Oracle Life Sciences Safety One Argus

Release Notes



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Overview

Oracle Safety One Argus 2026.1.04 is a patch release that delivers targeted enhancements and fixes across intake processing, case form, CIOMS form extraction configuration, Smart Coding, and the Gen AI Narrative service. These updates improve user configuration, accuracy and efficiency of the Smart Coding solution, and reduce manual effort through more reliable intake coding, case processing, and system operations.

- Prerequisites
- Affected features

Prerequisites

Safety One Argus 2026.1.01

Affected features

- Case form
- Smart Coding
- CIOMS form extraction
- Gen AI Narrative service

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What's new in this release

This section describes the enhancements made in the Oracle Safety One Argus 2026.1.04 patch. These changes also apply to Oracle Argus Safety.

- Smart MedDRA Coding enhancements
- Structured document data extraction enhancement
- CIOMS form extraction configuration
- Gen AI Narrative enhancements

Smart MedDRA Coding enhancements

Summary

Smart MedDRA Coding now combines suggestions from historical coding data and the AI model to improve coding efficiency. Additional configuration controls and user interface enhancements support more efficient human review.

Description

Configuration Changes

Argus Console now provides additional controls for Smart Coding suggestions, automatic coding, and historical coding data. These settings are available under: `Argus Safety > Console > System Management (Common Profile Switches) > Case Form Configuration > Modify Case Form Configuration > Auto-Encoding, Dictionary & Central Encoding`

The changes are as follows:

- The **Smart - Event Encoding** common profile switch is renamed to **Enable Smart Coding**. This switch is independent of the selection/deselection of the **Events & Indications** checkbox. That is, the smart coding suggestions are available in the MedDRA browser even when the Events & Indications checkbox is unchecked.
- The following enterprise-level switches are added:
  - **Threshold to display suggestions in MedDRA Browser (in Percentage)** is added to control the number of suggestions being displayed in the MedDRA browser. This switch is enabled when the Enable Smart Coding switch is checked and returns the results based on the pre-configured confidence score threshold.
  - **Enable Auto-coding for Smart Coding suggestions** is added to configure whether to auto-code the term returned by the Smart Coding solution or not based on the score threshold to enable you to review the term before coding. This switch can be enabled only when the Enable Smart Coding switch and the Events & Indications Auto-Coding checkbox are checked. The Threshold for auto encoding switch is moved under this switch. By default, this switch is unchecked.
  - **Historical Coding data time period** is added to specify the start and end date for historical coding data, based on when case records were last updated. This switch is enabled when the Enable Smart Coding switch is checked.

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* When Smart Coding is enabled, the historical period defaults to four years ending at the beginning of the previous calendar quarter. For example, enabling Smart Coding on 01-Sep-2025 sets the period to 01-Apr-2021 through 01-Apr-2025.

> **Note**
>
> This is to ensure that the most recent data is not included, as it may include cases for which coding is not yet reviewed or corrected.

* If Smart Coding was enabled before an upgrade, the default period is calculated using the upgrade date.
* Historical data load runs in the background, and the status is displayed in the Load Status field.

MedDRA browser and encoding enhancements

The MedDRA Browser has been enhanced to display AI and historical coding data suggestions ranked by confidence score. New icons identify AI or historical auto-coding data and signal when they require human review.

The MedDRA Browser displays Smart Coding suggestions in descending confidence-score order, whether the suggestion comes from the model or from historical data.

When auto-coding by using Smart Coding is enabled, the system displays an AI icon ( ).

When it auto-codes a term by using historical data, it displays a Historical Coding icon ( ). Both icons signal that human review is required. The application removes the blue manual-review icon that was displayed when an auto-coded Smart MedDRA term had other suggestions with the same score.

You can review an auto-coded term from the MedDRA browser or from the Quality Check tab. Confirming the existing term changes the status icon to a green tick and records the result as verified.

Selecting a different term changes the icon to a green tick and records the result as manually overridden.

Selecting Cancel leaves the icon and coding status unchanged.

The system displays the `Coded with Smart Encoder using AI` message in the intake form when you hover over the Coding icon and if the terms are coded by Smart Encoder using AI. This text is updated when human action is taken. Similarly, when you use historical data, the `Coded with Smart Encoder using historical data` message is displayed.

Quality Check tab changes

Events that are auto-coded by Smart Encoder now include a Quality Check review action, allowing you to verify, override, or retain the coding status in the Intake form.

When an event is auto-coded by using Smart Coding, the Quality Check tab displays a review item with a **Verify** action. To solve it, you can take the following steps:

Select **Verify**, or select **OK** in the MedDRA Browser without changing the term, to change the status icon to a green tick and mark the event as **Coded with Smart Encoder and Verified**.

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Select a different term in the MedDRA Browser to change the status icon to a green tick and mark the event as **Coded with Smart Encoder but manually overridden**.

If you select **Cancel**, the application retains the current status icon and coding status, such as **Coded with Smart Encoder using AI** or **Coded with Smart Encoder using Historical data**.

Structured document data extraction enhancement

Summary

Structured document extraction now corrects page rotation and sequencing to improve extraction accuracy and ensure extracted information is accurately highlighted in the document, supporting efficient human review.

Description

When you submit a supported document for extraction, the application:

- Standardizes page rotation across the document.
- Corrects page sequence when it can identify page numbers.
- Extracts data from the adjusted document.
- Displays both the adjusted and original documents in the intake form. The adjusted document serves as the primary document for extraction. A Document Type badge next to the document name in the document viewer's selection menu distinguishes it from the original source document.
- Retains the original source document, as well as the modified document, and attaches both documents to the case form when you create an initial case for an intake record or merge it as a follow-up.

The application supports these adjustments for supported extraction formats, including text and image-based PDF, DOC, and DOCX files.

CIOMS form extraction configuration

Summary

Coded event extraction enhancement for CIOMS reports.

Description

When a CIOMS report includes a preferred term (PT) or a lowest-level term (LLT), the system now maps that term to the **Description to Be Coded** field in the intake form and uses it as provided during coding.

The coding process uses the mapped term to find an exact match, which prevents the system from coding the event again from the verbatim term.

Gen AI Narrative enhancements

Summary

The Gen AI Narrative feature has been enhanced with a new section order, the DD-MMM-YYYY default date format across all narrative sections, and additional data fields that are included in the generated output.

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Description

This release introduces the following enhancements to the Gen AI capabilities for the Narrative section:

1. Updated section order
   The order of narrative sections has been updated: `Opening Statement > Medical and Drug History, Concomitant Products > Suspect Products > Adverse Events > Lab Data > Treatment Products > Autopsy (if Event is fatal) > Action Taken (Rechallenge/ Dechallenge) > Causality Assessment > Reporter Comments`
2. Default date format
   Dates are required to be displayed in the **DD-MMM-YYYY** format, such as **02-Jan-2024**.

   > **Note**
   >
   > This default date format applies across all sections, including but not limited to receipt, onset, therapy, and lab/test dates.

3. New data fields
   The following new data fields are added to the generated output:

   In the Opening Statement section:

   - General > Reporter Information > **Country**;
   - Patient > Patient Details > **Age Group** (consider Patient Age group if age is not present);
   - Additional Information > References > **Reference ID**;
   - Additional Information > References > **Reference Type**; If available, the **World Wide Unique Identification** number is given preference;
   - Analysis > Case Summary > **Case level seriousness**.

   In the Medical History section, Patient > Other Relevant History > **Notes**.

   In the Family History section, Patient > Other Relevant History > **Notes**.

   In the Concomitant Products section, Products > Product Information > **Formulation**.

   In the Suspect Products section, Products -> Product Information > **Formulation**.

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What's fixed in this release

This release includes bug fixes related to the Oracle Cloud Infrastructure (OCI) Generative AI service and a case form issue.

- Gen AI Narrative messaging issue
- Gen AI Narrative Lab data issue
- Re-Challenge and De-Challenge sections displayed incorrect information
- Causality issue in generated narratives
- Gen AI Narrative generation for large cases issue
- Case lock not released

Gen AI Narrative messaging issue

Before

If Gen AI could not generate narrative, the system displayed the following general message: Unable to generate narrative result. (Bug 38920897)

After

If Gen AI can not generate narrative, the system displays user friendly message, when applicable.

Impacted areas

Gen AI service

Gen AI Narrative Lab data issue

Before

For a specific case record, each line in the Lab Data paragraph of the Gen AI narrative began with a hyphen. (Bug 38648299)

After

Lines in the Lab Data paragraph of the Gen AI narrative no longer begin with hyphens.

Impacted areas

Gen AI service

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Re-Challenge and De-Challenge sections displayed incorrect information

Before

If de-challenge or re-challenge values were not present in a case, then those values were mentioned in the narrative as not specified or not reported, which is incorrect. (Bug 38819952)

After

Re-challenge and de-challenge information is included in the narrative only when present in the case.

Impacted areas

Gen AI service

Causality issue in generated narratives

Before

When you generated a narrative, it could incorrectly change an event's causality. For example, it could describe an implied related event as related. (Bug 38819927)

After

Generated narratives preserve event causality as provided.

Impacted areas

Gen AI service

Gen AI Narrative generation for large cases issue

Before

Narrative generation using Gen AI failed for a case record that contained large amount of data, for example 100 events and 100 products. (Bug 38647693)

After

Gen AI can generate a narrative for larger cases.

Impacted areas

Common function

Case lock not released

Summary

Case closure did not release lock after user confirmation. (Bug 39655146).

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Before

For users with the Route on Close Case access, closing a saved case did not consistently release its lock. This issue occurred due to the deprecation of the unload event in Google Chrome and Microsoft Edge. As a result, affected cases could remain marked as in use by the previous user, limiting other users to read-only access.

After

When a user with the Route on Close Case access saves and closes a case in Google Chrome or Microsoft Edge, the case lock is released, allowing other authorized users to open and edit the case.

> **Note**
>
> You can apply this patch even if you previously applied the recommended registry-change workaround.

Impacted module

Case form

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