

Oracle Life Sciences Safety One Argus

Release Notes



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Overview

Oracle Safety One Argus 2026.1.02 is a patch release that delivers targeted enhancements for intake processing, merge follow-up handling, E2B processing, data blinding, and usability across Safety One Argus workflows. These updates are intended to improve case-processing efficiency, strengthen data integrity, and reduce manual effort during intake review and merge operations.

This release inherits business process flows, regulatory compliance requirements, integration requirements, deployment options, and system requirements from Oracle Safety One Argus 2026.1.01 unless otherwise noted.

- [Prerequisites](#)
- [Affected features](#)
- [Compatibility](#)

Prerequisites

Safety One Argus 2026.1.01

Affected features

See the following list of affected Safety One Intake features:

- Audit log
- Intake form
- Intake processing
- Intake Worklist

The following lists shows the Argus Safety impact:

- Case form > Event Assessment
- CIOMS II
- Dictionary loading
- E2B(R3) export (EMA)
- E2B(R3) export (FAERS)
- E2B import > View Difference window

Compatibility

- Oracle Argus Safety 2026.1.02
- Oracle Argus Insight 2026.1.02
- Oracle Argus Analytics 8.4.4
- Oracle Life Sciences Empirica Signal and Oracle Life Sciences Empirica Topics 2025.4.01

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What's new in Oracle Safety One Argus

These Safety One Argus enhancements benefit intake processors, workflow managers, and users involved in merge follow-up workflows.

- [Unlock a case during merge follow-up](#)
Unlock a case during merge follow-up processing without navigating separately to Argus Safety.
- [Intake-only processing for CROs](#)
You can send files after intake processing to external systems with this Intake form enhancement.
- [Unstructured AI/ML text extraction enhancement](#)
AI/ML extraction from unstructured text is now supported without the need to associate it with an Intake form field.
- [Improved protection for the blinded Batch/Lot field](#)
The Batch/Lot # field has been enhanced for better blinded data protection.
- [Merge handling for auto-calculated fields enhancement](#)
You can now select incoming and current values for auto-calculated fields, whether they can be calculated or not.
- [Dropdown search results order enhancement](#)
The exact matching results are now displayed on the top of the type-ahead/drop-down fields based on the search text.
- [Review support for disabled dependent fields during merge](#)
Higher visibility for reviewing data changes for disabled dependent fields.
- [Follow-up row added for Initial E2B records accepted as follow-up](#)
The incoming Intake ID value is captured now and a new follow-up row is created.
- [Auto-populated Justification field for E2B auto-accept](#)
When auto-accepting an E2B record, the system now captures the auto-accept notes against the follow-up row that is created.
- [Amendment and Nullification reports follow-up enhancement](#)
For intake processors, the amendment checkbox is selected and an amendment reason is displayed as justification against the follow-up row that is created when an amendment and nullification E2B record is ingested.
- [Deterministic merge behavior for repeating entities](#)
The system has been enhanced to merge the updates to one single matching entity with the least sort ID.
- [Unique attachment names during merge](#)
Attachment file names are enhanced for clarity.

Unlock a case during merge follow-up

Unlock a case during merge follow-up processing without navigating separately to Argus Safety.

You can unlock an Argus case directly in Safety One Argus when opening the Merge Viewer window from either the Duplicate Search, Intake Worklist, or Intake Monitor windows.

This enhancement eliminates the need to separately navigate to Argus Safety to unlock a case during merge follow-up processing.

Note

If auto-accept cannot proceed because the case is locked, the record is marked for a Merge Follow-up task in the Intake Worklist for manual acceptance.

Intake-only processing for CROs

You can send files after intake processing to external systems with this Intake form enhancement.

Contract Research Organizations (CROs), which are responsible for Intake-only processing for their customers, leverage Consolidated Intake and send E2B messages to the sponsor's safety database. Thus, the Intake-only processing feature has been enhanced to support a human-in-the-loop functionality for reviewing extracted data before submission and agency-based E2B generation.

Common Profile Switch rename

The **Reporting Destination for Email Configuration** Argus Console switch has been renamed to **Reporting Destination (for E2B file and/or Email configuration)**.

E2B(R3) generation

Once Intake processing is complete, the E2B(R3) file for the Intake record is now generated based on the reporting destination selected in Console > System Configuration > Common Profile Switches > Intake > Intake Processing > Reporting Destination (for E2B file and/or Email configuration). Thus, the file is sent to the target system based on the selected method of submission, either e-mail address or E2B(R3) file format which is applicable for REST APIs.

All E2B(R3) profiles are available for selection from the **Reporting Destination (for E2B file and/or Email configuration)** drop-down.

Review Record task in Intake Worklist

Intake records are always marked for the Review Record task in the Intake Worklist, so that you can review the extracted data before submission.

Submit button

When you click **Submit**, validation checks for the generated E2B file are performed before the file is sent. These checks are based on the reporting destination you selected in the **Reporting Destination (for E2B file and/or Email configuration)** common profile switch.

Validation error messages are either displayed in the Intake form or in a structured ICSR validation report.

Intake ID

In the generated E2B file, the Intake ID is now included as a **Safety Report Unique Identifier**, regardless of whether the record is transmitted via API or email.

Unstructured AI/ML text extraction enhancement

AI/ML extraction from unstructured text is now supported without the need to associate it with an Intake form field.

The unstructured text used for extraction is displayed and managed on the Extraction Viewer window, instead of being directly tied to a field displayed on the Intake form, such as the Narrative field.

Improved protection for the blinded Batch/Lot field

The Batch/Lot # field has been enhanced for better blinded data protection.

Blinded data protection has been enhanced for the Batch/Lot # field in Safety One Argus and Argus Safety. This enhancement applies to the duplicate search and match-score card functionalities across the application.

Merge handling for auto-calculated fields enhancement

You can now select incoming and current values for auto-calculated fields, whether they can be calculated or not.

The Merge Follow-up window now provides better control over auto-calculated fields. When available, the system displays auto-calculated values while still allowing you to view and select Incoming and Current values. You can also manually enter a custom value.

Thus, the system applies the following value order:

1. Manual entries
2. Auto-calculated value
3. User-selected Incoming or Current value
4. System recommendations

If a manual value is cleared, the system recalculates the field when possible. Difference reports continue to display Incoming, Current, and Merged values.

For new records, such as new product and event combinations, auto-calculated values are displayed when calculation is possible.

If the calculation is not possible, the field is left blank.

Dropdown search results order enhancement

The exact matching results are now displayed on the top of the type-ahead/drop-down fields based on the search text.

Type-ahead and drop-down search results are now ordered to make it easier for you to select the more relevant matches. When you search in a drop-down field, the results are displayed in the following order:

1. Exact matches
2. Values that start with the entered text
3. Values that contain the entered text

When you tab out of a field, the exact match is selected, if available. If there is no exact match, then the first *starts-with* or *contains* match is selected. If no results are available, the field remains unchanged. This behavior applies across Safety One Argus windows, including the Intake form, Duplicate Search, and Merge Follow-up.

Review support for disabled dependent fields during merge

Higher visibility for reviewing data changes for disabled dependent fields.

Merge review behavior has been enhanced for fields that are enabled or disabled based on the parent field values.

When a dependent field is disabled because of the recommended parent value, the system still highlights the field for review when there is a data change. You can change the parent value to enable dependent fields and review and you can select Incoming and Current values, where applicable.

This update helps you understand and resolve data differences that were previously hidden when dependent fields were disabled.

Follow-up row added for Initial E2B records accepted as follow-up

The incoming Intake ID value is captured now and a new follow-up row is created.

When an initial intake record with no follow-up row is merged into an existing case or intake record, the system now creates a follow-up row by using the initial receipt date of the incoming record. The incoming Intake ID is displayed on this row as well, and auto-accept notes are added to the justification field where applicable.

For follow-up intake records, the system retains one initial receipt date and adds follow-up receipt dates as follow-up rows. If the initial receipt date already exists in the case as either the initial date or a follow-up date, it is not added again.

Auto-populated Justification field for E2B auto-accept

When auto-accepting an E2B record, the system now captures the auto-accept notes against the follow-up row that is created.

For E2B auto-accept processing, the auto-accept notes from the profile switch are now captured in the Justification field of the follow-up row created during merge.

This reduces manual entry and provides consistent justification details for follow-up rows created through auto-accept processing.

Amendment and Nullification reports follow-up enhancement

For intake processors, the amendment checkbox is selected and an amendment reason is displayed as justification against the follow-up row that is created when an amendment and nullification E2B record is ingested.

Safety One Argus now creates a follow-up row by using the initial receipt date when an incoming E2B report has the same initial receipt date and most recent receipt date and when the report is identified as an amendment or nullification.

For amendment reports, the amendment checkbox is selected and the amendment reason is displayed in the justification field. For nullification reports, the nullification reason is displayed in the justification field and copied to the related action item as the nullification reason, where applicable.

If the incoming record is not an amendment or nullification report, no follow-up row is created because the initial and most recent receipt dates are the same in this case.

Deterministic merge behavior for repeating entities

The system has been enhanced to merge the updates to one single matching entity with the least sort ID.

When merging a follow-up record, if the same product name is added multiple times and thus there are more than one potential matches for the repeating entities in the current case, Safety One Argus now merges the incoming values into the matching current-case entity with the lowest sort ID. This prevents incoming dosage or product details from being applied inconsistently across matching entities.

Unique attachment names during merge

Attachment file names are enhanced for clarity.

When an incoming record and a current record contain attachments with the same file name, Safety One Argus now appends the incoming Intake ID to the incoming attachment file name during merge.

For example, if both records contain an `ICSR Validation Report.pdf` attachment, then the incoming attachment is renamed to include the incoming Intake ID, such as `ICSR Validation Report_US2604-0000002.pdf`. This preserves the original file name while also ensuring that each attachment can be identified clearly.

3

What's new in Oracle Argus Safety

This section describes the enhancements made in the Oracle Argus Safety 2026.1.02 patch. These changes also apply to Oracle Safety One Argus.

- [EC MIR 7.3.1 Regulation Updates](#)

EC MIR 7.3.1 Regulation Updates

Summary

Support for EC Manufacturer Incident Report (MIR) version 7.3.1 sub-version SB-11010 and XSD changes (Enhancements 39125316 and 39324105).

Description

Argus Safety has been updated to support the European Commission's MIR version 7.3.1 sub-version SB-11010, released in March 2026, along with the XSD updates published in April 2026, ensuring continued compliance with the latest regulatory requirements.

This change is limited to:

- Updating the MIR 7.3.1 PDF report to reflect the new sub-version identifier (SB-11010)
- Updating the MIR XSDs to make the `similarIncImdrfCodesAnnexA` element optional for the following MIR report types:
 - Combined Initial and Final
 - Final (Reportable Incident)

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

① Note

For additional details on MIR configuration, FAQs, and mappings, refer to the *EC Manufacturer Incident Report (MIR) Best Practices* document and the *MIR 7.3.1 Export Mappings* sheet.

4

What's fixed in Oracle Safety One Argus

This patch includes fixes for issues identified in intake forms, intake processing, audit logging, and source filtering.

- [Non-intake fields ignored merge preferences](#)
When you processed E2B R3+ follow-up data, fields not included in the Intake form did not follow your configured merge preferences. The system always used the default merge behavior, which could keep outdated information or prevent expected updates during case processing. (39088218)
- [Audit logs displayed incorrect event and product details](#)
When you reviewed intake record audit logs, event assessment and attachment entries sometimes displayed internal system IDs instead of readable names. The audit log could also show incorrect event and product sequence numbers. (39004000)
- [Country codes were not resolved on quick tab-out](#)
When you entered A2 or A3 country codes in the Country field and quickly tabbed out, the value was cleared instead of resolving to the correct country. The issue occurred in the Search, Intake, and Merge forms when suggestions had not fully loaded. (39003618)
- [Document pane could not be collapsed or expanded](#)
The document pane could not be collapsed or expanded within the Intake form window. You could only move the pane to a separate pop-up window, which limited available space for reviewing and entering intake data. (38856424)
- [Source filters returned no results for special characters](#)
When you filtered consolidated intake worklists by source values that contained special characters such as { (curly braces), the Worklist and Monitor windows did not return matching records. This issue affected filtering for certain EMA-related sources even though the cases were visible in the grid. (39029870)
- [Intake Worklist column preferences were not retained](#)
When you customized columns in the Intake Worklist, your selected column preferences were not retained after navigating away, logging out, or returning to the application. The worklist reverted to the default column layout instead of preserving your saved view. (38436937)
- [Custom E2B files failed to process in the Intake Worklist](#)
When you processed custom E2B (R2) or E2B (R3) files through the Intake Worklist, files containing the / (forward slash) special character would fail. (38180247)

Non-intake fields ignored merge preferences

When you processed E2B R3+ follow-up data, fields not included in the Intake form did not follow your configured merge preferences. The system always used the default merge behavior, which could keep outdated information or prevent expected updates during case processing. (39088218)

Before

When you imported follow-up data for E2B R3+ cases, fields that were not available in the Intake form always used the system's default merge behavior. Configured merge preferences,

including Force Update, were ignored for these fields. Because of this, existing case information could remain unchanged even when incoming follow-up data was intended to replace or remove it. In some situations, outdated reporter details or duplicate records were retained after follow-up processing. This behavior made case updates inconsistent and required you to manually review and correct merged case information before completing case processing activities.

After

The application now applies configured merge preferences to E2B R3+ fields, even when those fields are not included in the Intake form. When you process follow-up data, the system correctly applies the selected merge option so existing case information is updated, retained, or removed according to your configured rules.

Impacted Areas

Intake processing

Audit logs displayed incorrect event and product details

When you reviewed intake record audit logs, event assessment and attachment entries sometimes displayed internal system IDs instead of readable names. The audit log could also show incorrect event and product sequence numbers. (39004000)

Before

When you viewed audit logs for intake records, event assessment and attachment entries could display system identifiers instead of meaningful values such as event names, product names, or attachment file names. In some cases, deleting an event during intake processing could create duplicate event entries after saving.

After

Audit logs now display readable event names, product names, and attachment file names instead of system identifiers. Event and product numbering is displayed correctly, and deleting events no longer creates duplicate entries during save operations.

Impacted Areas

Audit log

Country codes were not resolved on quick tab-out

When you entered A2 or A3 country codes in the Country field and quickly tabbed out, the value was cleared instead of resolving to the correct country. The issue occurred in the Search, Intake, and Merge forms when suggestions had not fully loaded. (39003618)

Before

When you entered a valid A2 or A3 country code, such as **US** or **USA** in the Country field and quickly moved out of the field, the system cleared the value instead of resolving it to the correct country name. The country was only populated if you waited for the suggestion list to finish loading before tabbing out or if you manually selected a suggestion.

After

The Country field now correctly displays valid A2 and A3 country codes even when you quickly tab out before suggestions finish loading.

Impacted Areas

Intake form

Document pane could not be collapsed or expanded

The document pane could not be collapsed or expanded within the Intake form window. You could only move the pane to a separate pop-up window, which limited available space for reviewing and entering intake data. (38856424)

Before

When you opened the Intake form, the document pane remained fixed on the screen and did not provide an option to collapse or expand it. This behavior reduced the available space for reviewing intake details and entering data. Although you could open the document viewer in a separate pop-up window, the main pane itself could not be hidden or restored within the form.

After

You can now collapse and expand the document pane directly within the Intake form.

Impacted Areas

Intake form

Source filters returned no results for special characters

When you filtered consolidated intake worklists by source values that contained special characters such as { (curly braces), the Worklist and Monitor windows did not return matching records. This issue affected filtering for certain EMA-related sources even though the cases were visible in the grid. (39029870)

Before

When you applied source filters in the Consolidated Intake Worklist or Monitor windows, records with source values containing curly braces, such as {HA} EUROPEAN UNION (EVHUMAN-E2B), were not displayed in the filtered results. The cases were visible in the worklist grid, but filtering by the same source displayed no data. The issue mainly affected EMA-related sources and occurred because the system could not correctly process special characters during source look-up.

After

Source filters now correctly return records for source values that contain special characters, including curly braces.

Impacted Areas

Intake Worklist

Intake Worklist column preferences were not retained

When you customized columns in the Intake Worklist, your selected column preferences were not retained after navigating away, logging out, or returning to the application. The worklist reverted to the default column layout instead of preserving your saved view. (38436937)

Before

When you added, removed, or reordered columns in the Intake Worklist, the customized view was not consistently retained across sessions. After you navigated to another Intake window, logged out, or reopened the application, the worklist often reverted to the default column configuration.

After

The Intake Worklist now retains your selected column preferences across sessions.

Impacted Areas

Intake form

Custom E2B files failed to process in the Intake Worklist

When you processed custom E2B (R2) or E2B (R3) files through the Intake Worklist, files containing the / (forward slash) special character would fail. (38180247)

Before

When you uploaded custom E2B files via the Intake Worklist, the system could fail to process files containing / characters in certain document type values. This issue affected custom E2B (R2) and (R3) files and prevented successful intake processing unless you manually modified the file content.

After

The system now correctly processes custom E2B (R2) and (R3) files containing / characters in document type values.

Impacted Areas

Intake processing

5

What's fixed in Oracle Argus Safety

This section describes the issues that were fixed in the Oracle Argus Safety 2026.1.02 patch. These fixes also apply to Oracle Safety One Argus.

Topics:

- [Unable to display listedness data](#)
- [Unable to generate CIOMS II line listing report](#)
- [Unable to load dictionary due to user creation issues](#)
- [Unable to transmit DEVICECOMPONENT elements in EMA E2B\(R3\)](#)
- [Unable to use Unselect All during new data import](#)
- [Incorrect population of REPORTERCOUNTRYR3\[C.2.r.3\] element](#)
- [Incorrect export of MSK value in the FAERS E2B\(R3\) report](#)
- [Unable to close a case after Medical Review](#)

Unable to display listedness data

Summary

Event Assessment auto-listedness displays as Unknown when event groups are configured in datasheets (Bug 39210682).

Before

When an event group was configured and associated with a datasheet, and the same datasheet was then associated to a Product license, the system did not automatically determine the listedness during case data entry for the event configured in the event group. As a result, the listedness in Case form > Events > Event Assessment section was populated as Unknown, instead of deriving it from the datasheet/license configuration.

After

The system now correctly displays the listedness data in Case form > Events > Event Assessment section by deriving it from the associated Product datasheet/license configuration for the event configured in the event group.

Impacted module

Case form > Event Assessment

Ported from

8.4.4.5

Unable to generate CIOMS II line listing report

Summary

CIOMS II Line Listing Generation is slow (Bug 39118117).

Before

When the CIOMS II line listing report was generated with DLP version enabled over a long date range, the selection criteria included a large number of case revisions, which impacted performance and resulted in slow report generation or report generation failures.

After

The system now generates the CIOMS II line listing report with improved performance when handling large volume of case revision records.

Impacted module

CIOMS II

Ported from

8.4.4.5

Unable to load dictionary due to user creation issues

Summary

Dictionary loading failure due to user creation issues triggered by Customer Password Policies (Bug 39282130).

Before

During dictionary loading from Argus Console > Dictionary Management, the system created a schema using an auto-generated password. In some customer environments, database password policies rejected the generated password. As a result, schema creation failed, which caused the dictionary loading process to roll back.

After

The system now loads the dictionary successfully without failure or rollback, regardless of database password policies.

Impacted module

Dictionary loading

Unable to transmit DEVICECOMPONENT elements in EMA E2B(R3)

Summary

DEVICECOMPONENT tags are not transmitted in EMA E2B(R3) (Bug 39118853).

Before

The DEVICECOMPONENT elements (G.k.2.2.EU.9.r.1 to G.k.2.2.EU.9.r.4) were not being transmitted to EMA E2B(R3) even though the data exists in the Case Form > Products > Device > Device Component Information section.

After

EMA E2B(R3) report transmits DEVICECOMPONENT elements when device component data exist in the case form.

Impacted module

E2B(R3) export (EMA)

Unable to use Unselect All during new data import

Summary

Bulk Uncheck option is not getting applied to new data imported as part of follow-up import (Bug 39256623).

Before

When receiving follow-up E2B, in the ICSR Pending > ICSR Difference report screen, users were unable to use the Unselect All option to clear all incoming data in a single action. Even after selecting the Unselect All option, some items, specifically new data, remained selected, requiring users to manually uncheck each parent item one by one before proceeding with case acceptance.

After

When receiving follow-up E2B, in the ICSR Difference report screen, users can use the Unselect All option to clear all incoming data in a single action. All selections are removed as expected, allowing users to quickly proceed with case acceptance and then enter the required information.

Impacted module

E2B Import - View Difference

Incorrect population of REPORTERCOUNTRYR3[C.2.r.3] element

Summary

Non-US REPORTERCOUNTRYR3[C.2.r.3] element incorrectly masked when Protect Confidentiality is enabled in FAERS E2B(R3) (Bug 38804679).

Before

In the FAERS E2B(R3) profile, when the Protect Confidentiality option was enabled for a case with a non-US reporter country, the REPORTERCOUNTRYR3[C.2.r.3] element was incorrectly populated with MSK NullFlavor even though valid source data (ISO country code) was available.

After

If valid data is available in the Source field, the REPORTERCOUNTRYR3[C.2.r.3] element always populates with the corresponding ISO 3166-1 country code, regardless of the Protect Confidentiality option settings. MSK or other NullFlavors are transmitted only when users explicitly provide and allow them.

Impacted module

E2B(R3) export (FAERS)

Incorrect export of MSK value in the FAERS E2B(R3) report

Summary

Negative ACK due to multiple MSK values transmitted for patient race in FAERS E2B(R3) report (Bug 38896603).

Before

When multiple patient race values with associated NCI codes were entered in a case with the Protect Confidentiality option enabled for the patient, the FAERS E2B(R3) report generated using the out-of-the-box (OOTB) profile incorrectly exported the MSK (MASKED) value multiple times for the PATIENTRACE[FDA.D.11.r.1] element. This resulted in a negative acknowledgment (ACK) from the FDA.

After

When the Protect Confidentiality option is enabled for the patient, the FDA E2B(R3) FAERS report appropriately masks the race information and populates the PATIENTRACE[FDA.D.11.r.1] element only once with the MSK NullFlavor, irrespective of the number of race entries in the case.

Impacted module

E2B(R3) export (FAERS)

Unable to close a case after Medical Review

Summary

Unable to close case after Medical Review in Worklist > New (Bug 39329308).

Before

When you selected a case from Worklist > New, invoked the Medical Review screen through the right-click menu, clicked the Cancel button, and then tried to close the case again using the same menu, the system incorrectly displayed a message indicating that the case was still open and could not be closed.

After

The system now correctly allows formal closure of a selected case from the Worklist > New screen through the right-click menu after the Medical Review screen is closed using the Cancel button, without displaying the error message.

Impacted module

Medical Review

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Product Verification Pack (PVP)

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

The latest PVP for Oracle Safety One Argus is made available on [My Oracle Support](#). The patch containing the PVP for Oracle Safety One Argus is **35790103**.

To complete the steps below, you need the following:

- A My Oracle Support account. If you don't have one, please 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. Patch passwords expire periodically.
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, 35790103, and press **Return**.
 5. Select **Apply**.
 6. Select the patch from the list of results.
 7. Select **Download**.
 8. Enter the password for this patch. Passwords are case sensitive.
 9. Select **Unlock**.
 10. Select the ZIP file to start the download.