure Private Key Alias

Summary

Configure Private Key alias in Argus for handling multiple certificates in Oracle B2B (Enhancement 36839445)

Description

To support multiple host AS2 identifiers, the Oracle B2B integration was enhanced in Oracle Argus Safety 8.4.3. For each host AS2 identifier, an alias for host certificate must also be configured.

A new field is introduced in Argus Console > Code Lists > Argus > Reporting Destination > EDI > Company Key to capture the alias for host certificate or DOC ID. This value is read by Oracle B2B Outbound Jar and is used for fetching the matching Company Key from B2B configuration which is populated into the message header.

Configure additional Company AS2 Identifier

Summary

Configure additional Company AS2 Identifier in Argus for creating Gateway Header in Oracle B2B as required by PMDA (Enhancement 36896253)

Description

A new field is introduced in Argus Console > Code Lists > Argus > Reporting Destination > EDI > Company AS2 Identifier to configure the host AS2 identifier. If this value is different from the value in the Company Identifier field, then this value is read by the Oracle B2B Outbound Jar and displayed in the header as follows:

```
FROM_PARTY=AS2 Identifier: <CompanyAS2Identifier>
```

Enhancements to Oracle Argus Safety Japan

The following are the enhancements to Oracle Argus Safety Japan:

- PMDA E2B(R3) updates
- PMDA E2B import to populate specific license only
- Allow free text for IMDRF and JFMDA terms
- Japan Literature Intake updates
- Local fields updates

PMDA E2B(R3) updates

Summary

PMDA E2B(R3) updates (Enhancement 36191301)

Description

PMDA E2B(R3) is updated as per the J Item OID and code list published on 17-Jan-2024 as below:

- A new code list value, Phase I/III (第Ⅰ/Ⅲ相), is added to Console > Code list > Argus > Study Development Phase.

  This code list is added as Allowed Value for MHLWPHASEOFSTUDIES[J2.13.r.3] for PMDA E2B(R3) profile.
- The E2B_R3 code for DEV_PHASE in Console > Code list > Flexible Data Re-Categorization is set to 6.
- The MHLWPHASEOFSTUDIES[J2.13.r.3] [Ver] is updated from 1.1 to 1.2.

For more information, refer to A*rgusInterchange844_PMDA E2B(R3) Export Import Mappings.xlsx*.

PMDA E2B import to populate specific license only

Summary

Populate specific license only on PMDA E2B import for non-study case when switch is User Selected License only (Enhancement 35613967)

Description

When Common Profile Switch > Argus J > Japan License to be available in case for Assessment and reporting, is set to User Selected License only, the PMDA E2B(R3) ICSR import for a Japan domestic non-study case populates only the specific Japan license in the Event Assessment tab and PMDA tab.

The specific license is same as the license displayed in the Products tab.

Allow free text for IMDRF and JFMDA terms

Summary

Allow free text for IMDRF and JFMDA terms (Enhancement 35634362)

Description

You can enter IMDRF and JFMDA free text in the IMDRF coding screen and JFMDA coding screen respectively, when it is selected from the following sections of the case form:

- Product > Device > Health Impact Information
- Product > Device > Evaluation / Investigation Code Information section
  - Evaluation Coding – Method / Type
  - Evaluation Coding – Result / Findings
  - Evaluation Coding – Conclusion
- Product > Device > Device component information
- Product > Device > Medical Device Problem Coding
- Event > Clinical Sign Coding

You can either select any term from standard IMDRF or JFMDA dictionary, or choose to add the free text from the coding window. This free text is then populated in the case form in the IMDRF term field or JFMDA term field.

- When free text is added in IMDRF term, the IMDRF code is appears as <not available>, only in the case form.
- When free text is added in JFMDA term, the JFMDA code is auto populated and stored with value 999-9999.

The JFMDA Code field is added to the case form English screens, to make you aware when a Japanese free text is entered in the JFMDA code field, by displaying 999-9999.

- When the JFMDA term field has free text, the global user is allowed to select a new or different IMDRF value without removing the JFMDA data.
- When the IMDRF term field has free text, the Japanese user is allowed only to enter free text.

If you select any term from the standard JFMDA dictionary that contains corresponding IMDRF code and term, then an error message is displayed that the IMDRF free text cannot be overwritten.

The JFMDA free text and the 999-9999 code are transmitted in the PMDA device XML and paper forms.

Japan Literature Intake updates

Summary

Support product selection during Japan Literature Intake (Enhancement 31191760x)

Description

The Worklist > Literature Intake > Processing tab is enhanced with a new context menu option, 製品の指定 (Assign Products).

When you select this option, a list of Japanese products (configured in Argus Console) appear as per the assigned Product Family (製品群) in the Processing tab. You can select one or more products for that literature record.

Selected products are displayed under the new column, 製品名 (Product Name), in the grid in the Processing tab and Processed tab.

After processing the literature record, the Book-in screen populates the product name(s) assigned by you in the literature record. These products are then added to the case created for the literature record. If the product name(s) is not assigned in the literature record, then the product family name(s) is populated as per the existing functionality.

You can also use this feature to select products to be populated in the case created for the literature record.

Local fields updates

Summary

Local fields updates (Enhancements 36393831, 36721125, 29149299, 36506603, 35504168, and 36842668)

Description

The following fields are editable for the Oracle Argus Safety Japan users in a locally unlocked case:

- Case Form > Events > Seriousness Criteria > Other > Other text (J)
- Case Form > Products > Product Information > J drug code in a study case for a broken study or not blinded study
- Case Form > General > Amendment / Follow up Justification (J) in an existing follow-up record, if there are no final generated Japanese reports against that follow-up record
- Case Form > Product > Device > Causality, Listedness, Suspicion or Risk fields in the Device Problem section and Health Impact section
- Case Form > Events > Clinical Sign > Suspicion or Risk

Additionally, the Amendment check box available in the Case Form > General tab is now added to the Case Form > Analysis > PMDA tab as a read-only field.

Merged Patches

The following patch has been merged with Oracle Argus 8.4.4:

- 8.4.2.1
- 8.4.2.001
- 8.4.3.1
- 8.4.3.2

Download Oracle Argus 8.4.4

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/Argus Insight—**36775782**
   b. Argus Mart—**36775790**
   c. Argus Analytics—**36775796**
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 8.4.4 Installer.

Install Oracle Argus 8.4.4

To install Oracle Argus Safety and Oracle Argus Insight, see the *Oracle Argus Safety and Oracle Argus Insight 8.4.4 Installation Guide*.

To install Oracle Argus Mart, see the *Oracle Argus Mart 8.4.4 Installation Guide*.

To install Oracle Argus Analytics, see the *Oracle Argus Analytics 8.4.4 Installation Guide*.

Upgrade Oracle Argus database

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

To upgrade Oracle Argus Safety, see:

- Database upgrade version
- Upgrade Oracle Argus Safety from 8.1.x to 8.4.4
- Upgrade Oracle Argus Safety from 7.x to 8.0 and 8.0.0.x to 8.1

Database upgrade version

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

- Oracle Argus Safety
  - 8.1
  - 8.1.1
  - 8.1.2
  - 8.1.2.1 to 8.1.2.6
  - 8.1.3 to 8.1.3.2
  - 8.2
  - 8.2.0.1 to 8.2.0.8
  - 8.2.1 to 8.2.1.11
  - 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 to 8.4.0.3
  - 8.4.1
  - 8.4.2
  - 8.4.2.001
  - 8.4.2.1
  - 8.4.3
  - 8.4.3.1
  - 8.4.3.2
- Oracle Argus Insight
  - 8.1 to 8.4.4 including merged patches
- Oracle Argus Mart
  - 8.1 to 8.4.4 including merged patches

- Oracle Argus Analytics
  - 8.1 to 8.4.4 including merged patches

Upgrade Oracle Argus Safety from 8.1.x to 8.4.4

See the *Oracle Argus Safety and Oracle Argus Insight 8.4.4 Installation Guide*.

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

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

   Refer to the *Oracle Argus Safety and Oracle Argus Insight 8.4.4 Installation Guide, Section Oracle Components.*
4. From Oracle Argus Safety `8.9.9.003` patch (patch ID: 30398730), use one of the following upgrade folders and paste it on the server where Oracle Client is installed.
   - To upgrade from 7.x to 8.0, use `.\Argus_Database_Upgrade\1-Upgrade_from_7x_to_80`.
   - To upgrade to 8.0.0.x to 8.1, use `.\Argus_Database_Upgrade\2-Upgrade_from_800x_to_81`.

     When copied, update the `dbinstaller.properties` file as mentioned below:
     - **ArgusSecurekey** location
     - **TDE** attribute (if required) with the required connection details.
     - All the user details present in the properties file.
     - Parameters as specified for the Oracle Argus Safety Database setup.
       For more details, refer to the *Oracle Argus Safety and Oracle Argus Insight 8.4.4 Installation Guide, Section Oracle Argus Safety Database Upgrade*.

     Alternatively, to upgrade Oracle Argus Safety from the user interface, go to the `2-Upgrade_from_800x_to_81\dbinstaller` folder, open the command prompt, and run the `dbinstallerUI.bat` file as an administrator.

     For more details to upgrade from the user interface and for silent upgrade (using the `dbinstaller.bat` file), refer to the *Oracle Argus Safety and Oracle Argus Insight 8.4.4 Installation Guide, Section Oracle Argus Safety Database Upgrade*.
5. Upgrade Oracle Argus Safety from 8.1.x to 8.4.4.
6. Validate the Oracle Argus Safety and DLP Schema, refer to the *Oracle Argus Safety and Oracle Argus Insight 8.4.4 Installation Guide, Section Validate Oracle Argus Safety Database*.
7. Verify the validation log file and make sure that there are no errors, missing and invalid objects. Ignore any extra objects in validation due to dlp_case_rev_master_bkp and tmp_dcrm_upd_data, these objects are related to dlp_case_rev_master correction script.

Revision History

Date, Version	Description
May 2025, Version 2	Added more information to the Gen AI Narrative and Smart Event Encoder features.
February 2025, Version 1	Initial version of the release notes.