Oracle Life Sciences Safety One Argus

Release Notes

Release 2026.1.03
G58739-01
August 2026

Oracle Life Sciences Safety One Argus Release Notes, Release 2026.1.03

G58739-01

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Overview

Oracle Safety One Argus 2026.1.03 is a patch release that delivers targeted enhancements and fixes across intake processing, regulatory reporting, E2B(R3) workflows, and dictionary management. These updates strengthen data privacy and integrity, improve regulatory compliance and report accuracy, and reduce manual effort through more reliable intake coding, case processing, and system operations.

Prerequisites

Safety One Argus 2026.1.01

Affected features

See the following list of affected Safety One Argus features:

- Intake processing
- Intake form

The following lists shows the Argus Safety impact:

- Advance Conditions
- Dictionaries
- E2B(R3) import
- E2B(R3) export (EMA)
- E2B(R3) export (FAERS)
- E2B(R3) report (FAERS)
- Global home page
- IMDRF dictionary loading
- MIR 7.3.1 XML and PDF report

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What's new in this release

This section describes the enhancements made in the Oracle Argus Safety 2026.1.03 patch. These changes also apply to Oracle Safety One Argus.

Enhanced data masking for matching results involving blinded Batch/Lot information

Summary

Match Score and Match Type values masking enhancement for blinded Batch/Lot values. (39455378)

Description

When the Batch/Lot value is blinded in a selected match but not blinded in the incoming record, the Match Score and Match Type values are now also masked on the Duplicate Search Result window.

This enhancement prevents indirect disclosure of blinded Batch/Lot information and strengthens data privacy by ensuring that matching metadata cannot be used to infer protected values.

EC MIR 7.3.1 regulation updates—May and June 2026

Summary

Support for EC Manufacturer Incident Report (MIR) version 7.3.1 sub-version SB-11154 and XSD changes (Enhancements 39402093).

Description

To ensure continued compliance with the latest regulatory requirements, Argus Safety is updated to support the European Commission Manufacturer Incident Report (MIR) version 7.3.1 > sub-version SB-11154, published in May 2026 along with the XSD updates published in June 2026.

Changes include:

- Updated the MIR 7.3.1 report to reflect the latest sub-version identifier (SB-11154).

- Updated the MIR 7.3.1 XSD schema to make the `howWereDetermined` element mandatory in the `similarIncidents` block for Combined Initial and Final report, and Final (Reportable Incident) report.

There are no changes to the report layout, data mappings, or business rules.

> **Note**
>
> For additional details refer to the *MIR 7.3.1 Export Mappings* sheet.

ICH E2B(R3) Implementation Guide updates—July 2025 revision

Summary

ICH E2B(R3) package v1.10 updates for the dose/strength units (Enhancements 39413913).

Description

Argus Safety is enhanced to align with the Dose and Strength Unit flags introduced in the ICH E2B(R3) package v1.10 (E2B CL25: ICH-DOSESTRENGTH-UNIT codelist).

Changes include:

- Updated the Dosage Unit codelist to incorporate the Dose and Strength Unit flags as per the ICH codelist.
- Updated the allowed values for the following E2B(R3) elements in the ICH, MFDS, and NMPA profiles:
  - DRUGSTRUCTUREDOSAGEUNIT [G.k.4.r.1b]
  - DRUGCUMULATIVEDOSAGEUNITR3 [G.k.5b]
  - STRENGTHUNIT[G.k.2.3.r.3b]

> **Note**
>
> The FDA and PMDA E2B(R3) profiles are not updated as these authorities are yet to confirm their adoption to dose and strength unit updates.

ICH E2B(R3) package v1.11 updates for Observe Study Type

Summary

ICH E2B(R3) package v1.11 updates for Observe Study Type (Enhancements 39413959).

Description

Argus Safety is enhanced to support the new Observe Study Type values introduced in the E2B CL8 ICH-STUDY-TYPE-REVISED codelist of ICH E2B(R3) package v1.11.

Changes include:

- Codelist
  The following Observe Study Type values are added to the Case Classification codelist:

  - Patient Support Program (E2B Code = 4)
  - Market Research Program (E2B Code = 5)
  - ODCS-Digital Activity (E2B Code = 6)
- ICH, EMA, and NMPA E2B(R3) profiles
  The new values are added to allowed values for OBSERVESTUDYTYPE [C.5.4].
- EMA E2B(R3) Validation
  The existing OBSERVESTUDYTYPE [C.5.4] validation for EVHUMAN/EVPM cases is updated to include the new Observe Study Type values.
- NMPA E2B(R3) Mapping
  The new Observe Study Type values are added to the REPORTCATEGORY [C.1.CN.2] mapping logic to derive the following report category values:
  - Domestic Post-Market Case (NMPA code = 12)
  - Foreign Post-Market Case (NMPA code = 22)
- MFDS E2B(R3) Mapping
  Updated mapping for the OTHERSTUDIESTYPE[C.5.4.KR.1] element to map the following new Observe Study Type values to 4 – Other:
  - 4 – Patient Support Program
  - 5 – Market Research Program
  - 6 – ODCS-Digital Activity
- ICH and EMA E2B(R2) Mapping
  Updated mappings for the OBSERVESTUDYTYPE[A.2.3.3] element to map the following Observe Study Type values to 3 – Other Studies:
  - 4 – Patient Support Program
  - 5 – Market Research Program
  - 6 – ODCS-Digital Activity
- E2B(R3) Mapping
  The same mapping as in E2B(R2) is applied temporarily to the OBSERVESTUDYTYPE[C.5.4] element for the E2B(R3) FDA, PMDA, MFDS, and eVAERS profiles. This interim mapping is based on the ICH Information Paper Regarding Alignment with the ICH E2D(R1) Guideline until the respective regulatory authorities confirm support for the new Observe Study type values.

> **Note**
>
> Based on the latest update from the EMA, it is recommended that customers continue using the existing Observe Study Type values for EMA submissions. The new Observe Study Type values introduced as part of the ICH E2B(R3) package updates must be used only after EMA officially announces support for the new values.

Updated FDA FAERS R3 allowed values for UCUM test unit codes

Summary

The test units UCUM codes as allowed limited values for FDA FAERS(R3) profile (Enhancement 39435482).

Description

The allowed laboratory test units for the FDA FAERS E2B(R3) factory profile is updated using the FDA draft list for TESTUNIT [F.r.3.3], aligning the supported UCUM test unit codes with the current EMA-accepted values. This enhancement expands the set of supported values, reducing validation and report generation errors caused by previously unsupported but valid UCUM codes. As a result, laboratory test unit values are now transmitted in TESTUNIT [F.r.3.3] whenever a matching supported value exists, rather than being sent in TESTRESULTTEXT [F.r.3.4] due to profile limitations.

Unmarked obsolete terms in IMDRF dictionary

Summary

Terms are not marked as Obsolete during IMDRF 2026 dictionary load (Enhancement 39583864).

Description

The IMDRF dictionary import process has been enhanced to consistently identify retired terms. After the IMDRF 2026 dictionary is loaded, all terms containing the word **Retired** in the Status column of the IMDRF Annex, including entries such as **Retired (<YYYY>)**, are now marked as obsolete (soft deleted) in the IMDRF repository. As a result, these terms are no longer available for coding, ensuring consistent handling of all retired IMDRF terms during dictionary import.

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What's fixed in this release

This release includes bug fixes related to intake forms, intake processing, advanced conditions, dictionaries, E2B(R3) import, E2B(R3) export (EMA), E2B(R3) export (FAERS), the global home page, IMDRF dictionary loading, MIR 7.3.1 XML and PDF report.

Inactive Argus codelist values missing asterisk prefix in read-only Intake form fields

Before

Inactive Argus codelist values were not prefixed with an asterisk when displayed in Read-only mode on the Intake form if the value was configured with the Display value set to False in the codelist. (39349081)

After

Inactive codelist values are now consistently prefixed with an asterisk in the read-only Intake form.

Impacted Areas

Intake form

Follow-up awaiting acceptance notification displayed in a case even after follow-up was marked as invalid in Safety One Argus

Before

After upgrading to Safety One Argus, auto-rejected ICSR follow-up reports from the Consolidated Intake Worklist could still generate Follow-up Awaiting Acceptance case notifications in the corresponding Argus case. (39156260)

After

Auto-rejected ICSR follow-up reports no longer generate case notifications in Argus. Case notifications are created only for valid reports that are pending acceptance. If notifications were previously created for rejected reports, you can remove them by raising a Support ticket.

Impacted areas

Intake processing

UCUM-coded Dosage, Laboratory, and Strength units not mapped to codelist values on the Intake form

Before

Dosage, Laboratory, and Strength units extracted from source documents as Unified Code for Units of Measure (UCUM) codes were not mapped to the corresponding Intake form codelist values. Because coding was based only on the unit name, UCUM codes (for example, mg) remained uncoded instead of being mapped to the corresponding codelist value (for example, milligram). As a result, the UCUM code was displayed on the Intake form and generated a review item on the QC tab. (39701377)

After

The coding logic now matches the extracted unit values by unit name first and, if no match is found, by UCUM code. This change ensures that extracted UCUM codes, such as mg, are correctly mapped to their corresponding codelist values, such as milligram, on the Intake form. Furthermore, no unnecessary QC review items are generated.

Impacted areas

Intake processing

MedDRA loading failed at Dictionary terms loading is in progress step

Summary

MedDRA loading fails at the Dictionary terms loading is in progress step in ADB (Bug 39550305).

Before

In Oracle Autonomous Database (ADB), loading a MedDRA dictionary failed during the Dictionary Terms loading step because the required permissions had not been granted for certain MedDRA dictionary tables.

After

When you load a MedDRA dictionary in ADB, the required permissions for the affected MedDRA dictionary tables are granted automatically, eliminating the need for manual intervention.

Impacted area

Dictionaries

Ported from

Safety One Argus 25.1.0.6

Study Type and Study Phase were not populated from Study Coding

Summary

Study Type and Study Phase are not populated from Study Coding. (39763721)

Before

When a study was auto-coded as a company-study upon document extraction, the Observe Study Type and Study Phase fields from the study configuration are not populated. However, when the study was manually coded from the Intake form window, these fields were correctly populated from study configuration.

After

The Observe Study Type and Study Phase fields from the study configuration are now populated, both when a study was auto-coded and when it is manually coded from the Intake form.

Impacted area

Intake form

Quality Review displayed unchanged fields as updated during E2B (R3) follow-up merge

Summary

Quality Review displayed unchanged fields as updated during E2B (R3) follow-up merge. (39552502)

Before

When you performed the Merge Follow-up action, unchanged fields were incorrectly marked for review on the QC and Field tabs of the Intake form. This issue occurred even if there were no changes in the Argus case value and incoming value.

After

During merge follow-up, unchanged fields are no longer marked for review on the Intake form.

Impacted area

Intake form

Cause of Death Description as Reported field not flagged for review during follow-up merge

Summary

Cause of Death > Description as Reported fields did not display the current and incoming drop-down when updated, but displayed matched on form and updated in the QC list (Bug 39552579)

Before

During the Merge Follow-up task, when the incoming Cause of Death > Description as Reported value differed from the current Argus case value, the field was not flagged for review on the Intake form. The current and incoming values were not displayed in the corresponding drop-downs, and the field appeared as matched on the form. However, the QC tab correctly displayed the field as updated.

After

During follow-up merge, when the incoming Cause of Death > Description as Reported value differs from the current Argus case value, the Intake form now correctly identifies the field for review and displays the current and incoming values. The review status on the form is now consistent with the updated status displayed on the QC tab.

Impacted area

Intake form

Incorrect population of DRUGLASTPERIOD[G.k.9.i.3.2a]

Summary

DRUGLASTPERIOD[G.k.9.i.3.2a] element incorrectly populated for EMA(R3) profile (Bug 39403901).

Before

In the EMA E2B(R3) report, the DRUGLASTPERIOD[G.k.9.i.3.2a] and DRUGLASTPERIODUNIT[G.k.9.i.3.2b] elements were populated as DRUGSTARTPERIOD[G.k.9.i.3.1a].

After

In the EMA E2B(R3) report, the DRUGLASTPERIOD[G.k.9.i.3.2a] and DRUGLASTPERIODUNIT[G.k.9.i.3.2b] elements are populated based on the Onset from Last Dose value for the corresponding product and event.

Impacted module

E2B(R3) export (EMA)

Incorrect SAFETYREPORTID[C.1.1] and COMPANYNUMB[C.1.8.1] for cases with MedWatch and R2 initial reports

Summary

Incorrect SAFETYREPORTID[C.1.1] and COMPANYNUMB[C.1.8.1] in FAERS R3 Report in cases with both Medwatch and R2 initial reports (Bug 39613567).

Before

When an FAERS E2B(R3) report was generated for a case for the first time, and both MedWatch and E2B(R2) reports had previously been submitted to the FDA, the system incorrectly populated the SAFETYREPORTID[C.1.1] and COMPANYNUMB[C.1.8.1] elements with the Manufacturer Control Number (MCN) from an earlier MedWatch submission (Form 3500A or Form 14) instead of the SAFETYREPORTID[A.1.0.1] and COMPANYNUMB[A.1.10.1/ A.1.10.2] from the most recent E2B(R2) submission.

After

When an E2B(R2) report is submitted for a case report, the system uses the SAFETYREPORTID[A.1.0.1]and COMPANYNUMB[A.1.10.1/ A.1.10.2] generated by the R2 submission for all subsequent E2B(R3) reports. In this scenario, the Manufacturer Control Number (MCN) from the earlier MedWatch report is not reused. The MCN from Box G9, mapped to SAFETYREPORTID[C.1.1] and COMPANYNUMB[C.1.8.1], are used only when the initial submission was a paper MedWatch report and no electronic submission, such as an E2B(R2) report, exists.

Impacted module

E2B(R3) export (FAERS)

MIR 7.3.1 PDF report discrepancy

Summary

MIR 7.3.1 PDF report discrepancy between Initial and Combined Initial and final and Final (Reportable) report types (Bug 39593191).

Before

In MIR 7.3.1 PDF reports, the value displayed for the RELATIONSHIPINCIDENTSUBSTANCE [4.2.c] element changed between the initial report and the Final Reportable and Combined Initial/Final MIR report types, even though the underlying source case data remained unchanged.

After

For MIR 7.3.1 submissions, the mapping logic is revised for the RELATIONSHIPINCIDENTSUBSTANCE [4.2.c] element to ensure that, when the source case data remains unchanged, the value displayed in the Final Reportable and Combined Initial/Final MIR report types is consistent with the value displayed in the Initial MIR report. Similarly, the mapping logic is revised for the SUSPICIONRELATIONSHIP[4.1.b]element to ensure that, when the source case data remains unchanged, the value remains consistent across all MIR report types.

Impacted module

MIR 7.3.1 XML and PDF report

ICSR Accept failure for multiple Sender Diagnosis[H.3.r] blocks

Summary

E2B(R3) import with multiple SENDERDIAGNOSISINFO[H.3.r] creates ICSR Accept failure (Bug 39482016).

Before

ICSR Accept failed when the E2B(R3) XML file contained multiple SENDERDIAGNOSISINFO[H.3.r] blocks.

After

ICSR Accept is successful when the E2B(R3) XML file contains multiple SENDERDIAGNOSISINFO[H.3.r] blocks. The system imports the first block into the imported case.

Impacted module

E2B(R3) import

Ported from

8.4.4.6

Unable to modify an Advanced Condition

Summary

Unable to view or edit an Advanced Condition with lengthy query text (Bug 39550399).

Before

When users tried to open and modify previously saved Advanced Conditions containing lengthy SQL query text, the system displayed a blank Advanced Conditions screen, preventing users from viewing the existing configuration or making any updates.

After

The system correctly displays Advanced Conditions containing lengthy SQL query text, allowing users to view and modify the existing configuration.

Impacted module

Advance Conditions

Ported from

8.4.4.6

Incorrect TESTUNIT UCUM code in the FAERS E2B(R3) report

Summary

FAERS R3 TESTUNIT UCUM code is incorrect for (MILLIGRAM PER DECILITRE) value in the CFG_M2 table (Bug 39550351).

Before

When you selected the coded value mg/dL – MILLIGRAM PER DECILITRE in the Case Form > Patient > Lab Data > Result Unit, the FAERS E2B(R3) report incorrectly populated the free-text field TESTRESULTTEXT[F.r.3.4] instead of the structured field TESTUNIT[F.r.3.3]. This issue occurred due to incorrect factory configuration in allowed values, where the UCUM code was defined as mg/dl instead of the correct value mg/dL.

After

The factory configuration in allowed values is corrected to mg/dL, resulting in proper mapping and correct population of the TESTUNIT[F.r.3.3] field in the FAERS E2B(R3) report.

Impacted module

E2B(R3) export (FAERS)

Ported from

8.4.4.6

Unable to create a new enterprise after upgrade

Summary

Creation of new enterprise after upgrade failed if there were deleted Manufacturer code list records (Bug 39565281).

Before

In a multi-tenant environment, creating a new enterprise after upgrading to version 8.4.4.3 or later failed when the Manufacturer code list contained deleted records before the upgrade. This issue occurred because the SRN attribute was incorrectly added as an active (non-deleted) entry for Manufacturer code list records that had been deleted before the upgrade. As a result, the inconsistent code list entries caused enterprise creation to fail.

After

After upgrading to version 8.4.4.3 or later, the system keeps deleted Manufacturer code list records in the deleted state and saves the SRN attribute as deleted for those records. As a result, the system successfully creates new enterprises without errors.

Impacted module

Global home page

Ported from

8.4.4.6

Unable to generate FAERS E2B(R3) manual nullification report

Summary

FAERS R3 manual nullification report generation issue due to incorrect LOCALCRITERIAREPORTTYPE[FDA.C.1.7.1] element (Bug 39565257).

Before

FAERS E2B(R3) nullification reports failed to generate in certain scenarios because validation errors occurred or the FDA returned a negative ACK due to an incorrect LOCALCRITERIAREPORTTYPE[FDA.C.1.7.1] element.

The root cause was the incorrect value of LOCALCRITERIAREPORTTYPE[FDA.C.1.7.1] element which was derived based on time-frame calculated using Common Profile Switches > Reporting > Scheduling > Time Frame for manual nullification. This caused inconsistencies in report classification. For example, the system incorrectly classified an original 15-day report as a >15-day report.

After

FAERS E2B(R3) nullification reports are generated successfully by populating the LOCALCRITERIAREPORTTYPE[C.1.7.1] element with the same value from the previously submitted report to the same destination when C.1.7 is True.

If C.1.7 is set to False or NI, FDA.C.1.7.1 is populated with a value of 2. Additionally, if the most recently submitted report for the same case and regulatory authority was an E2B(R2) report, C.1.7 is populated with NullFlavor = NI.

Impacted module

E2B(R3) export (FAERS)

Ported from

8.4.4.6

Word document unavailable in Argus attachments after intake promotion

Summary

Word document did not open in Argus > Attachments, when an intake record was promoted after a process involving extraction. (Bug 39881059)

Before

When a Word document was ingested through Safety One Argus, the system generated a PDF for extraction. However, only the system-generated PDF was added to the Attachments section of the Argus case, and the original Word document was not included. As a result, the source document was not available to open or view from the Argus case.

After

Both the original Word document and the system-generated PDF are now added to the Attachments section of the Argus case. You can open and view both attachments successfully.

Impacted module

Intake processing