Oracle Life Sciences Argus

What's New

Release 2026.1.01
G50232-02
April 2026

Oracle Life Sciences Argus What's New, Release 2026.1.01

G50232-02

Contents

Preface

This preface contains the following section:

- Related resources

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.

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About this release

Argus Safety 2026.1.01 adopts a new versioning scheme for clarity and consistency across the application suite. The format of release number is YYYY.Q.RR, where:

- YYYY represents the year of the release, like 2026.
- Q is the quarter in which the release is made, like 1 for Q1, 2 for Q2, and so on.
- RR is the sequential number of the release, like 01.

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What's New

Technology Stack

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

- Oracle Database Server 19c (19.18+)
- Oracle Database Client 19c (19.18+)
- Oracle B2B 12.2.1.4 + B2B Patch 37539806 + UMS Patch 37930589
- Axway 2.6 UP 2025-11
- Oracle Analytics Server 2025

See:

- Dictionary support

Dictionary support

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

Dictionary	Supported versions
MedDRA Dictionary	29.0 (March 2026) 28.0 (March 2025), 28.1 (September 2025) 27.0 (March 2024), 27.1 (September 2024) 26.0 (March 2023), 26.1 (September 2023)

Dictionary	Supported versions
WHO Drug Dictionary (Format: B3 and C3, both English and Chinese)	March 2026 March 2025, September 2025 March 2024, September 2024 March 2023, September 2023
Link Korea (Format: B3 and C3)	March 2026 March 2025, September 2025
J Drug Dictionary	April 2025, October 2025 April 2024, October 2024 April 2023, October 2023
JFMDA Dictionary	6.0 and above
IMDRF Dictionary	2024 (Annex A to G, separate excel files) 2025 (Annex A to G, one consolidated excel file)

Oracle Argus Compatibility Matrix

Application	Compatible Version with this Argus Safety Release
Oracle Argus Analytics	8.4.4
Oracle Argus Insight	2026.1.01
Oracle Argus Mart	2026.1.01
Oracle Life Sciences Empirica Signal and Oracle Life Sciences Empirica Topics	2025.4.01

Enhancements to Oracle Argus Safety

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

- Regulatory enhancements
- Case processing enhancements
- Dictionary enhancements
- Technical enhancements

Regulatory enhancements

- EMA(R3) masking rule updates
- HTTPS support for EMA E2B(R3) reporting
- Mapping changes for E2B(R3) reports for Null Flavor data
- Support for EC Manufacturer Incident Report (MIR) version 7.3.1
- MHRA Windsor framework updates
- Logic update for 15-day report in NDA report
- MedWatch 3500A January 2025 updates

- Default MedWatch profile used for NDA reporting
- FAERS E2B(R3) updates for IND report
- Mapping changes for FAERS MEDICINALPRODUCT[G.k.2.2]

EMA(R3) masking rule updates

Summary

EMA(R3) masking rules as per GVP Module VI Addendum II publication (Enhancement 38245158)

Description

EMA published guidelines on good pharmacovigilance practices (GVP) Module VI Addendum II – Masking of personal data in individual case safety reports submitted to EudraVigilance. Argus is enhanced to support updated regulatory guidance.

The checkbox, Apply EMA Masking Rules, is added in the Console > Reporting Destination > Reports tab. When EMA R3 profile (standard or custom) is selected in Message Profile, the checkbox is enabled for selection. If this is set, then mapping changes are applied to the EMA E2B R3 report as per the masking rules defined in GVP Module VI Addendum II publication for elements that require changes in Argus.

> **Note**
>
> Other elements are not impacted as they already satisfy the defined rules.

- E2B(R3) data elements to be masked
  - REPORTERTITLE[C.2.r.1.1]
  - REPORTERGIVENAME[C.2.r.1.2]
  - REPORTERMIDDLENAME[C.2.r.1.3]
  - REPORTERFAMILYNAME[C.2.r.1.4]
  - REPORTERORGANIZATION[C.2.r.2.1]
  - REPORTERDEPARTMENT[C.2.r.2.2]
  - REPORTERSTREET[C.2.r.2.3]
  - REPORTERPOSTCODE[C.2.r.2.6]
  - REPORTERPHONE[C.2.r.2.7]
  - PATIENTGPMEDICALRECORDNUMB[D.1.1.1]
  - PATIENTSPECIALISTRECORDNUMB[D.1.1.2]
  - PATIENTHOSPITALRECORDNUMB[D.1.1.3]
  - PARENTIDENTIFICATION[D.10.1]
- E2B(R3) data elements to be left blank
  - SENDERTITLE[C.3.3.2]
  - SENDERGIVENAME[C.3.3.3]
  - SENDERMIDDLENAME[C.3.3.4]

  - SENDERFAMILYNAME[C.3.3.5]
  - SENDERSTREETADDRESS[C.3.4.1]
  - SENDERCITY[C.3.4.2]
  - SENDERSTATE[C.3.4.3]
  - SENDERPOSTCODE[C.3.4.4]
  - SENDERCOUNTRYCODE[C.3.4.5]
  - SENDERTELR3[C.3.4.6]
  - SENDERFAXR3[C.3.4.7]
- E2B(R3) data elements send the data without masking
  - REPORTERCITY[C.2.r.2.4]
  - REPORTERSTATE[C.2.r.2.5]
  - PATIENTINITIAL[D.1]
  - PATIENTBIRTHDATER3[D.2.1]
  - PARENTBIRTHDATER3[D.10.2.1]
  - PATIENTINVESTIGATIONNUMB[D.1.1.4]

For more details, refer to *ArgusInterchange2026.1.01_E2B (R3) Export Mappings.xlsx - EMA E2B(R3) export mapping document.*

HTTPS support for EMA E2B(R3) reporting

Summary

EMA Phasing out HTTP URLS to use HTTPS for E2B(R3) reporting (Enhancement 38561645)

Description

EMA has announced that HTTP access to schemas will be phased out by April 2026 due to security concerns. To align with this directive, this release introduces support for HTTPS schema references for the following profiles:

- ICH-ICSR V3.0 MESSAGE TEMPLATE – EMA
- ICH-ICSR V3.0 ACKNOWLEDGMENT TEMPLATE – EMA
- E2B R3+ (Safety One Intake profile, applies only to Safety One Argus)

Custom profiles created from these factory profiles will also reference HTTPS, ensuring secure data transmission and compliance with EMA requirements. There is no impact on the reports that are already transmitted before upgrade.

Mapping changes for E2B(R3) reports for Null Flavor data

Summary

Enhancement to E2B(R3) reports when Protect Confidentiality is enabled and case data has null flavor (Enhancement 38051289)

Description

The Argus E2B(R3) generation logic is enhanced to correctly handle Null Flavor values when the Protect Confidentiality flag is enabled. Previously, allowed Null Flavor values (e.g., UNK,

ASKU) were replaced with MSK during transmission. With this enhancement, Null Flavor values entered in the case are retained as-is, and MSK is applied only when actual patient/ reporter data is present and confidentiality must be protected. This change ensures compliance with ICH E2B(R3) guidelines and EMA GVP masking rules.

Impacted profiles include:

- EMA E2B(R3) – ICH-ICSR V3.0 MESSAGE TEMPLATE – EMA
- FDA E2B(R3) – ICH-ICSR V3.0 MESSAGE TEMPLATE – FAERS

Support for EC Manufacturer Incident Report (MIR) version 7.3.1

Summary

Support for EC Manufacturer Incident Report (MIR) version 7.3.1 (Enhancements 38335935 and 38509479)

Description

Argus Safety is enhanced to support the Manufacturer Incident Report (MIR) version 7.3.1 (SB-10781) published by the European commission in December 2025.

> **Note**
>
> The European Commission released MIR version 7.3.1 (SB-11010) in March 2026. We will support this update in a future release. SB-11010 includes only technical corrections to the PDF and does not introduce any new regulatory content or data fields.

The enhancements include new Interchange profiles, new fields to support new elements, code list have been updated with new values and attributes, length changes to existing case form fields.

Code list updates
The following flexible code lists are enhanced:

- New factory data value is added for Medical Device Info
- New factory data and attributes are added for Device UDI System and Risk Class Type
- New attribute is added for Manufacturer

Configuration related updates
The following are new fields included in License configuration screen:

- Issuing Entity Basic UDI-DI
- Device Description
- Agency Delivering Scientific Opinion
- Name(s) of Medicinal Product associated with the device

Interchange mapping
A new profile, EC-MIR V7.3.1 MESSAGE TEMPLATE, is provided with default export mappings. There are no updates made to the existing MIR 7.2.1 profile, as the users with reporting obligation to European Commission are expected to use the MIR 7.3.1 profile.

For mapping changes, see the *ArgusInterchange_2026.1.01_MIR7.3.1_Export Mappings sheet*.

Report generation, tracking and transmission
MIR reports can be scheduled or generated manually or automatically. The MIR viewer allows you to preview the report and to switch between XML and PDF formats.
When the final MIR report is generated, it can be transmitted manually or automatically via Argus services. MIR reports are transmitted to the configured agency by email only, and the report is sent in XML or PDF format based on the reporting destination configuration. You can track transmission of MIR reports in the Bulk Reporting screen, and you can view submitted reports under Worklist > Bulk Transmit.
Regenerating an MIR 7.3.1 report for a previously generated MIR 7.2.1 report with the status set as New data available is not supported. It is recommended to create a follow-up MIR instead of regenerating the report.

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

Case Form enhancements
New fields have been added in Products > Device window to capture additional device related data to support MIR reporting:

- Issuing Entity UDI-DI
- Issuing Entity Unit of Use UDI-DI

When coding is performed using IMDRF annexures, if there is no appropriate IMDRF code available to describe information required in the relevant Annexures, the European Commission (EC) recommends the use of specified default IMDRF codes along with a brief explanation of why a suitable code or term could not be selected. In Prior version of Argus, you were allowed to select either a IMDRF code or enter free text in the IMDRF lookup corresponding to various annexures. If you selected the IMDRF code along with free text, then the IMDRF code was cleared and only the free text was retained. Now, if you select an IMDRF code and enter free text, then the IMDRF code and the free text data are retained in the relevant fields available in the sections listed below.

- Annex A—Products > Device > Device Problem Information
- Annex B , Annex C, Annex D—Products > Device > Evaluation /Investigation Code Information
- Annex E—Events > Clinical Signs IMDRF Code
- Annex F—Products > Device > Health Impact Information
- Annex G—Products > Device > Device Component Information

In the Products > Device > EU/CA Device window, the Does the incident represent a serious public health threat? field is renamed to Does the incident qualify to be reported?. When you set this field to Yes, then the new field introduced Manufacturer awareness date of reportability is automatically populated with the current system date, which can be changed to the user's preferred date.
The following enhancements have been made to the Products > Device > Similar Incidents window:

- Similar Incident Analysis Based on field is added, with a new dropdown option Annex C.

- New EEA+TR+XI fields have been introduced to capture results of counts of similar incidents and devices.

> **Note**
>
> The existing EEA+CH+TR fields are retained only for displaying legacy case data and in MIR 7.2.1 profile mappings but are not used in MIR 7.3.1 XML export mapping. The identification and computation of count of similar incidents and devices is performed outside the Oracle Argus system, and fields are provided to capture the results in the Similar Incidents window.

Argus Safety Japan enhancements for JFMDA
As a Japanese user, if you select any term from the standard JFMDA dictionary that is associated with a different IMDRF code than the one entered by the global user, then an error message is displayed indicating that the IMDRF free text cannot be overwritten.
When there are data already available containing IMDRF code and term in a globally locked and locally unlocked case, a Japanese user is now able to successfully add the JFMDA code associated with the same IMDRF code.

Field length enhancements
Data length for the following fields has been increased as per guidelines from European Commission:

- EU/CA Device tab
  - Remedial Action by HC Facility is changed from 1000 AN to 2000 AN
  - Rationale for Not Reportable is changed from 2000 AN to 4000 AN
  - Rationale is changed from 2000 AN to 4000 AN
- Products > Device tab
  - Preliminary Comments is changed from 2000 AN to 4000 AN
  - QC Result is changed from 2000 AN to 4000 AN

For changes to the Case Form fields and Argus Console fields, see the *OracleArgusSafety2026.1.01_CaseForm_Console_Updates_Summary document*.

For more information on MIR report configuration and FAQ details, see the *Manufacturer Incident Report (MIR) Best Practices*.

> **Note**
>
> With the introduction of the Textfields Printable Summary section in the MIR 7.3.1 (SB-10781) PDF report template, the previous PDF Grow field data output on the continuation page has been removed.
> For the list of text fields printed in this new section, refer to the *ArgusInterchange_2026.1.01_MIR7.3.1_Export Mappings sheet*.

MHRA Windsor framework updates

Summary

MHRA Windsor Framework updates (Enhancement 37661328)

Description

Windsor Framework came into force on 01 January 2025 to enable medicines to use the same packaging and labelling across the UK and allow additional medicines to be approved and licensed on a UK-wide basis by the MHRA.

Argus is enhanced to include a new License Category field in Console > Products and Licenses > License configuration. The License Category is a drop-down driven by a flexible code list, allowing single value selection per license.

The License Category values are configured in Console > Code Lists > Flexible Data Re-Categorization, under the following:

- Code List Name: LICENSE_CATEGORY_OTHER
- Factory values:
  - Category 1 – UK only license
  - Category 1 – UK and EU license
  - Category 2 – UK only license
  - Category 2 – UK and EU license

The License Category field is blank by default and is not a mandatory field. It does not appear in the case form. While this update is intended for UK licenses at the License level, it is available for all product licenses. Customers are advised to configure Products and Reporting Rules in order to adhere to MHRA Windsor framework guidelines.

For more information, refer to the *OracleArgusSafety2026.1.01_CaseForm_Console_Updates_Summary* document.

Logic update for 15-day report in NDA report

Summary

NDA report is enhanced to exclude non-expedited cases submitted to US-FDA from the List of 15-day reports section (Bug 19548533)

Description

The generation of NDA report from Argus is enhanced to refine the logic for inclusion of cases in NDA report's 15-Day Alert sections. The revised logic includes only expedited reports submitted to FDA in MedWatch, E2B, eVAERS, eMDR report forms and reporting timelines <= 15 days.The non-expedited cases (reports with reporting timelines exceeding 15 days) are excluded from List of 15-day Alert sections.

When the **Tab 3 Part 1: NDA Line Listing 15 Day Reports Submitted** and **Print ____ Forms for Agency _____ for all Cases in the Report and 15 Day Submitted Cases** parameters are selected in the inclusion criteria, the List of 15-Day Reports by System Organ Class and Additional Expedited Report Forms > 15 Day submitted cases sections of NDA report now include only Serious cases that meet the following criteria:

- Reports that are submitted to Primary Agency Specified in the inclusion criteria
- Report submission date that falls within the time period specified in the inclusion criteria
- Submission report formats are VAERS/eVAERS, MedWatch 3500A, eMDR or E2B
- Report submission due date is 15 days or less

- Message type[M.1.1] selected for E2B(R2) and Batch Message type[N.1.1] for E2B(R3), eVAERS is Expedited

Cases with Report submission due date greater than 15-days are excluded from the above sections.

The updated logic also impacts the case listings and tabulation in the following sections of the NDA report when selected in the inclusion criteria.

- Tab 3 Part 2: Tabulation by System Organ Class(SOC) of All Event Reports Submitted
- Tab 3 Part 3: Cases sent to FDA under another NDA

When the parameter 'Include Listing of Nullified 15-day Alert Cases Submitted During the Reporting Period' is selected in the inclusion criteria, only nullification reports that meet the following criteria are included:

- Reports that are submitted to Primary Agency Specified in the inclusion criteria
- Report submission date that falls within the time period specified in the inclusion criteria
- Submission report formats are VAERS/eVAERS or E2B
- Report submission due date is 15 days or less
- Message type[M.1.1] selected for E2B(R2) and Batch Message type [N.1.1] for E2B(R3), eVAERS is Expedited

MedWatch 3500A January 2025 updates

Summary

MedWatch 3500A template enhanced for January 2025 version (Bug 37562381)

Description

The MedWatch drug report generated in Argus is updated based on the January 2025 version of the MedWatch 3500A template published by the FDA. The changes are as follows:

- Box 3a Sex is renamed to 3 Sex and the Undifferentiated and Decline to answer options are removed.
- The contents of Box 3b are removed and the Section removed text is displayed in the box that before was used for printing box 3b Gender information.
- The Footer of the report is changed from Form FDA-3500A MedWatch(11/22) to Form FDA-3500A MedWatch(01/25).
- Content related to Privacy Act Statement / PRA information has been revised as per the latest template.

Default MedWatch profile used for NDA reporting

Summary

Default MedWatch profile used for NDA report (38240551, 38330511)

Description

A new common profile switch is provided for accurate case categorization in NDA/PADER periodic safety reports, when the Primary Agency is not linked to a MedWatch profile. This enhancement resolves prior misclassification of cases as initial submissions instead of follow-

ups in Tab1 line listing of NDA report and incorrect report sequence number in MedWatch reports generated as part of NDA report.

The common profile switch, **Default MedWatch Profile used for NDA report if Primary Agency is not configured with MedWatch Profile**, is added under System Configuration > Common Profile Switches > Reporting > Periodic and it is set to FDA MEDWATCH 3500A DRUG TEMPLATE by default. This switch displays a list of factory-defined and custom-created MedWatch profiles.

If the Primary Agency set in NDA/PADER does not have an associated MedWatch profile, the system uses the profile specified in a common profile switch to generate a MedWatch report when Line listing- Tab 1: FDA-3500A / VAERS Forms is selected in the NDA/PADER periodic report.

FAERS E2B(R3) updates for IND report

Summary

FAERS profile support for use cases with pre-ANDA and spontaneous IND causality validation (Enhancement 38191786)

Description

While generating an IND report from a spontaneous case, the system currently enforces a validation requiring at least one causality assessment source to be Sponsor. However, in the IND reports generated from spontaneous cases, the source may not always be a sponsor—it could be the Marketing Authorization Holder (MAH) or the pharmaceutical company itself.

In FAERS, the existing validation that enforces source to be a sponsor (Source = Sponsor) is removed for the IND report generated from spontaneous cases.

For spontaneous IND reports, the system now allows any value for the causality assessment source (like MAH or pharma company). The causality assessment is directly mapped to the following elements:

- DRUGASSESSMENTSOURCE [G.k.9.i.2.r.1]
- DRUGASSESSMENTMETHOD [G.k.9.i.2.r.2]
- DRUGRESULT [G.k.9.i.2.r.3]

Mapping changes for FAERS MEDICINALPRODUCT[G.k.2.2]

Summary

FAERS MEDICINALPRODUCT[G.k.2.2] value re-mapped to populate Product Name instead of Product Name as Reported (Enhancement 38481094)

Description

With the upgrade to version 8.4.4, in FAERS report, the MEDICINALPRODUCT[G.K.2.2] element transmitted the Product Name as Reported field from Case Form > Products whenever that information was available.

Mapping of the MEDICINALPRODUCT[G.K.2.2] element is updated to restore the application behavior in accordance to pre-Argus 8.4.4 functionality, ensuring that the encoded product name from the Case Form > Products > Product Information > Product Name field is correctly printed in the MEDICINALPRODUCT[G.K.2.2] element within the FAERS E2B(R3) report instead of the Product Name as reported field.

Case processing enhancements

Ability to track failed emails status

Summary

Ability to track failed emails status from Utilities > View Audit log

Description

When emails are sent from Argus Safety, the status of the failed emails is logged and can be viewed from the Utilities > View Audit log. You can retrieve the details of the failed emails by selecting the Category as E-mail and search, such as:

- Email subject
- Reason for failure
- Email IDs to which the email was sent
- User ID

The details of successful emails are no longer displayed.

> **Note**
>
> The Category E-mail/Fax field is renamed as the E-mail field, and fax entries are no longer displayed.

> **Note**
>
> This feature is applicable for emails sent from Argus Safety. It is not applicable for emails sent from Safety One Argus.

Allow zero value and enhance auto-calculation logic of Gestation Period at Exposure

Summary

Allow zero value and enhance auto-calculation logic for the Gestation Period at Exposure field in the Products tab (Enhancement 37812168)

Description

Argus Safety is enhanced to enter and save zero (0) as a valid value in the Case Form > Products > Gestation Period at Exposure field.

Additionally, the auto-calculation logic is refined as follows:

- The gestation period is automatically calculated as the difference between the Date of First Dose for the product and the LMP Date, when available.
- This auto-calculation is performed only if the Due Date (from Pregnancy information) is greater than or equal to the First Dose date for the product.

> **Note**
>
> - Both the First Dose and LMP Date fields must have complete dates for the calculation to proceed. If LMP Date and Due Date are available for both patient and parent, then the patient's data is prioritized for auto-calculation.
> - You can now manually enter or edit the Gestation Period at Exposure value. If a value is manually entered, the system will not overwrite this entry with the auto-calculated data upon saving.

The Gestation Period at Exposure value, including 0 with the unit Days/Weeks/Months/Trimester, is now correctly populated in the E2B(R2) and E2B(R3) files.

- E2B(R2) for ICH, EMA, FDA profiles
  - REACTIONGESTATIONPERIOD[B.4.k.10a]
  - REACTIONGESTATIONPERIODUNIT[B.4.k.10b]
- E2B(R3) for ICH, EMA, FDA, MFDS, NMPA and PMDA profiles
  - REACTIONGESTATIONPERIOD[G.k.6a]
  - REACTIONGESTATIONPERIODUNITR3[G.k.6b]
- During E2B(R3) and E2B(R2) files import, the UI fields for the Gestation Period at Exposure and Unit fields is populated when the value 0 and corresponding unit as present in the imported XML:E2B(R2) for ICH, EMA, FDA profiles.
  - REACTIONGESTATIONPERIOD[B.4.k.10a]
  - REACTIONGESTATIONPERIODUNIT[B.4.k.10b]
- E2B(R3) for EMA and PMDA profiles
  - REACTIONGESTATIONPERIOD[G.k.6a]
  - REACTIONGESTATIONPERIODUNITR3[G.k.6b]

For more information, refer to the *E2B(R3) and E2B(R2) Export and Import mapping* documents.

Study drug data population in a study case

Summary

Updates to data population in case form product tab in study cases (Enhancements 32817082, 38290389, 36877711, 30481629, and 37634347)

Description

When a study drug is selected in a study case, the data in specific fields are populated based on the selected study drug. Data population of the case form fields is enhanced:

- for a blinded study when broken and study drug is selected
- for a not blinded study added to the study case and study drug is selected
- when the study drug already selected is replaced with another study drug
- when a new study drug is added to the case using the Add study drug option
- study drugs are selected though EOSU lite, EOSU advanced

Fields that are enhanced:

- Drug authorization country—This field is populated based on the Country of Incidence.
- Market authorization holder, Authorization type, Authorization number, WHO Record ID
  - If study drug selected is associated with Study Configuration > Primary License (when configured in Console), then populate data based on the Primary License.
  - If study drug selected is not associated with Study Configuration > Primary License (when configured in Console), then populate data based on the Individual Product License (when configured in Console).
  - If study drug is selected but if Study Configuration > Primary License is not configured and Individual Product License is not configured, then pick the license with license country = DAC. If there are multiple licenses for same country, pick the first license for that country as displayed in the Study Configuration > Product > License drop-down (order of display is based on License Country, License Number, Trade Name). If no matching license, do not populate data.
  - For WHO Record ID, if the data is not configured at the license level in console, then populate the data from product level in console if configured.
- Product Indication—This field is populated from Console > Product > Primary Indication based on the study drug selected. If user updates study drug in case form, refresh the Primary Indication as per the study drug selected. User can add, modify or delete the indication in case form.

> **Note**
>
> When a non-company study drug (like WHODrug) is selected or updated in Case Form > Products > Study Drug for a case with a not blinded study or unblinded study, then the Authorization Number, Drug Authorization country, Market Authorization Holder, Authorization type data are not populated, and it is cleared if it was already populated. WHO Record ID is populated from the corresponding WHODrug dictionary if using C3 format only.

Automatic switchover to Single Product View in Event Assessment screen based on threshold

Summary

Event assessment switches to Single Product view based on the configuration set for cases with a large volume of event assessment records (Enhancement 37689252)

Description

The Case Form > Event Assessment screen is enhanced to automatically switch to a single product view based on the values provided in the new common profile switch, Row limit for automatic switching to Single Product view. This new common profile switch has been added to Common Profile > Case Processing > Assessments.

Thus, the Event Assessment screen allows user operations for cases with a large number of records displayed on the Event Assessment window. The default value is set to 5000 and it is configurable within the range of 1 to 99,999. When the total number of rows in event assessment exceeds 5000, then the Event Assessment screen automatically displays assessments for only one product at a time.

When the single product view is set automatically in a case, the options to view All, Company Product(s), and Non-Company Product(s) are not available in the Event Assessment > Product selection list of values. This enables a responsive event assessment window and allows user operations for cases with a large number of records.

This new switch applies only to cases where the threshold exceeds the row limit for automatic switching to Single Product view.

Ability to identify user who generated report

Summary

Tracking of expedited report generation using routing entries (Enhancement 36130754)

Description

Tracking expedited (E2B and paper) reports generation and routing in the Report Details > Routing screen and audit logs is enhanced to capture entries for reports generated by both AG service and users.

When final reports are generated by the AG service or manually by users, a new row is now added to the Routing section in the Report Details > Routing screen invoked in the following locations:

- Case Form > Regulatory Reports > View Report Details
- Worklist > Reports > View Report Details
- Worklist > Bulk Transmit > View Report Details
- Worklist > Bulk ICSR Transmit > View Report Details
- Reports > Compliance > Expedited > View Report Details
- Reports > Compliance > Periodic > View Report Details
- Reports > Compliance > Submitted > Report Details
- Reports > Bulk Reporting > Report Details

- Local Affiliate > Report Distribution > Report Details
- Local Affiliate > Report Submission > Report Details

Each entry includes date/time, user, and associated comments. For paper and E2B reports generated by PSUR, CTPR, and NDA final reports, the date/time, user, and comments are similarly recorded in the Report Details screen.

Additionally, the Audit Log under Utilities > Logs > View Audit Log > Category > Cases now reflects the specific user (business or AG service) responsible for changing scheduled and generated states of expedited and periodic reports.

> **Note**
>
> Report state transition and user details are available for actions performed after the upgrade to the 2026.1.01 release. Report state transitions that occurred before the upgrade are not displayed.

Capture reason for late report

Summary

Reason for late submission can be captured for late regulatory reports

Description

Argus Safety and Argus Safety Japan is enhanced to track and document the reasons for late regulatory report submissions. A new justification type, Report Reason for Late Submission, is added in Console > Code Lists > Argus > Justifications.

Factory data reasons for late submission are provided in both English and Japanese as follows:

- Late due to belonging to backlog
- Late due to E2B technical problem
- Late due to holiday / office closure
- Late due to late case lock
- Late due to missing staff
- Late due to other priority work
- Late due to submission workload surge
- Not specified

The Submission tab in the Case Form > Regulatory Reports > View Report Details screen now includes:

- Submission Late (Yes/No)
- Determined On
- Determined By
- Reason for Late Submission (with Select button)

By default, the Submission Late option is set to No. When it is set to Yes, the Determined By and Determined On fields are automatically populated, and the Reason for Late Submission field is enabled (mandatory).

When a case is being saved with no input in the Reason for Late Submission field, an error message appears.

You can select a factory reason or enter a justification via a dialog (entries are not saved to List Maintenance). The existing framework for code list and justifications applies.

The Reason for Late Submission may be provided at any point in the report lifecycle, before or after marking it as Submitted.

For more information, refer to the *OracleArgusSafety2026.1.01_CaseForm_Console_Updates_Summary* document.

Processing Queue Status Dashboard

Summary

Introduction of the Processing Queue Status (Enhancement 38949047)

Description

A new Processing Queue Status Dashboard is introduced in Argus Safety to enhance user visibility and tracking status of outgoing report processing queues. This dashboard is available in English for both Argus Safety English and Argus Safety Japan environments.

This dashboard supports auto-email notification when the corresponding queue status result count exceeds the configured threshold.

Console updates
To access this dashboard, a new menu Processing Queue Status is added in Argus Console > Access Management> Argus > Groups> Group Information > Menus. This dashboard is enabled by default for the Administrator groups in both new and upgraded installations.

Case form updates
The new menu Processing Queue Status can be accessed from Argus Safety > Dashboards. This menu is available based on the access provided at user group level for each enterprise. The dashboard displays the following out-of-the-box processing queue status:

- Cases pending for auto scheduling of reports—Provides the count of cases that are pending for report scheduling.
- Reports pending for generation—Provides the count of reports (E2B and non E2B) that are pending for generation.
- Total reports generated per day—Provides the total number of reports that were generated in last 24 hours.
- E2B reports pending for Transmission via Gateway—Provides the count of E2B reports that are pending for report transmission via Gateway.
- E2B reports pending receiving ACK—provides the count of E2B reports that are pending receiving acknowledgement.

For each status, the dashboard displays the corresponding record count as determined by the respective SQL queries executed at the global level (across all enterprises). A Refresh button is provided to refresh the screen and get the current count of records for all queue status.
In addition, the auto-email notification for each queue status is supported based on the following parameter configuration in the CFG_QUEUE_SQLS table:

- THRESHOLD

- FROM_EMAIL
- NOTIFICATION_EMAIL

When the result count returned by the SQL query associated with each Queue Status exceeds the configured threshold value, an email notification is sent in the specified format using the CFG_QUEUE_SQLS.FROM_EMAIL column as the sender address and the CFG_QUEUE_SQLS.NOTIFICATION_EMAIL column as the recipient address.
The email notification is sent every 6 hours until the result count of the SQL query associated with the respective Queue Status is below the configured threshold value.

> **Note**
>
> - The new dashboard is applicable only for the outgoing reports from the Argus Safety application.
> - This new dashboard is not certified for customization (adding new queue status or modifying the out-of-the-box SQL queries).
> - The email notification frequency is fixed at every 6 hours and is not configurable.

More options for acknowledgement transmission parameter

Summary

Additional options for ACK transmission parameter in reporting destination

Description

The Suppress ACK transmission checkbox in Console > Reporting Destination > EDI tab is converted into a drop-down with following options:

- Generate and Transmit Ack
- Generate Ack and Suppress transmission of Ack
- Suppress generation and transmission of Ack

Before the upgrade, an existing reporting destination may have had the Suppress ACK transmission check box either selected or cleared. After the upgrade, that setting is reflected in the drop-down as follows::

- If Suppress ACK transmission was checked, the drop-down shows Suppress generation and transmission of Ack.
- If Suppress ACK transmission was unchecked, the drop-down shows Generate and Transmit Ack.

There is no change in functionality for these options:

- If ACK Transmission is set to Generate and Transmit Ack, the system generates and sends an acknowledgement (ACK) for each received ICSR.
- If ACK Transmission is set to Suppress generation and transmission of Ack, the system does not generate or send an acknowledgement (ACK) for the received ICSR.

> **Note**
>
> For E2B reports processed via the gateway or sFTP channel, it's recommended not to use Generate Ack and Suppress transmission of Ack, because Argus does not provide a way to view or track the acknowledgements generated with this setting.

Global Home Page updates

Summary

Naming convention changes in the Global Home Page

Description

Updates are made to the names shown in Global Home page > Application Access drop-down. Only the labels changed—there is no impact to the application, functionality, or links.

- Argus Safety → Argus Home
- Argus Safety Case Book-In → Case Book-In
- Safety One Intake → Consolidated Intake (applies only to Safety One Argus)

Duplicate Search enhancements

Summary

Duplicate Search enhancements

Description

The Duplicate Search functionality is enhanced with improved search algorithms and configurable weights, thresholds, and related settings.

Duplicate Search weights and thresholds are managed in Argus Console > System Management (Common Profile Switches) > Case Processing > Duplicate Search > Smart Search Configuration File.

You can:

- Download the default settings as an Excel file,
- Update the settings in Excel, and
- Upload the revised file back through the UI.

The following enterprise switches are added under Common Profile Switches > Duplicate Search:

- Enable Transposed Date Matching (default Yes): Allows transposed dates to match (e.g., 03-Jan-2026 matches 01-Mar-2026).
- Enable Numerical Scoring for Patient Age (default Yes): Enables fuzzy age matching (e.g., 20 matches 21) for the Patient Age field. For exact age matching on the Patient Age during duplicate search, set this switch to No.

Dictionary enhancements

- Self-service dictionary management updates

Self-service dictionary management updates

Summary

Enhancements to dictionary loading and MedDRA re-coding self-service tools (Enhancements 35514161, 36721721, 36019096, and 35353788)

Description

The dictionary management self-service tool is enhanced to improve system reliability and usability.

Dictionary loading

- **Improved load experience**—The Dictionary Type field is moved before the Dictionary File field to enable you to select the dictionary type first and review key details before initiating a load, such as the last version loaded, last updated date, and current status.
- **Automatic version detection for all dictionaries**—The dictionary version is now automatically derived from the uploaded files for all supported dictionaries except EDQM. Previously this feature was limited to MedDRA dictionary loading. If a required version file is missing, a clear error message guides you to resolve the issue.
- **Enhanced load handling and cancellation**—You can now cancel a dictionary load that hangs due to incomplete backend setup or unforeseen errors. If a load takes too long, it can be safely canceled without administrative intervention, improving responsiveness, and minimizing downtime.
- **Automated configuration file (MDB) handling**—While loading the dictionary, the configuration file (MBD file) are automatically picked from the installation folder based on the selected dictionary type. This streamlines the loading process by removing the need for manual acquisition or identification of MDB files. After Argus upgrade, the application automatically uses the latest MDB/configuration file available for the corresponding dictionaries. If Argus has not been upgraded but support for the latest MedDRA versions is required, the functionality to upload new MDB files remains available.

MedDRA Recode

- **Historical MedDRA recode logs**—To ensure critical log data is preserved and accidental overwriting is prevented, you can now download the last three historical MedDRA recode logs for both update and view-only executions.
- **Multiple enterprise log management**—When recoding is performed across multiple enterprises in a single execution, the system now generates a master ZIP file that contains individual ZIP files for each enterprise's recode logs with enterprise short name prefixed in the ZIP file name for easy identification. This streamlined approach simplifies review and access to log data. Additionally, Argus provides the option to automatically email the individual logs to the user who initiated the recode once the process is complete using the general email Argus Service.

- **Controlled MedDRA recode in update mode**—MedDRA recoding in the Update mode is now permitted only when the system is in Maintenance mode, providing greater oversight and safety when performing MedDRA updates. You must have Global Admin privileges to enable or disable the Maintenance mode.
- **Country of Interest (COI) in MedDRA logs**—The Country of Interest (COI) column is now included in the MedDRA recode logs to displaying the country information provided in the Case Form > General Information section. This enhancement simplifies country-specific audits and analysis during the recoding process.

WHODrug dictionary updates in March 2026

Summary

WHODrug March 2026 release changes (Enhancement 37960647)

Description

Argus Safety now supports loading and coding with the latest WHODrug Global and Chinese C3/B3 dictionaries (March 2026), fully aligned with UMC's updated format requirements. All changes are managed exclusively through the Self-Service Dictionary Management module.

A new configuration file (MDB file), WHODrug_2026_01.mdb, enables loading of zipped CSV files for Global C3/B3 dictionaries. The system continues to support TXT files for Global dictionaries published before March 2026.

Key updates include:

- Loading of zipped CSV files for Global C3/B3 dictionaries
- Seamless handling of the removal of PP.csv and PRG.csv files
- Validation of mandatory files during upload
- Support for the new archivedrecord.csv file and the new field Umc_Product_Id in the MP.CSV file
- An Archived? column added to the WHODrug coding screen to identify legacy records from the archivedrecord.csv file, ensuring accurate case coding

In addition, to align with UMC standards, all references to WHO Medicinal Product ID have been updated to WHO Record ID across Argus screens, case reports, the WHODrug coding screen, and search filters. This is a label update only—the functionality and existing mappings of the WHO Record ID field remain unchanged.

For more information, refer to the *OracleArgusSafety2026.1.01_CaseForm_Console_Updates_Summary* document.

Deprecation of Dictionary Management Client/Server tool

Summary

Deprecation of the Dictionary Management Client/Server tool

Description

Starting with this release, the Dictionary Management client/server application tool is deprecated and permanently removed from the application server. This tool is no longer included in the installer. All dictionaries previously loaded using this tool will remain available for coding and related activities.

To ensure continued efficiency, use the Self-Service Dictionary Management feature available in the Argus Console. This feature enables:

- Loading of WHODrug, MedDRA, JFMDA, IMDRF, and Link Korea dictionaries
- Loading of Smart Event Encoder datasets
- MedDRA recoding in view and update mode, including log download capabilities

> **Note**
>
> The Cloud operations team will no longer manage dictionaries for cloud customers. It is advised to not log Change Requests (CRs) related to dictionary loading or MedDRA recoding.

Support for WHODrug Link Korea dictionary

Summary

Support WHODrug Link Korea loading, configuration and coding (Enhancements 32483505 and 35361980)

Description

Oracle Argus Safety is enhanced to support loading, configuration, and coding of WHODrug Link Korea dictionary.

Loading dictionary
New options are added in Console > Tools > Dictionary Management > Dictionary Loader to support loading or overwriting the WHO Drug Link Korea B3 and C3 dictionaries. You can load the Link Korea dictionaries starting from March 2025.

The dictionary zip file must include the required files for either the B3 or C3 formats. As the Link Korea dictionary does not use an MDB file, you do not need to select one.

Before loading Link Korea, make sure the matching WHODrug Global dictionary version is already loaded; otherwise, Link Korea cannot be loaded. Set the profile switch for WHODrug Global to C3 when loading Link Korea C3 dictionary, or to B3 when loading Link Korea B3 dictionary.

Required files:

- Link Korea C3: LinkKorea_MPID.csv (for 2025 dictionaries), LinkKorea_RecordId.csv (for dictionaries released from 2026 onwards) LinkKorea_Cas.csv, Version.csv
- Link Korea B3: LinkKorea_DrugCode.csv, LinkKorea_Cas.csv, Version.csv

Other features, such as email notifications, work the same as for global dictionary loading.

Configuring dictionary
A new common profile switch is added to set Drugs(Korea) based on the Global dictionary format and version. The Ingredients code list now includes a new column, MFDS Ingredient Code, which is populated during Link Korea dictionary loading for matching ingredients using the CAS number. You can also add, edit, or delete the MFDS Ingredient Code as needed.

Drug Coding screen updates
A search criterion for MFDS Product Code has been introduced. When the Link Korea dictionary is enabled in the common profile switch, drug searches in WHODrug will also display matching MFDS Product Code records in the drug coding screen based on the Link Korea dictionary.
Additional information such as Formulation, Strength, MAH, and MFDS Ingredient Codes is also displayed to assist user selection. The selected data from the drug coding screen is populated into the Console or Case Form configuration.
The MFDS section may display one-to-one, one-to-many, or no matching records for the selected WHODrug, depending on the matching criteria.
For Link Korea C3, matching is performed based on the WHO Record ID between the Link Korea table and WHODrug Global. For Link Korea B3, matching is based on the WHO Drug Code between the Link Korea table and WHODrug Global.

Configuring license
A new field, MFDS Product Code, is added in the Business Configuration > Licenses screen to configure MFDS product code for the Korea license.

Drug coding in case form
For company products, the MFDS Product Code in the Products tab is populated based on the Console > License > MFDS Product Code field for the selected license. In the Substance Information section, corresponding MFDS Ingredient Code is populated from the Ingredients code list.
For non-company products, both the MFDS Product Code and MFDS Ingredient Codes are populated based on the selected record in the Drug Coding screen.
When MFDS Product Code is selected in the Drug Coding screen, then the same is populated in the Other Relevant History section of both the Patient tab and Parent tab.

Generate report
The MFDS E2B(R3) report generated for Korea cases (domestic post-marketed) populates both MFDS Product Code and MFDS Ingredient Code in regional elements based on the data entered in the case form.

Mapping logic has not changed for the following elements:

- 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]

Load IMDRF Annexures via consolidated file

Summary

Loading of IMDRF Annexures data from a single file containing all the annexures

Description

The 2025 Excel release of IMDRF terminology is now consolidated into a single file, with each annex presented on a separate sheet within that file. The structure and layout of each annex sheet remain consistent with the previous release.

Self-service IMDRF loading now allows you to upload a single Excel file containing Annexes A to G, with or without FDA columns.

Technical enhancements

Generate batch paper reports in background

Summary

Perform batch report generation in the background for paper reports

Description

The batch report generation process is enhanced to run in the background, ensuring reports are produced without affecting user activities. These reports can be downloaded later and as many times as needed.

A new option, Background Generation, is added under the Case Actions > Open > Batch > Scheduling section. For report generation, use this option along with the Run At option to send reports to background generation.

Paper reports in draft mode, final mode, and final mode (save with case, mark as submitted) are now generated in the background.

The report generation status is displayed in the Utilities > Batch Reports screen with the details like:

- Report Title
- Reporting Destination
- Report Form
- Report Format (Draft/Final)
- User Name
- Next Run
- Date
- Report Generation Status

When the report is in the Generated state, click the report link under the Report Form column to download the generated report. Generated paper reports are retained for 3 days. After 3 days, the generated paper reports are removed from the Batch Reports screen. You can configure the number of days for which the generated reports are retained via the CMN_PROFILE_ENTERPRISE.DAYS_AFTER_REMOVE_BATCH_REPORT common profile switch. This profile switch can be configured from the backend only.

> **Note**
>
> There is no change to any other existing functionality of batch reports, such as, E2B batch reports generation.

The following options are removed as part of this enhancements;

- Printer
- Run Now

Support for modern authentication in Oracle B2B

Summary

Support for Modern Authentication in Oracle B2B (Enhancement 37521614)

Description

Microsoft is deprecating Basic Authentication for Exchange Online, enforcing full removal by December 2026. To comply and maintain compatibility with Microsoft 365, Oracle B2B 12.2.1.4+ integrated with Oracle Argus Safety,when updated with the July 2025 CPU patch, now supports Modern Authentication (OAuth 2.0) for email callouts.

Auto email notification support for ETL status

Summary

Auto email notification for ETL status in Argus Mart and Argus Analytics

Description

Argus Safety is enhanced to support configuring sender and recipient email addresses for automated ETL status notifications for Argus Mart and Argus Analytics.

Console changes
In the default enterprise, when the ETL Dashboard Utility is configured, three new parameters are introduced under System Configuration > System Management (Common Profile Switches) > Argus Mart.

- Enable ETL Notifications via Email
- ETL Notification Sender
- ETL Notification Receivers

> **Note**
>
> When Enable ETL Notification via Email is set to Yes, at least one valid recipient email address must be provided.

A new Argus Analytics node is added under System Management (Common Profile Switches). It uses the same parameters as described above to configure automated Argus Analytics ETL status email notifications.
When Enable ETL Notifications via Email is set to Yes on the Argus Mart or Argus Analytics screen, the system sends ETL status emails to the configured sender and recipient addresses.

> **Note**
>
> - These changes are available in English for both Argus English and Argus Japan.
> - In Safety One Argus, ETL Notification Sender is not used; the system uses the sender address from System Configuration > SMTP Configuration > Global From Address.
> - Automated email notifications applies to both initial and incremental ETL, for success and failure statuses.

Enhancements to Oracle Argus Safety Japan

The following are the enhancements to Oracle Argus Safety Japan:

PMDA Device report updates

Summary

PMDA Device Form 8 & Form 10 enhancement (Enhancement 35634058, 35634389, 35634345, 36353330, 35963017,35633846, and 35634461)

Description

This release introduces enhancements to the PMDA Device XML Form 8 and Form 10 to align with regulatory compliance, and reporting accuracy for PMDA Device reporting.

- Pr.6 CONCOMITANT MEDICAL DEVICE from Free Text—To support more flexible and accurate data entry, a new free text field titled “Concomitant Device Comments” (併用医療機器コメント) has been introduced under Products tab > Device tab > Device Information section.
- Narrative generation is enabled for this field. Data entered in this field is transmitted in PMDA Device Form 8 and Form 10 element CONCOMITANTMEDICALDEVICE [Pr.6]
- Partial Date for Date of Event—Partial Dates like year (CCYY) or year & month (CCYYMM) entered in Argus J > Product tab > Device tab > PMDA Device Information (PMDA 機器情報) section>Date the problem occurred (不具合発生日) field is transmitted in PMDA Device Form 8 and Form 10 element DATEOFEVENT [M.3]
- Custom Device Code list Flexibility—Console code lists for ‘Device Classification’ and ‘Device Outcome’ now support add/copy/delete functionalities for custom values, allowing better support for evolving medical technologies.
- Default Report View Configuration—Organizations can now set a default viewing format for PMDA Device Reports. Under Common Profile Switches > Argus J > Reporting > Device Report, a new option titled “Default viewing format of the PMDA Device Report” has been added in the section “File attachments allowed for PMDA Device Profile.” This allows you to configure the preferred format—XML, Decoded, or Paper View—for easier and consistent report viewing.

- Improved Patient Age in Decades representation—When patient age is captured in “decades” in the case form, it is converted and displayed in line with Japanese conventions for reporting in the elements NUMBEROFAGE[Pa.2.1] and UNITOFAGE[Pa.2.2]. For example: If the case form specifies “9 decades”, the report output will display “80 歳代” [In their 80s]
- BRANDNAME [Pr.1] Mapping Update for Combination Products—BRANDNAME [Pr.1] mapping for combination device products (PMDA Device Classification 1 "Combination product (drug)") is now updated to populate drug trade name based on the combination product definitions configured in the COMBO_PRODUCT_RELATIONSHIP flexible code list for Japan device license for which the report is scheduled.
- XML Filename Enhancement—The Argus case number is now included in the PMDA Device XML filename, making it easier for users to identify and manage report files. Existing: `Alphanumeric D<hyphen>Sender's identifier (S.5)<hyphen>Report date(S.1)<hyphen>Unique file/sequence number.xml ( English alpha numeric)`

  New Format: `Alphanumeric D<hyphen>Sender's identifier (S.5)<hyphen>Report Generated Timestamp<hyphen> /case number and Two Capital Alphabetical Letters.xml`

  Example: D-ryakumei-20200401000125-case1AA.xml
- Accurate Nullification Reporting—PMDA Device Nullification (cancellation) reports now pulls data from the most recently submitted report, rather than the current case data, as per regulatory requirement.
- Enhancements to Validation Messaging—Validation message for Approval Number [Pr.4] now specify that alphanumeric values are accepted for the Approval Number to align with the allowed format, preventing user confusion. Additionally, improved validation logic for optional PMDA Device data elements are provided to ensure compliance and reduce reporting errors when report is marked ‘Complete’.

For more information, refer to *ArgusInterchange2026.1.01_PMDA Device Export Mappings.xlsx*.

Japan DSUR report updates

Summary

Japan DSUR report updates

Description

JDSUR report configuration and mappings are enhanced as per the revised PMDA R3 guidance for Clinical Studies. An option is added to select additional study products in report configuration. These are printed in Form 1 and Form 2, with Form 2 repeated for each study product.

Report configuration updates
The report configuration lists the available additional 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 except the study products already selected in the Selected Products (選択された製品) list box. You can select any additional study products to be included in the JDSUR report.

Form 1 updates
In Form 1, a new column for 被験薬以外の治験使用薬情報 (Drugs used in clinical trials other than the investigational drug) is added just below the 主要先進国における承認状況 (Approval

Status in major developed countries). This prints the products selected in the JDSUR Configuration > Product Selection tab > Selected Additional Study Products field. Details like Generic Name, Product Type, Clinical Compound Number of the Study, and Notification Number of the Study are printed.

Form 2 updates
Form 2 is repeated for each product selected under Selected Products (選択された製品) list box and Selected Additional Study Products (選択された治験薬) list box. A new column for 治験使用薬の記号・名称等 (Code/Name of the Clinical Trial-Use Medicine) is added to the form. For study products configured in Selected Products, the new column prints Clinical Compound Number, and Study ID. For study products configured in Additional Study Products, the new column prints Generic Name, Product Type, and Study ID.

Product Type code list
A new standard code list is introduced for Product Type. The values added here are displayed for user selection in the Console > Studies > Product Type dropdown in English and J data entry screens.

For more information on the JDSUR updates, refer to the *JDSUR report mapping guide*.

Enhanced Excel export of Japan literature intake

Summary

Enhanced Excel export of Japan literature intake (Enhancement 36994776)

Description

When exporting to Excel from the Worklist > Japan Literature Intake section, the following additional information is included in the export when generated from the Import, Processing, and Processed tabs.

- Header line as Import, Processing, or Processed record list
- Username that generated the report
- Date and Time of the report generation
- Filter criteria used

Export of case form lab data

Summary

Export of case form lab data in a globally locked and locally unlocked case (Enhancement 38173401)

Description

When a case is globally locked and locally unlocked, the Export button in the Patient tab > Lab Data section is enabled for Argus Japan users. The Export button creates an excel file with lab data as provided in the case form in a specific format. This Excel sheet is used for review and updates. This Excel sheet can also be imported into case form using the Import button in the Lab Data section.

Merged patches

The following Argus Safety patches are merged with Oracle Argus 2026.1.01:

- 8.4.3.001
- 8.4.3.201
- 8.4.3.202
- 8.4.3.3
- 8.4.3.4
- 8.4.3.5
- 8.4.4.1
- 8.4.4.2
- 8.4.4.201
- 8.4.4.202
- 8.4.4.3
- 8.4.4.301
- 8.4.4.4

The following Consolidated Intake patches are merged with Oracle Argus 2026.1.01:

- 25.1.0.1
- 25.1.0.2
- 25.1.0.201
- 25.1.0.202
- 25.1.0.3
- 25.1.0.301
- 25.1.0.4

Download Oracle Argus 2026.1.01

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—**37835561**
   b. Argus Mart—**37835574**
   c. Argus Analytics—**36775796**

> **Note**
>
> There is no new build for Argus Analytics 2026.1.01, use the same build as Argus Analytics 8.4.4.

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 2026.1.01 Installer.

Install Oracle Argus 2026.1.01

To install Oracle Argus Safety and Oracle Argus Insight, see the *Oracle Argus Safety and Oracle Argus Insight 2026.1.01 Installation Guide*.

To install Oracle Argus Mart, see the *Oracle Argus Mart 2026.1.01 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 2026.1.01
- 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
  - 8.4.2.002

  - 8.4.2.1
  - 8.4.3
  - 8.4.3.001
  - 8.4.3.1
  - 8.4.3.2
  - 8.4.3.201
  - 8.4.3.202
  - 8.4.3.3
  - 8.4.3.4
  - 8.4.3.5
  - 8.4.4
  - 8.4.4.1
  - 8.4.4.2
  - 8.4.4.201
  - 8.4.4.202
  - 8.4.4.3
  - 8.4.4.301
  - 8.4.4.4
- Oracle Argus Insight
  - 8.1 to 2026.1.01 including merged patches
- Oracle Argus Mart
  - 8.1 to 2026.1.01 including merged patches
- Oracle Argus Analytics
  - 8.1 to 8.4.4 including merged patches

Upgrade Oracle Argus Safety from 8.1.x to 2026.1.01

See the *Oracle Argus Safety and Oracle Argus Insight 2026.1.01 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 2026.1.01 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 2026.1.01 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 2026.1.01 Installation Guide, Section Oracle Argus Safety Database Upgrade*.

5. Upgrade Oracle Argus Safety from 8.1.x to 2026.1.01.
6. Validate the Oracle Argus Safety and DLP Schema, refer to the *Oracle Argus Safety and Oracle Argus Insight 2026.1.01 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.

Product Verification Pack (PVP)

The Product Verification Pack (PVP) is a collection of product release documents designed to help with your validation efforts.

The PVP is used by Oracle for certification purposes, and Oracle makes a new pack available to customers with every release (except patches). You can use the PVP as a blueprint for acceptance testing.

The latest PVP for Oracle Safety One Argus is made available on My Oracle Support after every release. The patch containing the PVP for Oracle Argus Safety is **31721002**.

Before you begin, you must have the following:

- A My Oracle Support account. If you don't have one, ask your Oracle contact for assistance.
- The current password for the PVP patch, which you can obtain from My Oracle Support by creating a service request.

> **Note**
>
> Patch passwords expire periodically.

Steps to download the PVP

1. Log in to your account at My Oracle Support.
2. Select **Patches**.
3. Select **Patch Name or Number**.
4. Enter the PVP patch number, 31721002, and press Return.
5. Click **Apply**.
6. Select the patch from the list of results.
7. Click **Download**.
8. Enter the password for this patch. Passwords are case sensitive.
9. Click **Unlock**.
10. Select the zip file to start the download.

Revision History

Date, Version	Description
April 2026, Version 2	Added details on the Product Verification Pack (PVP).
March 2026, Version 1	Initial version of the release notes.