

# Oracle Life Sciences Safety One Intake

## Release Notes



Release 25.1

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# Preface

This preface contains the following sections:

## Documentation accessibility

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

## Access to Oracle Support

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

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

- English interface Customer Support Portal (<https://hsgbu.custhelp.com/>)
- Japanese interface Customer Support Portal (<https://hsgbu-jp.custhelp.com/>)

You can also call our 24x7 help desk. For information, visit <https://www.oracle.com/life-sciences/support/> or visit <https://www.oracle.com/corporate/accessibility/learning-support.html#support-tab> if you are hearing impaired.

## Diversity and Inclusion

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

# 1

## Introduction

Oracle Safety One Intake is a cloud solution providing advanced intake capabilities for processing adverse event (AE) data from various sources.

It automatically analyzes structured and unstructured documents and converts them into cases for use in Oracle Safety One Argus and other supported safety database systems.

Oracle Safety One Intake 25.1 is provisioned by default for all Oracle Safety One Argus 25.1 customers. Advanced extraction capabilities using optical character recognition (OCR), artificial intelligence (AI), and machine learning (ML) are available for an additional subscription.

# 2

## What's new in Oracle Safety One Intake

This release introduces features designed to help Oracle Safety One Intake users process AE data and complete their work with maximum efficiency and accuracy.

### Topics:

- [Consolidated intake processing workflows](#)
- [On Hold Worklist for follow-up staging](#)
- [Auto-assignment of tasks](#)
- [Email intake enhancements](#)
- [Support for CIOMS forms](#)
- [Support for JPMA forms](#)
- [Easy navigation between case forms and follow-up records](#)
- [Integration with the OCI Health NLP and PII models](#)
- [Publish intake records to external systems](#)

### Consolidated intake processing workflows

The Intake Worklist now supports E2B imports, allowing you to process E2B records directly from the Intake Worklist. You can also perform Duplicate Search and Merge Follow-up tasks for incoming AE records, including E2Bs and other source documents, from the Intake Worklist.

With Oracle Safety One Intake 25.1, all incoming English E2Bs via the interchange service appear in the Intake Worklist with appropriate tasks automatically assigned. Details and actions previously available in the ICSR Pending and ICSR Processed reporting screens in Oracle Argus Safety are now accessible in the Intake Worklist and Intake Monitor List respectively. Additionally, E2B reports in the Intake Worklist now support PII restrictions and task assignments for enhanced compliance and workflow management.

Users working on E2B imports must be assigned the Intake Processor role to maintain uninterrupted access to E2B import workflows within the Intake Worklist.

When a new follow-up is received for an existing case, the system automatically adds a notification for the case processing user in the New/Open Worklist and the case form. This transition centralizes intake processing, integrating all key functionalities into one intuitive, consolidated interface for easier and faster task completion.

### On Hold Worklist for follow-up staging

With this release, intake processors can review a case follow-up and decide whether to merge it into the existing open case or put it on hold if the case is not ready (for example, because it is locked for reporting or submission).

Follow-ups that are put on hold are displayed in the new On Hold Worklist.

This feature provides additional benefits:

- Follow-ups received from trusted agencies (agencies configured for auto-accept) are automatically held if the original case is not ready to accept the follow-up. They are merged into the original case when it is ready.
- Follow-ups from agencies not configured for auto-accept are available for review, allowing the user to place the record on hold when the case is not ready, and are released back to the Intake Workflow list when the case is ready.
- Workflow managers can use the On Hold Worklist display to see details such as the hold reason and date, allowing them to effectively monitor and resolve issues.

## Auto-assignment of tasks

With this enhancement, records requiring manual intervention can be assigned automatically to intake processors so they can easily see what they need to work on next, either at the start of their day or when their current task is complete.

They can identify and open the top priority record from the records already assigned to them; if no record is assigned, they can request one. They can also choose to start working on another record as soon as they have finished processing their previous one.

This enhancement means workflow managers no longer have to triage and assign intake records individually or through a third-party tool, providing a significant increase in workflow efficiency and processing turnaround.

## Email intake enhancements

This release includes enhancements to the email processing features of Oracle Safety One Intake.

- Administrators can specify the email sources that should be processed for AE information in the email body to ensure maximum data extraction.
- The system can automatically extract AE data from email bodies, allowing intake processors to focus on reviewing and validating the information rather than on manual entry.
- Intake processors can annotate extracted AE data directly in the email body for better context and traceability.

## Support for CIOMS forms

With this release, Oracle Safety One Intake provides an out-of-the-box recipe for automatically extracting drug safety information from CIOMS forms.

Automating this process improves efficiency and consistency in data entry, significantly reducing the time intake processors have to spend on manual input for CIOMS data.

## Support for JPMA forms

This release includes a demonstration recipe that showcases Oracle Safety One Intake's ability to automatically extract drug safety information from JPMA forms.



Note: This recipe provides a foundation for automated processing of Japanese documents, and we are actively working to expand our capabilities to support end-to-end Japanese intake in future releases.

## Easy navigation between case forms and follow-up records

With this release, you can open cases associated with pending and processed reports directly from Oracle Safety One Intake.

Additionally, after a follow-up is accepted and merged with the case, the follow-up section in the case record includes a link to the intake record in Oracle Safety One Intake.

This enhancement allows users to review cases quickly when they need to check for duplicates or merge cases, for example.

## Integration with the OCI Health NLP and PII models

This release includes support for using the OCI Health natural language processing (NLP) and personally identifiable information (PII) models with Oracle Safety One Intake.

These models allow better prediction of adverse event attributes from unstructured text. The enhancement is available out of the box for intake designers to configure in the document recipe. It supports the following attributes:

Section	Attribute
Patient	Patient Age
Patient	Patient Gender
Event	Event Description as Reported
Product	Product Name
Dosage	Strength
Dosage	Frequency
Dosage	Route of Admin
Dosage	Duration
Dosage	Formulation

## Publish intake records to external systems

This release provides the ability to publish intake records processed in Oracle Safety One Intake to external systems.

With Oracle Safety One Intake 25.1, you can publish intake records in E2B(R3)-compliant format from Oracle Safety One Intake to any sponsor-owned safety database. The data can be sent through email or REST APIs.

A primary use case for this feature is to support CRO customers who are responsible for intake processing only and publish the results to their own customers for case management.

# 3

## Changes to the Argus Console

Changes have been made to the Argus Console to support the 25.1 enhancements to Oracle Safety One Intake.

### Configuration for the On Hold Worklist

Configuration options for the On Hold Worklist feature are available through the Argus Console at **System Configuration > Workflow > States > Hold Follow-up Merge during Intake**. You can customize the configuration based on the case workflow states and include advanced conditions. See [On Hold Worklist for follow-up staging](#).

### Configuration for the Intake Only feature

Configuration options for the Intake Only feature, described in [Publish intake records to external systems](#), are available through the Argus Console at **System Configuration > System Management (Common Profile Switches) > Intake Processing at enterprise level**. If your company is a CRO, you can choose whether you want to perform intake processing only for your customer, or both intake processing and case processing.

### Configuration for task auto-assignment

This feature is described in [Auto-assignment of tasks](#). In the Argus Console, you can choose to automatically assign the next intake task to intake processors when they complete their current task; see **System Configuration > System Management (Common Profile Switch) > Workflow > Case Routing > Enable Auto opening of the next case/intake record**.

### Configuration for narrative processing

If you have subscribed to advanced extraction features, you can enable Artificial Intelligence/Machine Learning-based E2B narrative processing through the Argus Console at **Codelist > Argus Codelist > Reporting Destination > EDI > Allow Narrative Processing During Intake**.

# 4

## Features added in earlier releases

For information about enhancements in earlier versions of Oracle Safety One Intake, please refer to the releases notes for that version.

- [Oracle Safety One Intake 24.1 Release Notes](#)
- [Oracle Safety One Intake 23.4 Release Notes](#)
- [Oracle Safety One Intake 23.3 Release Notes](#)

# 5

## Compatibility and browser requirements

Oracle Safety One Intake 25.1 is compatible with Oracle Safety One Argus 25.1.

### **Browser requirements**

- Google Chrome version 103.0.5060.53 or later
- Microsoft Edge version 103.0.1264.37 or later

# 6

## Known issues

For information about known issues in this release, please see the article [Oracle Safety One Intake Documentation \(Doc ID 3024370.1\)](#) on [My Oracle Support](#). Workarounds are provided where available.

# 7

## 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 the pack available to customers with every release (except patches). You can use the PVP as a blueprint for acceptance testing.

The PVP for Oracle Safety One Intake is available on [My Oracle Support](#). For information on how to download a PVP, follow the instructions in [Oracle Argus Product Verification Pack](#). The patch containing the PVP for Oracle Safety One Intake is **35790103**. Please note that the product name appears as Oracle Safety One Argus in the patch listing.