Oracle Life Sciences Safety One Intake
User Guide

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Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Related resources](#)
- [Access to Oracle Support](#)

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.

Related resources

All documentation and other supporting materials are available on the [Oracle Help Center](#).

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.

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About Oracle Safety One Intake

Oracle Safety One Intake is an advanced pharmacovigilance system that optimizes the handling of Adverse Event (AE) documents.

Oracle Safety One Intake provides multiple options for ingesting AE documents, including manual uploads, automatic uploads via API, email, or Electronic Data Interchange (EDI).

> ⓘ **Note**
>
> All automated features, including OCR/ML extraction, require an additional subscription to Oracle Safety One Intake. For more information, reach out to your Oracle point of contact.

Oracle Safety One Intake processes AE documents into cases, in a sequential workflow. The workflow is as follows:

1. Via email, API, Electronic Data Interchange or through direct user upload, documents are ingested by Oracle Safety One Intake.

2. As part of this step, Oracle Safety One Intake marks records that require manual review - this may involve reviewing and confirming extracted information, correcting validation errors, or providing any missing data.

3. Oracle Safety One Intake classifies the document.

4. To extract adverse event data from the document, Oracle Safety One Intake utilizes Optical Character Recognition (OCR) and Machine Learning (ML). As part of this step, Oracle Safety One Intake marks records that require manual review, which can involve reviewing and confirming extracted information, correcting validation errors, or providing any missing data. For unidentified documents, the option to perform manual data entry is available.

5. The system then checks the document against other, already ingested documents, marking it for Duplicate Search or Merge Follow-up. Users manually compare the data of records with these statuses, then either accept or reject them..

6. If the target system is configured to accept data automatically, the data will be converted into a new case or will be merged with an existing one.

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Set up Oracle Safety One Intake

To begin working in Oracle Safety One Intake, there are several steps you must take.

- [Prerequisites](#)
  To start working, you must first receive your Oracle Identity Cloud Service (IDCS) account as well as the product URL from your organization's delegated administrator.

- [Accounts and roles](#)
  From your delegated administrator, you must obtain all the roles necessary for working in the Oracle Argus Safety Console.

- [Username and password](#)
  You will receive your username and password via email once your delegated administrator creates your account in Oracle IDCS.

- [Product URL](#)
  Your delegated administrator is responsible for sharing the product URL with all Oracle Safety One Intake users at your organization.

- [Scale and layout](#)
  To properly view and use Oracle Safety One Intake, your computer must first fulfill several requirements.

Prerequisites

To start working, you must first receive your Oracle Identity Cloud Service (IDCS) account as well as the product URL from your organization's delegated administrator.

Accounts and roles

From your delegated administrator, you must obtain all the roles necessary for working in the Oracle Argus Safety Console.

If you are responsible for user role management or would like to find out more about roles and permissions in the Oracle Argus Safety Console, see Add users and assign roles, in the Oracle Safety One Intake Administration Guide.

Username and password

You will receive your username and password via email once your delegated administrator creates your account in Oracle IDCS.

Product URL

Your delegated administrator is responsible for sharing the product URL with all Oracle Safety One Intake users at your organization.

Bookmark the URL you receive from your delegated administrator, not the URL that appears in your browser once you access the application.

> ✅ **Tip**
>
> If you cannot bookmark a typed URL in your browser, you can bookmark the URL that appears after you access the application, then edit the bookmark, and add the URL you received from your delegated administrator.

Scale and layout

To properly view and use Oracle Safety One Intake, your computer must first fulfill several requirements.

The supported screen scale (zoom) is 100%. If the scale is not set to 100%, this may distort or truncate the user interface.

The recommended screen resolution is 1440 x 900 and above. Depending on the device you are using to display Oracle Safety One Intake, the supported layout may vary.

> ⓘ **Note**
>
> For Oracle Safety One Intake to work optimally, disable the pop-up blocker in your browser's settings. You should also access Oracle Safety One Intake in a single tab or window.

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Get started with Oracle Safety One Intake

Oracle Safety One Intake can automatically extract adverse event attributes from structured and unstructured form text. This significantly reduces the human effort to perform safety source document extraction, and it allows the adverse events that don't require manual review to be converted into cases sooner.

> ⓘ **Note**
>
> All automated features, including OCR/ML extraction, require an additional subscription to Oracle Safety One Intake. For more information, reach out to your Oracle point of contact.

- [Log in](#)
  Includes step-by-step guidance on how to safely log into Oracle Safety One Intake.

- [Log out](#)

- [Know your role](#)
  When working with AE documents in Oracle Safety One Intake, you can have either an intake processor role or a workflow manager role.

- [Navigating](#)
  Once you have logged in, you will be redirected to the Intake Worklist page, which also serves as the home page.

- [Switch between enterprises](#)
  Oracle Safety One Intake offers the capability for users to work across several enterprises, all at once.

Log in

Includes step-by-step guidance on how to safely log into Oracle Safety One Intake.

To log in to Oracle Safety One Intake, follow the steps below.

1. In your browser's address bar, enter the URL for Safety One Intake.

2. When the login screen appears, enter your username and password.

3. Click **Login**.

After logging in, you are taken to the Intake Worklist, which is the home page. From there, you can choose to navigate to different pages as needed. To do so, select the **Navigation Menu** ☰ on the top left corner of the screen, and select either **Intake Worklist** or **Intake Monitor**.

The version number and Oracle Safety One Intake environment can be seen from any page by selecting the **User menu** TP from the top right corner of the page, then selecting **About Argus**.

To access the Oracle Safety One Intake documentation, select the **User menu** [TP] from the top right corner of the screen and then click **Help**.

Log out

To log out, select the **User menu** [TP] in the top right corner and then select **Logout**.

Know your role

When working with AE documents in Oracle Safety One Intake, you can have either an intake processor role or a workflow manager role.

For a complete list of roles involved in the processes of Oracle Safety One Intake, see User role attributes.

- Intake processor
  As an intake processor, your responsibilities include handling the intake records uploaded to Oracle Safety One Intake.

- Workflow manager
  If you have the workflow manager role assigned, your primary responsibility revolves around ensuring accurate assignment and timely processing of incoming records within the established service-level agreement.

Intake processor

As an intake processor, your responsibilities include handling the intake records uploaded to Oracle Safety One Intake.

Optionally, you may be associated with a user group. Based on your permissions, you can access ingested AE documents affiliated with your site, those assigned specifically to you, and those assigned to other members within your user group.

Workflow manager

If you have the workflow manager role assigned, your primary responsibility revolves around ensuring accurate assignment and timely processing of incoming records within the established service-level agreement.

As an authorized user, you can assign records to the appropriate users to help prevent delays in processing. You can also access all AE documents that have been ingested and are associated with your site.

Navigating

Once you have logged in, you will be redirected to the Intake Worklist page, which also serves as the home page.

Depending on your requirements, you can select the **Navigation Menu** [≡], located on the top-left corner of the page, and choose one of the following options:

- **Intake Worklist**

- **Intake Monitor**

- **On Hold Worklist**

> ✅ **Tip**
>
> You can also return to the Intake Worklist from any page by clicking **Navigation Menu** ☰, in the top-right corner.

To access information on the Oracle Argus Safety version number and the name of the Oracle Safety One Intake environment you are currently using, select the **User menu** [TP] in the top-right corner and select **About**.

For quick access to relevant documents and training materials, select the **User menu** [TP] in the top-right corner and select **Help**.

You can also access a detailed view of each intake record by clicking one of the hyperlinked IDs from the list of records.

Switch between enterprises

Oracle Safety One Intake offers the capability for users to work across several enterprises, all at once.

Each enterprise can be configured separately, with its own set of permissions for users, user groups, and intake records, as well as AE document interpretation method.

As a workflow manager, you can switch between enterprises and work as you would normally, without losing progress on either enterprise you have access to. Each enterprise has its own set of associated records and configurations. Administrators can also set up new enterprises or copy enterprise configurations.

Whenever you switch between enterprises, what you see in the Intake Worklist and the Intake Monitor changes.

The enterprises are listed alphabetically. Should you have access to more than 10 enterprises, an enterprise browser with search capabilities is available.

> ⓘ **Note**
>
> Preferences such as applied filters, your search history, filter suggestions, or your column settings are saved for each of the enterprises you have access to.

1. On the upper right-hand side of the page, select the **Navigation menu** ☰.

2. Select **Switch Enterprise**, then select the enterprise environment you would like to change to.

> ⓘ **Note**
>
> This menu item will not be available unless you have access to at least two enterprises.

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Uploading documents

Oracle Safety One Intake can ingest Adverse Event (AE) documents automatically, but depending on your role, you may also be able to upload AE documents manually.

- [Understanding which documents to add](#)
  The Oracle Safety One Intake system can be configured to automatically process a range of AE document types.

- [Upload documents automatically](#)
  Oracle Safety One Intake can ingest documents automatically via email, Electronic Data Interchange (EDI), and APIs.

- [Upload documents manually](#)
  One of the ways of processing AE documents using Oracle Safety One Intake is through manual upload, using the user interface.

Understanding which documents to add

The Oracle Safety One Intake system can be configured to automatically process a range of AE document types.

Supported AE document types

Oracle Safety One Intake can normally ingest the following types of AE documents:

- AE reports in the form of email, spontaneous AE forms, or call center AEs.

- Company websites, company adverse event reporting portals, voice to text transcriptions, chatbot text.

- Clinical Serious Adverse Events (SAEe), in the form of papers, fax, or a digital format.

- Literature cases and Medical Literature Monitoring ICSRs.

- E2B(R2) and E2B(R3) files.

To find out which document types are supported for your organization, contact your delegated administrator.

Supported file types

By default, Oracle Safety One Intake supports the following file types:

Table 4-1   Safety One Intake supported file types for ingestion

File type	Format
Image	VSD, TIF, TIFF, PSD, PS, PNG, JPG, JPEG, BMP, GIF
Text	DOC, DOCX, TXT, RTF, PDF, MSG, WPD
Spreadsheet	XLS, XLSX, CSV
Other	MDB, ZIP, DICOM, DCM, PPT
Markup	XML, SGML, SGM

> ⓘ **Note**
>
> Your delegated administrator configures the file types you can upload to Oracle Safety One Intake.

Supported file types for automated processing

Automatic extraction only works for the following:

- E2B R2 and R3 files.
- Text and image-based files, such as faxes or scanned documents. These can only be in DOC, DOCX, and PDF formats.

  > ⓘ **Note**
  >
  > DOC, DOCX, and PDF extractions require an additional subscription to Oracle Safety One Intake. For more information, reach out to your Oracle point of contact.

- Extraction for DOC, DOCX, and PDF files requires recipe configuration. For more information, see [Create a new recipe configuration](#).

Upload documents automatically

Oracle Safety One Intake can ingest documents automatically via email, Electronic Data Interchange (EDI), and APIs.

Oracle Safety One Intake supports integration with email clients. This is set up by your administrator. With this integration, emails and their attachments can be ingested in the Oracle Safety One Intake system.

By means of EDI, Oracle Safety One Intake can ingest E2B adverse event reports.

Oracle Safety One Intake also supports integration with third party systems and applications through REST APIs, through which AE documents can be ingested automatically. For more information, see [REST API for Safety One Intake](#).

The following are a few of the sources of data which can normally be used to ingest data via API:

- Social media
- Document management systems
- Product complaint systems
- Sales consultants
- Medical Information (MI) systems
- Clinical Trial Post-Authorization Safety Study (PASS)
- Affiliate Patient Supports Programs (PSP)

Upload documents manually

One of the ways of processing AE documents using Oracle Safety One Intake is through manual upload, using the user interface.

To ingest your documents, follow the steps below.

1. In the upper-right corner of the Intake Worklist, select the **Actions** and then select **Upload Document**.

2. Follow the on-screen instructions to continue uploading the document.

> ✅ **Tip**
>
> You can also drag and drop one or several documents to the browser tab where you have Oracle Safety One Intake open.

3. Select the **Site** dropdown, then select the site you would like to ingest the document for.

4. Select **Process Reports**.

> ⓘ **Note**
>
> Processing your reports can take up to several minutes to complete.

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Managing assignments

Depending on your role, you may be able to assign and unassign records. You can also take advantage of the automatic assignment function. Read more about record assignment in the topics below.

- **Manage assignments as a workflow manager**
  As a workflow manager, you are authorized to manage assignees for intake records. In the Intake Worklist, you can assign records to individuals or user groups.

- **Manage assignments as an intake processor**
  As an intake processor, you can assign a record to yourself or unassign a record that has been assigned to you.

- **Possible errors in assignment and what you should do**
  You may receive an error as you assign or unassign records. See the table below for detailed explanations of the errors you may receive, as well as the actions you should take to fix them.

- **Automatic record assignment**
  To facilitate the smooth running of the intake process, records requiring manual intervention can be assigned automatically to intake processors, upon request. This is for them to easily see what they need to work on next, either at the start of their day or when their current task is complete.

Manage assignments as a workflow manager

As a workflow manager, you are authorized to manage assignees for intake records. In the Intake Worklist, you can assign records to individuals or user groups.

You can assign a record to an individual or group in three distinct ways:

- Using the **Assign** hyperlink, as you upload documents to Oracle Safety One Intake.

- Using the **Actions** menu, from the Intake Worklist. Using this method, you can manage the assignees of your records in bulk.

- Using the **Expand Details** button for each individual record.

You can have either a single user or a single user group assigned to a record.

1. Depending on your requirements, perform one of the following:

   - Once a document has been uploaded, select the **Assign** hyperlink.

   - In the Intake Worklist, check the boxes of one or several records, on the left, then select the **Actions** button on the upper right, and choose **Assign**.

   - Select a record, then select **Expand Details** at the top of the records frame, then choose **Assignment**.

   All three options open a panel where you can assign a record by selecting from a list of groups and users.

2. In the panel, you can select which groups or users to assign the record to.

> **✓ Tip**
>
> Use the search bar to narrow down the number of assignees.

3. Once you have made your selection, select **Confirm Assignment**.

4. Check that your selection is reflected in the **Assigned To** column in the Intake Worklist.

> **ⓘ Note**
>
> Keep an eye out for notifications, at the bottom of the page. If you receive an error message, select **View Errors** to see why it occurred. For more information on the errors you may receive, see Possible errors in assignment and what you should do.

Manage assignments as an intake processor

As an intake processor, you can assign a record to yourself or unassign a record that has been assigned to you.

To assign or unassign records, follow the steps below.

1. In the Intake Worklist, select one or more records by checking their boxes on the left.

2. Select the **Actions** button, then select one of the following:

    •   **Assign to me**

    •   **Unassign**

You are only allowed to unassign the records that are assigned to you.

> **ⓘ Note**
>
> Keep an eye out for notifications, on the bottom of the page. If you receive an error message, select **View Errors** to find out why this has happened. For more information on the errors you may receive, see Possible errors in assignment and what you should do.

Possible errors in assignment and what you should do

You may receive an error as you assign or unassign records. See the table below for detailed explanations of the errors you may receive, as well as the actions you should take to fix them.

Table 5-1   Possible assignment errors and how to fix them

Error	Why has this happened?	Actions to take
Intake Complete	The record no longer needs manual intervention.	Refresh the Intake Worklist. This may clear the record from your roster.
Read Only	A different user is currently working on the record.	Retry your action periodically until the record is no longer busy.

Table 5-1   (Cont.) Possible assignment errors and how to fix them

Error	Why has this happened?	Actions to take
Restricted Access to Site	The selected user does not have access to the record due to a site restriction.	Reach out to your delegated administrator.
Task Status Changed	The system has begun processing the record and manual intervention is no longer required. The record could have also been assigned to a different user or could have been assigned to a user group you currently do not have access to.	Refresh the Intake Worklist. This may clear the record from your roster.

Automatic record assignment

To facilitate the smooth running of the intake process, records requiring manual intervention can be assigned automatically to intake processors, upon request. This is for them to easily see what they need to work on next, either at the start of their day or when their current task is complete.

Intake processors can open the top priority record from the records already assigned to them; if no record is assigned, they can request one by clicking the **Open Next Record** in the top right corner of the Intake Worklist.

> ⓘ **Note**
>
> The **Open Next Record** button is only displayed if auto-assignment is enabled in configuration.

Intake processors can also begin working on a record in the Intake Worklist or Intake Monitor. Once they have finished working on their record, the system automatically prompts them to begin working on the next available record or return to either the Intake Worklist or the Intake Monitor, depending on where they have originally begun working on the record .

While it is typically the responsibility of workflow managers to assign records to users or groups of users, they 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.

> ⓘ **Note**
>
> Workflow managers can still manually assign records. For more information, see [Manage assignments as a workflow manager](#).

When it comes to automatic record assignment, the system prioritizes the records that are already assigned to a user. If the user has no records assigned, the system checks for records assigned to the group the user is part of. If the user group have no assigned records, the system automatically selects an unassigned record from the Intake Worklist using the following criteria:

- Seriousness: the primary criterion used by the Oracle Safety One Intake system.

- Intake date: the secondary criterion used by the Oracle Safety One Intake system, ensuring that the record with the earliest intake date is assigned first. This ensures that the SLA is adhered to.

Workflow managers and intake processors can also opt to assign intake records to themselves. As a workflow manager, you can select **Actions** on in the Intake Worklist, then select **Open Next Record**. As an intake processor, you can select **Open Next Record** from the top right corner of the Intake Worklist.

Whenever users select **Open Next Record** and there are no records requiring user intervention, the system notifies them of this.

If a record is unassigned by an intake processor, the system will not re-assign the record to the same intake processor. Instead, the record will be assigned to a different intake processor.

6

Working with the Intake Worklist

Learn more about processing incoming records in the topics below.

- [Get familiar with the Intake Worklist](#)
  The Intake Worklist is a central list within the Oracle Safety One Intake system which contains all the records that require manual intervention.

- [Simplify worklist management using views](#)
  For a better overview of your tasks, you can switch between views of the Intake Worklist.

- [Optimize the data being displayed using columns](#)
  By default, the Intake Worklist displays a predetermined set of columns. This can easily be personalized to match your needs.

- [Fine-tune your worklist with advanced filters](#)
  You can search for specific sets of records by applying filters on any columns from the Intake Worklist. You can use one or several of the quick filter suggestions or you can easily create your own.

- [Refresh the Intake Worklist](#)
  The Intake Worklist refreshes automatically after most of the significant actions you take. Nonetheless, you have the option of refreshing the Intake Worklist manually.

Get familiar with the Intake Worklist

The Intake Worklist is a central list within the Oracle Safety One Intake system which contains all the records that require manual intervention.

The Intake Worklist can contain records from both manual and automatic uploads. For more information on uploading records to Oracle Safety One Intake, see [Uploading documents](#).

To identify the source of a record, see the **Source** column. This column can have the following values:

- *User Uploaded*: this indicates that a user has uploaded the record manually, via the user interface.

- API source names, as configured by your administrator.

- Email source names, as configured by your administrator.

- EDI agency name, as configured by your administrator.

For efficient allocation, each record from the Intake Worklist is associated with a specific manual task you need to complete as an intake processor.

The records you can see in the Intake Worklist depend on your permissions:

- As a workflow manager, what you see in the Intake Worklist depends on site security.

- As an intake processor, what you see in the Intake Worklist depends on site and user group security.

You can access task-specific information without leaving the Intake Worklist by selecting **Expand Details** for individual records.

Simplify worklist management using views

For a better overview of your tasks, you can switch between views of the Intake Worklist.

The options visible to you may change depending on your role:

Table 6-1   List of Intake Worklist views

Views	Applicable User Role	Description
All	Workflow Manager	Lists all the intake records, regardless of the assignment. As a workflow manager, this will be your default view when you log in for the first time.
Assigned to Group	Workflow Manager, Intake Processor	Lists the intake records that are: • assigned to you • assigned to your user group • assigned to fellow members of your user group • unassigned
Assigned to Me	Workflow Manager, Intake Processor	Lists the intake records that are assigned to you. As an intake processor, this will be your default view when you log in for the first time.

1. Once you have logged in, select the **Views** drop-down in the top left corner.

2. From the drop-down menu, select your desired view.

> ⓘ **Note**
>
> The view you have selected does not change if you log out of Oracle Safety One Intake. You still have the same view when you log back in.

3. Sort your view according to your preferences. You can sort the records based on columns, either ascending or descending, by selecting **Sort Ascending** ⬦ . By default, the records are sorted based on their date of intake, in ascending order.

Optimize the data being displayed using columns

By default, the Intake Worklist displays a predetermined set of columns. This can easily be personalized to match your needs.

1. On the right side of the page, select the **Columns menu** ⊞ .

2. In the Columns window, ensure the appropriate columns are visible by checking the right side of the Select Columns panel. Columns with a pin icon 📌 are fixed and cannot be removed.

3. Select any additional columns you would like to add from the Available section, on the Select Columns panel.

4. Select **Apply** once you are happy with your selection of columns. Your choice of columns and arrangement are saved for future logins.

5. In the Intake Worklist, rearrange your columns by dragging and dropping them along the header.

Fine-tune your worklist with advanced filters

You can search for specific sets of records by applying filters on any columns from the Intake Worklist. You can use one or several of the quick filter suggestions or you can easily create your own.

1. Make sure you are on the Intake Worklist. For more information on navigating to the Intake Worklist, see Navigating.

2. Depending on what you would like to filter for, choose one or several of the existing quick filter suggestions, available below the search bar.

    Alternatively, create a filter of your own by selecting the **More Filters** and choosing one of the options from the list.

    Your active filters will appear in the search bar at the top of the page.

    You may also select a set of filters you have previously applied from the history list. These are marked appropriately with the history icon ⏱. The filter history appears once you select search bar. Up to ten instances of previously used filters are stored.

    > ⓘ **Note**
    >
    > The filters you apply are saved until you remove them.

3. In the search bar, select the filter you would like to configure, then select or enter the required value to refine your filter.

    Blue text indicates the value a filter is actively changing your results for.

The Intake Worklist will automatically refresh. If you would like to refresh the list of records manually, see Refresh the Intake Worklist.

> ⓘ **Note**
>
> If none of your records match the filters you have applied, the Intake Worklist will ask you to either **Refresh Data** or **Clear Filters**.

Refresh the Intake Worklist

The Intake Worklist refreshes automatically after most of the significant actions you take. Nonetheless, you have the option of refreshing the Intake Worklist manually.

The following actions trigger an automatic refresh for the Intake Worklist:

• When you navigate from a different page to the Intake Worklist

• As you sort your records

- After you modify your filters

- Once you switch views

To refresh the Intake Worklist manually, follow the steps below.

1. Make sure you are on the Intake Worklist. For more information on navigating to the Intake Worklist, see [Navigating](#).

2. Depending on your role, perform one of the following: .

   - As a workflow manager, select **Refresh** from the top right corner of the page.

   - As an intake processor, select **Actions**, then **Refresh**.

7
Using the On Hold Worklist

The On Hold Worklist enables workflow managers and intake processors to review records that have been put on hold.

Overview

Whenever the Oracle Safety One Intake system is unable to add a follow-up record to a case, the record is put on hold and is accessible through the On Hold Worklist.

Follow-up records can be put on hold for the following reasons:

Table 7-1   Reasons for records to be put on hold

Reason	Description
Case in workflow state not accepting follow-up merge	The current workflow state of the case is configured to not accept Follow-up Merge.
	For more information, see Configuring Case Workflow in *Oracle Argus Safety Administrator's Guide*.
Case is locked	The case is locked and cannot currently accept follow-up documents.
	For more information on lock or unlocking cases, see Lock or unlock a case in *Oracle Argus Safety User's Guide*.
Case is in use	The case is currently open and a different user is working on it. The system may also still be working on the case.

Records can be put on hold manually or automatically:

- Whenever a user accepts a follow-up record, but the destination case cannot accept a follow-up record due to the reasons outlined above, Oracle Safety One Intake prompts the user to either put the record on hold or discard it altogether.

- If Auto-Accept is enabled and the destination case cannot accept a follow-up record due to the reasons outlined above, the record is automatically put on hold.

> ⓘ **Note**
>
> Your administrator is responsible for configuring the Auto-Accept feature on a source by source basis.

Once the reason is lifted, the record is returned to the normal Oracle Safety One Intake flow.

- [Work with records that are on hold](#)
  As an intake processor or a workflow manager, using the On Hold Worklist, you can find out in more detail why a record has been put on hold.

Work with records that are on hold

As an intake processor or a workflow manager, using the On Hold Worklist, you can find out in more detail why a record has been put on hold.

For more information on the reasons why a record can be put on hold, see [Using the On Hold Worklist](#).

1. Make sure you are on the On Hold Worklist. For more info on navigating to the On Hold Worklist, see [Navigating](#).

2. Filter and customize the layout of the On Hold Worklist to best suit your needs. For more information, see [Fine-tune your worklist with advanced filters](#), as well as [Optimize the data being displayed using columns](#).

> **✓ Tip**
>
> You can select **Actions**, then **Clear Filters** to remove the filters you have applied.

3. Check the box of the record you would like to work on, select **Expand Details**, then **Start Work**.

4. In the View Difference dialog, identify the reason why the record was put on hold.

5. Perform one of the following:

   - Select **Reject Follow-up** to reject the intake record. The record is cleared from the On Hold Worklist.

   - Select **Close** and the record will remain unchanged.

   - Select **Print List** to export a report of all the differences to PDF.

6. Optionally, you can export all of the records in the On Hold Worklist. To do so, select **Actions**, then **Export**.

8

Working with your records

Learn more about working with your records in the topics below.

- [Possible tasks related to processing your records](#)
  Once you have uploaded your AE documents to Oracle Safety One Intake or the AE documents have been automatically ingested, you may need to take further action before they are processed.

- [Validating a record](#)
  Once your documents have finished uploading, they may be associated with the Check Validity task. As part of this task, you not only have to validate and group the documents, but also designate a document as primary.

- [Organizing documents in a record](#)
  As an intake processor, you can flexibly organize the AE documents contained in a record. This is to appropriately group documents whenever a record includes multiple cases, copy relevant documents between cases, or mark documents as primary.

- [Working with the data in your documents](#)
  Learn more about working with the AE document data in the topics listed below.

- [Finding duplicates and merging follow-ups](#)
  Learn more about working with your records in the topics below.

Possible tasks related to processing your records

Once you have uploaded your AE documents to Oracle Safety One Intake or the AE documents have been automatically ingested, you may need to take further action before they are processed.

Table 8-1   Possible tasks related to processing your records

Task	Possible reasons
Check Validity	• Multiple documents are uploaded manually at once. For guidance on grouping case documents, see Group your documents. • The API or email source which is sending documents over to Oracle Safety One Intake is configured to request manual triage. For more information on marking a record as valid, see Validating a record. • The uploaded document is password protected or the email is confidential. In this scenario, you may have to reject the record and reupload it as part of a new record. For more information on rejecting a report, see Reject a record. • One or several documents that have been uploaded have been marked as malicious. In this scenario, you may have to reject the record and reupload it as part of a new record. For more information on rejecting a report, see Reject a record. • The size of the incoming email exceeds the configured maximum limit. Your administrator is responsible for setting the maximum size for manually uploaded documents. Contact your administrator directly for more information on changing the maximum upload size. • The incoming document is not of a supported type. You can reject the record and reupload it as part of a new record. For more information on rejecting a report, see Reject a record. For more information on configuring file types and sizes for incoming email and documents, see Understanding which documents to add.
Review Record	• The OCR/ML-extracted data has been marked as Low Confidence. For more information on working with low confidence data, see Work with Low Confidence data. ⓘ **Note** All automated features, including OCR/ML extraction, require an additional subscription to Oracle Safety One Intake. For more information, reach out to your Oracle point of contact. • Essential details are missing. In this scenario, you can manually add missing data to a record. For more information, see Add missing data. • Various validation issues.

Table 8-1   (Cont.) Possible tasks related to processing your records

Task	Possible reasons
Create New Record	• Whenever the document is unidentified, you can add data to a new record manually. For more information, see <u>Manually add data to a new record</u>.
Duplicate Search	• Whenever the system is unable to locate a matching case for a document, indicating it may be the initial document of a new case, this task is associated with said document. Users can then manually designate it as a follow-up. For more information, see <u>Process Duplicate Search records</u>.
Merge Follow-up	• A record is associated with this task whenever it contains documents that are follow-ups to an existing case record. • Only applies to E2B records.

Validating a record

Once your documents have finished uploading, they may be associated with the Check Validity task. As part of this task, you not only have to validate and group the documents, but also designate a document as primary.

For more information on the possible reasons behind the Check Validity task, see <u>Possible tasks related to processing your records</u>.

1. Make sure you are on the Intake Worklist or the Intake Monitor. For more information on navigating to these pages, see <u>Navigating</u>.

2. Select the record you would like to validate by clicking on its ID. Alternatively, you can check the box of the record you would like to work on, select **Expand Details**, then **Start Work**.

> ⓘ **Note**
>
> If you are trying to work on a record which is not assigned to you, you will be prompted to continue with or without assigning that record to you.

3. In the panel on the left, switch between AE documents as required.

4. Work with the data as required. For more information on working with the data in your documents, see <u>Working with the data in your documents</u>.

> ⓘ **Note**
>
> If your record has multiple documents which require your intervention, you can navigate between them in the panel on the left.

5. Select one of the following, in the upper right corner:
    • **Submit**, to validate the document.

- **Reject**, for which you must select a justification or provide a custom justification by choosing **Other**.

Organizing documents in a record

As an intake processor, you can flexibly organize the AE documents contained in a record. This is to appropriately group documents whenever a record includes multiple cases, copy relevant documents between cases, or mark documents as primary.

Depending on your work, you can perform the following actions:

- Mark a document as primary
  Whenever multiple AE documents are associated with the same case, as an intake processor, you are required to designate a primary document for automatic extraction.

- Group your documents
  Whenever multiple AE documents correspond to multiple, separate cases, as an intake processor you are required to group the documents such that one group is connected to a single case.

- Add or remove a copy of a document to or from a group
  As an intake processor, you can create copies of AE documents, which are automatically added to groups within your record. You can also copy documents from groups.

- Separate your documents into groups
  As an intake processor, you can split all the documents contained within a record into individual groups, for potential cases.

- Mark a document as invalid
  As an intake processor, once you have checked a document in a record, you can mark it as invalid. Based on the contents of the document, you can select a reason for marking it as invalid.

Mark a document as primary

Whenever multiple AE documents are associated with the same case, as an intake processor, you are required to designate a primary document for automatic extraction.

1. Make sure you are on the Intake Worklist. For more info on navigating to the Intake Worklist, see Navigating.

2. Check the box of the record you would like to work on, select **Expand Details**, then select **Start Work**. You can also click the hyperlink record ID.

> ⓘ **Note**
>
> If you are trying to work on a record which is not assigned to you, you will be prompted to continue with or without assigning that record to you.

3. In the panel on the left, switch between AE documents as required.

4. Above the panel, select **Mark Primary** to mark a document as primary. Repeat this action for each group from your record.

   You can identify primary records based on Primary ˬ.

> ⚠️ **Warning**
>
> You can only undo marking a document as primary by discarding the changes you have made to the entire record.

5. Once you have finished working on your record, select **Confirm**.

Group your documents

Whenever multiple AE documents correspond to multiple, separate cases, as an intake processor you are required to group the documents such that one group is connected to a single case.

1. Make sure you are on the Intake Worklist. For more info on navigating to the Intake Worklist, see [Navigating](#).

2. Select the record you would like to validate by clicking on its ID. Alternatively, you can check the box of the record you would like to work on, select **Expand Details**, then **Start Work**.

> ℹ️ **Note**
>
> If you are trying to work on a record which is not assigned to you, you will be prompted to continue with or without assigning that record to you.

3. In the panel on the left, switch between AE documents as required.

4. Select **Add group** at the top.

5. Select **Move to Group**, then choose the group you would like to move your document to.

> ✅ **Tip**
>
> You can also drag and drop your document to the appropriate group.

6. Once you have finished working on your documents, select **Confirm**.

Add or remove a copy of a document to or from a group

As an intake processor, you can create copies of AE documents, which are automatically added to groups within your record. You can also copy documents from groups.

1. Make sure you are on the Intake Worklist. For more info on navigating to the Intake Worklist, see [Navigating](#).

2. Select the record you would like to validate by clicking on its ID. Alternatively, you can check the box of the record you would like to work on, select **Expand Details**, then **Start Work**.

> ℹ️ **Note**
>
> If you are trying to work on a record which is not assigned to you, you will be prompted to continue with or without assigning that record to you.

3. In the panel on the right, switch between AE documents as required.

4. Depending on your requirements, perform one of the following:

   • Select **Copy**, then choose the group you would like the document copied to. If the record you are working on has one group, you will be prompted to create a new group.

   • Select **Options** ⎡···⎤, then **Remove Copy**.

Separate your documents into groups

As an intake processor, you can split all the documents contained within a record into individual groups, for potential cases.

> ⚠ **Warning**
>
> Using this feature will split any existing groups. To undo this action, you may have to discard all actions you have performed on a record.

1. Make sure you are on the Intake Worklist. For more info on navigating to the Intake Worklist, see Navigating.

2. Select the record you would like to validate by clicking on its ID. Alternatively, you can check the box of the record you would like to work on, select **Expand Details**, then **Start Work**.

> ⓘ **Note**
>
> If you are trying to work on a record which is not assigned to you, you will be prompted to continue with or without assigning that record to you.

3. At the top of the document viewer, select **Options** ⎡···⎤, then **Separate**.

4. Select **Separate** from the pop-up window.

Mark a document as invalid

As an intake processor, once you have checked a document in a record, you can mark it as invalid. Based on the contents of the document, you can select a reason for marking it as invalid.

Table 8-2   Reasons for invalidating a document

Reason	Description
No Company Product	The document makes no reference to a relevant pharmaceutical product.
Non-AE Document	The document falls outside the scope of AE documentation.
Other	Type your own reason for marking the document as invalid.

> ⓘ **Note**
>
> Administrators can make changes to the list of invalidation reasons. For more information, reach out to your administrator.

1. Make sure you are on the Intake Worklist. For more info on navigating to the Intake Worklist, see Navigating.

2. Select the record you would like to validate by clicking on its ID. Alternatively, you can check the box of the record you would like to work on, select **Expand Details**, then **Start Work**.

   > ⓘ **Note**
   >
   > If you are trying to work on a record which is not assigned to you, you will be prompted to continue with or without assigning that record to you.

3. In the panel on the left, switch between AE documents as required.

4. At the top of the document viewer, select **Mark Invalid**.

5. Select the reason for marking the document as invalid.

   If you have selected **Other**, type the reason for your choice and select **Mark Invalid**.

   > ⓘ **Note**
   >
   > To undo marking a document as invalid, simply return to the Intake Worklist using
   >
   > **Go Back to Worklist** ↑ above the list of AE documents.

Working with the data in your documents

Learn more about working with the AE document data in the topics listed below.

- Know the fields in the Review Form
  Whenever records are associated with the Create New Records task, you may be required to manually add data to fields belonging to several categories.

- Work with Low Confidence data
  As an intake processor, you can work with Low Confidence data for records associated with the Review Record task. Only data extracted using OCR/ML can be marked as Low Confidence. OCR/ML extraction requires an additional subscription to Oracle Safety One Intake. For more information, reach out to your Oracle point of contact.

- Add missing data
  Once the Oracle Safety One Intake system has finished extracting textual data from a document, it will automatically categorize it, which will be reflected in the Narrative tab. As an intake processor, you can further annotate data in the Narrative tab or add data manually. OCR/ML extraction requires an additional subscription to Oracle Safety One Intake. For more information, reach out to your Oracle point of contact.

- Reject a record
  As an intake processor, you can reject an entire record based on one of several criteria.

- [Process Merge Follow-up records](#)
  E2B documents received in Oracle Safety One Intake are automatically checked against existing cases in order to identify them as follow-ups. Whenever a case record is identified as following up on an existing case record, the system automatically assigns the Merge Follow-up task to it. As an Intake Processor, you can manually merge records that have this task associated with existing records.

- [Manually add data to a new record](#)
  Whenever a newly uploaded document is not recognized by Safety One Intake, you can transcribe that document manually.

Know the fields in the Review Form

Whenever records are associated with the Create New Records task, you may be required to manually add data to fields belonging to several categories.

The validation criteria reflect the format of data the respective fields accept. The system automatically marks any data that cannot be validated with a status of *Needs review*.

Table 8-3   General

Field name	Validation criteria
Receipt Date	Valid date format: DD-MON-YYYY
Country	N/A
Report Type	N/A

Table 8-4   Study

Field name	Validation criteria
Study Name	N/A

Table 8-5   Reporter

Field name	Validation criteria
Title	N/A
First Name	N/A
Middle Name	N/A
Last Name	N/A
Email Address	N/A
Country	N/A
Address	N/A
Healthcare Professional	Non-E2b Valid Yes or No Conversion: • (0, No, N, False, F) to No • (Yes, Y, True, T, 1) to Yes
Reporter Type	N/A

Table 8-6   Literature

Field name	Validation criteria
Literature Reference	N/A

Table 8-7   Patient

Field name	Validation criteria
Patient Initial	N/A
Patient ID	Non E2B field
DOB	Valid date format: DD-MON-YYYY
Age	Valid numeric value. For example, "one" will be converted to "1".
Unit	N/A
Age Group	N/A
Gender	N/A
Height	N/A
Unit	Non E2B field
Death Date	Valid date format: DD-MON-YYYY HH:MM

Table 8-8   Patient - Other Relevant History

Field name	Validation criteria
Category	Non E2B field
Description Condition Reported	N/A
Start Date	Valid date format: DD-MON-YYYY
End Date	Valid date format: DD-MON-YYYY
Ongoing	Valid Yes or No Conversion: • (0, No, N, False, F) is converted to No • (Yes, Y, True, T, 1) is converted to Yes
Notes	N/A

Table 8-9   Patient - Other Relevant Past Drug History

Field name	Validation criteria
Category	Non E2B field
Drug Name	N/A
Start Date	Valid date format: DD-MON-YYYY HH:MM
End Date	Valid date format: DD-MON-YYYY HH:MM
Notes	Non E2B field

Table 8-10   Lab Data

Field name	Validation criteria
Test Name	N/A
Date	Validation date format: DD-MON-YYYY HH:MM
Result	N/A
Unit	N/A
Low	N/A
High	N/A
Comments	N/A

Table 8-11   Events

Field name	Validation criteria
Event as Reported	N/A
Event LLT	N/A
Death	Valid Yes or No Conversion: • (0, No, N, False, F) is converted to No • (Yes, Y, True, T, 1) is converted to Yes
Life Threatening	Valid Yes or No Conversion: • (0, No, N, False, F) is converted to No • (Yes, Y, True, T, 1) is converted to Yes
Hospitalization	Valid Yes or No Conversion: • (0, No, N, False, F) is converted to No • (Yes, Y, True, T, 1) is converted to Yes
Disability	Valid Yes or No Conversion: • (0, No, N, False, F) is converted to No • (Yes, Y, True, T, 1) is converted to Yes
Congenital Anomaly	Valid Yes or No Conversion: • (0, No, N, False, F) is converted to No • (Yes, Y, True, T, 1) is converted to Yes
Other	Valid Yes or No Conversion: • (0, No, N, False, F) is converted to No • (Yes, Y, True, T, 1) is converted to Yes
Onset Date	Valid date format: DD-MON-YYYY HH:MM
Stop Date	Valid date format: DD-MON-YYYY HH:MM
Duration	N/A
Duration Unit	N/A
Outcome	N/A
Occur Country	N/A
Intensity	Non E2B field

Table 8-12   Product

Field name	Validation criteria
Product Name	N/A
Generic Name	N/A
Product Type	This field only has two values: 1. Suspect 2. Concomitant Default - Suspect
Obtain Drug Country	N/A
Manufacturer	N/A
Authorization Number	N/A
Action Taken	N/A
Indication	N/A

Table 8-13   Product - Dosage

Field name	Validation criteria
Dose	N/A
Unit	N/A
Start Date	Valid date format: DD-MON-YYYY HH:MM
End Date	Valid date format: DD-MON-YYYY HH:MM
Duration	N/A
Duration Unit	N/A
Frequency	Non E2B field
Batch/Lot #	N/A
Formulation	N/A
Dose Description	N/A
Route of Administration	N/A

Table 8-14   Narrative

Field name	Validation criteria
Narrative	N/A
Reporter Comment	N/A

Table 8-15   References

Field name	Validation criteria
References Type	Non E2B field
ID	N/A

Work with Low Confidence data

As an intake processor, you can work with Low Confidence data for records associated with the Review Record task. Only data extracted using OCR/ML can be marked as Low Confidence. OCR/ML extraction requires an additional subscription to Oracle Safety One Intake. For more information, reach out to your Oracle point of contact.

1. Make sure you are on the Intake Worklist. For more info on navigating to the Intake Worklist, see Navigating.

2. Select the record you would like to validate by clicking its ID. Alternatively, you can check the box of the record you would like to work on, select **Expand Details**, then **Start Work**.

> ⓘ **Note**
>
> If you are trying to work on a record which is not assigned to you, you will be prompted to continue with or without assigning that record to you.

3. In the panel on the left, switch between AE documents as required.

4. To filter your view, select the **Show Fields** dropdown, then choose **Needs Review**.

5. On the left, select the field you would like to review. Alternatively, you can identify which items need review using **Review and Edit** ⚠️, visible in the panel on the left.

> ✅ **Tip**
>
> Selecting one of the highlighted terms from the Narrative panel will automatically scroll down to its field.

6. Reject or accept the information contained within the field.

   • To accept the data, select **Confirm extraction** ✓ on the documents panel, to the left.

   • To reject the data, select **Reject extraction** ✗ on the right of the field.

   > ⓘ **Note**
   >
   > You can easily identify the fields you have interacted with using **Edited field** 🖉.

7. Optionally, you can re-send the Narrative section for extraction. To do so, select **Narrative Re-processing** 🔲.

8. Once you have verified the necessary data, select one of the following:

   • **Save**, to save your work and continue later.

   • **Submit**, to send the AE record for further processing.

   > ⓘ **Note**
   >
   > **Submit** is only available if Oracle Safety One Intake is configured for intake processing only.

   • **Search**, to open the Duplicate Search dialog. For more information, see Possible tasks related to processing your records.

Add missing data

Once the Oracle Safety One Intake system has finished extracting textual data from a document, it will automatically categorize it, which will be reflected in the Narrative tab. As an intake processor, you can further annotate data in the Narrative tab or add data manually. OCR/ML extraction requires an additional subscription to Oracle Safety One Intake. For more information, reach out to your Oracle point of contact.

1. Make sure you are on the Intake Worklist. For more info on navigating to the Intake Worklist, see Navigating.

2. Select the record you would like to validate by clicking on its ID. Alternatively, you can check the box of the record you would like to work on, select **Expand Details**, then **Start Work**.

> **ⓘ Note**
>
> If you are trying to work on a record which is not assigned to you, you will be prompted to continue with or without assigning that record to you.

3. Make sure the **All** filter is selected for the **Show Fields** dropdown at the top.

4. Do one of the following:

    • Annotate the data from the Narrative tab, on the right, by selecting the word you wish to annontate, then selecting one of the options at the top of the tab.

    • Select and type in one of the fields on the left.

> **ⓘ Note**
>
> You can easily identify the fields you have already interacted with using **Edited field** .

5. Once you have finished adding new data to the record, select one of the following:

    • **Save**, to save your work and continue later.

    • **Submit**, to send the AE record for further processing.

> **ⓘ Note**
>
> **Submit** is only available if Oracle Safety One Intake is configured for intake processing only.

    • **Search**, to open the Duplicate Search dialog. For more information, see Possible tasks related to processing your records.

Reject a record

As an intake processor, you can reject an entire record based on one of several criteria.

Table 8-16   Report rejection reasons

Reason	Description
No Company Product	The document makes no reference to a relevant pharmaceutical product.
Non-AE Document	The document falls outside the scope of AE documentation.
Other	Type your own reason for marking the document as invalid. You can write up to 255 characters, including spaces.
	Records that are rejected as part of the Duplicate Search task will have Other assigned as a reason for rejection. For more information, see

> ⓘ **Note**
>
> Administrators can make changes to the list of rejection reasons. For more information, reach out to your administrator.

1. Make sure you are on the Intake Worklist. For more info on navigating to the Intake Worklist, see Navigating.

2. Select the record you would like to validate by clicking on its ID. Alternatively, you can check the box of the record you would like to work on, select **Expand Details**, then **Start Work**.

> ⓘ **Note**
>
> If you are trying to work on a record which is not assigned to you, you will be prompted to continue with or without assigning that record to you.

3. Once you have checked the documents contained within the record, select **Reject Report**.

4. Select one of the following reasons for marking the document as invalid:

    • **No Company Product**

    • **Non-AE Document**

    • **Other**

    For more information on each of these options, see Mark a document as invalid.

5. If you have selected **Other**, type the reason for your choice and select **Mark as Invalid**.

> ⚠ **Warning**
>
> This action cannot be undone.

Process Merge Follow-up records

E2B documents received in Oracle Safety One Intake are automatically checked against existing cases in order to identify them as follow-ups. Whenever a case record is identified as following up on an existing case record, the system automatically assigns the Merge Follow-up task to it. As an Intake Processor, you can manually merge records that have this task associated with existing records.

Whenever you accept an incoming record as follow-up, you may also be prompted to hold the record.

For more details on the fields available in the View Differences dialog, see Use the View Differences Report in the *Oracle Argus Interchange User's Guide*.

1. Make sure you are on the Intake Worklist. For more info on navigating to the Intake Worklist, see Navigating.

> ✅ **Tip**
>
> You may also access records from the Intake Monitor. For a list of all available views and charts, see [Monitor records as a workflow manager](link).

2. Check the box of the record you would like to work on, select **Expand Details**, then select **Start Work**. You can also select the ID of the record you wish to work on.

3. In the View Differences dialog, compare the data of the incoming record with that of the existing case. Fields containing differences are highlighted.

4. Perform one of the following:

   - Select the checkboxes of the fields you wish to merge. Select **Accept Follow-up**, then confirm by selecting **Yes**.

   - Reject the record by selecting **Reject ICSR**.

   - Select **Search** to manually find other cases. For more information, see [Processing Duplicate Search records](link).

5. Once you are prompted to re-authenticate, enter your credentials and provide a justification for your choice.

Manually add data to a new record

Whenever a newly uploaded document is not recognized by Safety One Intake, you can transcribe that document manually.

To understand how to categorize your data for efficient processing, see [Know the fields in the Review Form](link).

1. Make sure you are on the Intake Worklist. For more info on navigating to the Intake Worklist, see [Navigating](link).

2. Check the box of the record you would like to work on, select **Expand Details**, then select **Start Work**.

3. In the field on the left, type the data you would like added to the record.

> ℹ️ **Note**
>
> You can easily identify the fields you have already interacted with using **Edited field** .

4. Once you have finished adding new data to the record, select one of the following:

   - **Save**, to save your work and continue later.

   - **Submit**, to send the AE record for further processing.

   > ℹ️ **Note**
   >
   > **Submit** is only available if Oracle Safety One Intake is configured by your administrator for intake processing only.

- **Search**, to open the Duplicate Search dialog. For more information, see Possible tasks related to processing your records.

Finding duplicates and merging follow-ups

Learn more about working with your records in the topics below.

- Work with Duplicate Search records
  Once Oracle Safety One Intake has associated the Duplicate Search task with a record, as an intake processor, you need to manually handle that record and determine whether it is an initial case or a follow-up.

- Work with Merge Follow-up records
  As an intake processor, you can verify the records associated with the Merge Follow-up task, then merge them with existing cases. When the system automatically matches an incoming record with an existing case, you can check the data of both records side by side and select specific fields to merge.

- Accept or reject records in bulk
  As an intake processor, you can accept or reject multiple records at once, depending on their status.

Work with Duplicate Search records

Once Oracle Safety One Intake has associated the Duplicate Search task with a record, as an intake processor, you need to manually handle that record and determine whether it is an initial case or a follow-up.

Understand why a record has been flagged as Duplicate Search

The Duplicate Search task is associated with a record in one of the following scenarios:

- For files compliant with the E2B standard: the system has found no matches among the existing cases in your Oracle Safety One Intake environment. Moreover, your administrator has not configured Oracle Safety One Intake to automatically accept cases as initial from the source of the new record.

- For PDF, DOC, and DOCX files: the data of the incoming documents requires no review.

- Oracle Safety One Intake has accepted the incoming record as initial, but the system has encountered an error.

The duplicate search function is available for records associated with the following tasks:

- Review Record

- Create New Record

- Duplicate Search

- Merge Follow-up

To handle a record associated with this task, you work in the Duplicate Search dialog, which automatically populates with the data the Oracle Safety One Intake system has already identified. To adjust the search for duplicates, you can select, deselect, or modify the fields as necessary.

For more details on the fields available in the Duplicate Search dialog, see Duplicate Search Dialog Box Fields in the *Oracle Argus Interchange User's Guide*.

The search results include a matching score, where a higher score means a better match.

> ⓘ **Note**
>
> If the **Score** column is not visible for your results, smart search may not be enabled. Contact your administrator for more information about the smart search feature.

Whenever you accept an incoming record as initial, Oracle Safety One Intake creates a new case. Conversely, whenever you accept an incoming record as follow-up, its data will be added to an existing case. Whenever you accept an incoming record as follow-up, you may also be prompted to hold the record. For more details, see Using the On Hold Worklist.

1. Make sure you are on the Intake Worklist. For more info on navigating to the Intake Worklist, see Navigating.

   > ✓ **Tip**
   >
   > You may also access records from the Intake Monitor. For a list of all available views and charts, see Monitor records as a workflow manager.

2. Select the ID of the record you would like to start working on.

   Alternatively, you may also tick the box of the record you wish to work on, select **Expand Details**, then **Start Work**.

3. In the Duplicate Search dialog, select or deselect the fields you would like to use to perform the duplicate search. For more information on this task, see Search for duplicate reports in the *Oracle Argus Safety User's Guide*.

4. In the **Results** section of the Duplicate Search dialog, perform one of the following:

   - If no duplicate has been found, select **Accept ICSR**.

   - Modify the search criteria and search again.

   - If duplicates have been found, you can select **Accept ICSR as Follow-up**. You can also select **View Differences** to compare details before that.

   - Select **Reject ICSR**. The system will then prompt you to re-authenticate. Once you have done so, you will be prompted to add a justification.

   Once you have performed one of the above, the intake record will no longer be present in your Intake Worklist.

Work with Merge Follow-up records

As an intake processor, you can verify the records associated with the Merge Follow-up task, then merge them with existing cases. When the system automatically matches an incoming record with an existing case, you can check the data of both records side by side and select specific fields to merge.

Understand why a record has been flagged as Merge Follow-up

The Merge Follow-up task is associated with a record in one of the following scenarios:

- For files compliant with the E2B standard: the system has found a matching case among the existing cases in your Oracle Safety One Intake environment. Moreover, your administrator has not configured Oracle Safety One Intake to automatically accept cases as follow-ups from the source of the new record.

- Whenever a record has been accepted as follow-up but has failed due to an error.

Whenever you accept an incoming record as follow-up, you may also be prompted to hold the record. For more information, see Using the On Hold Worklist.

For more details on the fields available in the View Differences dialog, see Use the View Differences Report in the *Oracle Argus Interchange User's Guide*.

1. Make sure you are on the Intake Worklist. For more info on navigating to the Intake Worklist, see Navigating.

   > ✅ **Tip**
   >
   > You may also access records from the Intake Monitor. For a list of all available views and charts, see Monitor records as a workflow manager.

2. Check the box of the record you would like to work on, select **Expand Details**, then select **Start Work**. You can also select the ID of the record you wish to work on.

3. In the View Differences dialog, compare the data of the incoming record with that of the existing case. Fields containing differences are highlighted.

4. Perform one of the following:

   • Select the checkboxes of the fields you wish to merge. Select **Accept Follow-up**, then confirm by selecting **Yes**.

   • Reject the record by selecting **Reject ICSR**.

   • Select **Search** to manually find other cases. For more information, see Processing Duplicate Search records.

5. Once you are prompted to re-authenticate, enter your credentials and provide a justification for your choice.

Accept or reject records in bulk

As an intake processor, you can accept or reject multiple records at once, depending on their status.

Before you work with this feature, you should be aware of the following:

• Only records with the following tasks associated can be accepted in bulk:

   – Duplicate Search

   – Merge Follow-up

• Records cam be rejected in bulk regardless of the tasks they have associated.

• As you use this feature, you may encounter one of the following errors:

Error	Applies to action	Description
Record in use	Accept, Reject	A different user is handling the record.
User not permitted	Accept, Reject	You do not have permission to access the record.
Acceptance not allowed for this task	Accept	One or several records do not have the Duplicate Search or Merge Follow-up tasks associated.

Error	Applies to action	Description
Intake complete	Accept/Reject	One or several records have already been accepted or rejected.
Case not ready	Accept	The target case does not accept a follow-up.

1. Make sure you are on the Intake Worklist. For more info on navigating to the Intake Worklist, see Navigating.

> ✓ **Tip**
>
> You may also access records from the Intake Monitor. For a list of all available views and charts, see Monitor records as a workflow manager.

2. Check the boxes of the records you would like to work on.

3. Select **Actions**, then select one of the following:

   • Accept

   • Reject

9
Monitoring your records

The Intake Monitor is a central list in the Safety One Intake system which displays all the records which have been uploaded, regardless of the requirement for manual intervention.

The purpose of the Intake Monitor is to provide an overview of the duration of conversion processes, in as much detail as necessary for your work.

Understanding record states in the Intake Monitor

In the Intake Monitor, records can have the following statuses:

- *Intake Processing*: records with this status are being processed by the system.

- *Processed*: records with this status have been processed by the system. These can also have the following sub-statuses:

  – *Processed-Invalid*

  – *Processed-Initial*

  – *Processed-Follow up*

- *On Hold*: records with this status have been automatically detected as follow-ups to existing records.

The Intake Monitor also provides insight into processing time, which presents the total time the Oracle Safety One Intake system took to process a record. Using this feature, you can get a feel for how long it typically takes to process a particular type of record.

- [Monitor records as a workflow manager](#)
  As a workflow manager, you can see the distribution of intake records based on a variety of metrics and charts.

- [Monitor records as an intake processor](#)
  As an intake processor, you can use the Intake Monitor to keep track of the records you have access to, all in one place. This includes records undergoing intake processing, records that have been put on hold, and records that have already been processed.

Monitor records as a workflow manager

As a workflow manager, you can see the distribution of intake records based on a variety of metrics and charts.

Available metrics

- Intake processing > 24hrs

- All Received

- In Progress

- Processed

These metrics can be accessed via separate tabs in the Intake Monitor. Each of the tabs has charts with sections. You can check the record count for every section of the chart by hovering

your mouse over it. You can also access further details about the data by right clicking on each section of each chart.

Charts to explore for records older than 24 hours

These charts provide an overview of all records which have taken more than 24 hours to process, thus exceeding the compliance period. These charts do not include records with a state of On Hold.

> ⓘ **Note**
>
> The color scheme of the charts reflects the median processing time for the records from each section. The charts' colors range from orange, indicating processing times closer to 24 hours, to deep red, which indicates processing times closer to 50 hours and beyond.

Table 9-1   Charts to explore for records older than 24 hours

Chart title	Chart sections	What you see	What you can do
Intake Processing > 24h by Task	• Check Validity • Review Record • Create New Record • Duplicate Search • Merge Follow-up • System Processing	This chart shows records that have exceeded the 24-hour compliance period, considering both manual and automatic tasks. The System Processing section includes all the background activities the Oracle Safety One Intake system performs, such as classification, data extraction, or case acceptance.	To get the number of records for each manual task, hover your mouse over each section of the chart.
Intake Processing > 24h by Site	One section for each site, as well as: • Other • No Value Present • All sites	This chart displays records that have exceeded the 24-hour compliance period, organized by site. The No Value Present section reflects the number of records that have no site and are currently in intake processing, and have breached the 24-hour compliance period. If a section for a site contains fewer than three percent of the total number of records (across all sites), these records will be added to the Other section.	To get the number of records for each manual task, hover your mouse over each section of the chart.

Table 9-1   (Cont.) Charts to explore for records older than 24 hours

Chart title	Chart sections	What you see	What you can do
Intake Processing > 24h by Type	One section for each type, as well as: • Unidentified • No Value Present • Other • All Types	This chart categorizes records that have exceeded the 24-hour compliance period, organized by type. For more information on the types of documents which can be uploaded to Oracle Safety One Intake, see [Understanding which documents to add](#). Records the types of which have not been identified are grouped under the Unidentified section of the chart. Records which have not yet been classified by the Safety One Intake system will be grouped under the No Value Present section of the chart. If the number of records under either of these sections is below three percent of the total number of records, then these records are grouped under the Other section.	To get the number of records for each manual task, hover your mouse over each section of the chart.
Intake Processing > 24h by Assignment	• Other • One section for each assignee • Unassigned	This chart categorizes records that have exceeded the 24-hour compliance period, organized by assignment. If the number of records under either of these sections is below three percent of the total number of records, then these records are grouped under the Other section.	To get the number of records for each manual task, hover your mouse over each section of the chart.
Records in Queue with Greatest Processing Time	N/A	This chart lists records that have exceeded the 24-hour compliance period and have the longest processing times.	For more details, click on each record's hyperlink.

Charts to explore for all records

You can gain insight into the number of records ingested by the Oracle Safety One Intake system in the last 30 days using the All Received metric. Within All Received, the following categories are available:

> ⓘ **Note**
>
> The color scheme of the charts reflects the median processing time for the records from each section. The charts' colors range from orange, indicating processing times closer to 24 hours, to deep red, which indicates processing times closer to 50 hours and beyond.

Table 9-2   Charts to explore for all records

Chart title	Chart section	What you see	What you can do
All Received by State	• In progress • Processed • On Hold	All records received in the last 30 days, grouped by their current state.	To see the number of records in each state, hover your mouse over each section.
All Received by Day	• In progress • Processed • On Hold	Records received in the last 30 days, grouped by the day they were received. The section pertaining to each day is further split between categories for the current states of its respective records.	To track records received on specific days and their processing status, hover your mouse over their respective section.
All Received by Site	• One section for each Site • Other • No Value Present • All Sites	All records received in the last 30 days, categorized by their current site. The No Value Present column reflects the number of records received within the last 30 days, that have no site associated. If the number of records under either of these sections is below three percent of the total number of records, then these records are grouped under the Other section.	To understand the distribution of records across different sites and their processing status in percentages, hover your mouse over each section.

Table 9-2   (Cont.) Charts to explore for all records

Chart title	Chart section	What you see	What you can do
All Received by Source	• One section for each Source • Other • No Value Present • All Sources	All records received in the last 30 days, sorted by their current source. If the number of records under either of these sections is below three percent of the total number of records, then these records are grouped under the Other section.	To understand the distribution of records across different sites and their processing status in percentages, hover your mouse over each section.

Charts to explore for In Progress

Table 9-3   Charts to explore for In Progress

Chart title	Chart section	What you see	What you can do

In Progress by Task	• Grouped under Manual Intervention:
	  – Check validity
	  – Review Record
	  – Create New Record
	• Grouped under System:
	  – System Processing
		All records currently in progress, grouped based on their status and necessity for intervention.
		
		The System Processing section includes all the background activities the Oracle Safety One Intake
			Right click on each section of the chart to be able to Filter, List the records included in that portion of the chart, or Export Data.

In Progress by Assignment	• Unassigned • Group • Assignee • Other	All records currently in progress, grouped based on the user group they are assigned to.	Right click on each section of the chart to be able to Filter, List the records included in that portion of the chart, or Export Data. You can also hover your mouse over each section of the chart to show the total number of records it contains, as well as the records' median processing time.

Charts to explore for Processed

Table 9-4   Charts to explore Processed

Chart title	Chart sections	What you see	What you can do
Processed Record Compliance	• Compliant • Not Compliant	Shows processed records from the last 30 days, categorized according to their SLA compliance.	Right click on each section of the chart to be able to Filter, List the records included in that portion of the chart, or Export Data. You can also hover your mouse over each section of the chart to show the total number of non-compliant versus processed records.
Processed Record States	• All Processed • Valid • Initial • Invalid • Invalid reason • Follow-up • Sent • Other	A breakdown of all the records which have been processed, grouped based on their statuses. Records with a status of Sent can only exist if Oracle Safety One Intake is configured for intake only. Records can only be assigned a status of Invalid whenever files in the E2B(R3) format encounter errors upon ingestion. This can also happen whenever validation errors occur during the processing of a record, such as length violations.	Right click on each section of the chart to be able to Filter, List the records included in that portion of the chart, or Export Data. You can also hover your mouse over each section of the chart to display the total number of records it is referencing, as well as their median processing time.
Case Acceptance Notification (ACK) Status	• Sent • Not Sent • Not Applicable • All Valid	Provides an overview of the case acceptance notifications (ACK) automatically sent out by the system.	Right click on each section of the chart to be able to Filter, List the records included in that portion of the chart, or Export Data. You can also hover your mouse over each section of the chart to display the total number of records it is referencing.

• [Access the view modes of the Intake Monitor](#)
   Depending on your role, you can access a range of metrics in the Intake Monitor. To learn how to navigate to these metrics, follow the steps below.

Access the view modes of the Intake Monitor

Depending on your role, you can access a range of metrics in the Intake Monitor. To learn how to navigate to these metrics, follow the steps below.

1. Make sure you are on the Intake Worklist. For more info on navigating to the Intake Worklist, see [Navigating](#).

2. At the top of the page, select one of the following tabs:

    • Intake Processing > 24hrs

    • All Received

    • In Progress

    • Processed

    For a detailed description on each of these views, see [Monitor records as a workflow manager](#).

Monitor records as an intake processor

As an intake processor, you can use the Intake Monitor to keep track of the records you have access to, all in one place. This includes records undergoing intake processing, records that have been put on hold, and records that have already been processed.

As an intake processor you can view records with the following states:

• Intake Processing

• On Hold

• Processed

• Accepted

• Invalid

The Intake Monitor enables you to perform the following actions:

• Sort your list of records based on a number of columns, such as Type, State, Task, Country, and many more.

• Click on one the ID of a record to access the page connected to its associated task. For example, selecting the ID of a record with a status of Review Record redirects you to the Review Record page.

• Select **Expand details** to view a summary of the data contained within that record.

• Export your list of records in the CSV format by selecting **Export**. This exports all of the records you have access to.

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Publish intake records to a sponsor-owned safety database for case processing

Oracle Safety One Intake supports publishing documents to external systems, such as other Oracle Argus Safety environments or other sponsor-owned safety platforms. This feature is useful for organizations who are responsible for intake processing only and publish the results to their own customers for case management.

For information on how to configure the external publishing features, reach out to your delegated administrator.

If your environment is configured to publish to external systems, Oracle Safety One Intake handles incoming documents as follows:

- To documents that are not compliant with the E2B(R3) format, such as DOC, DOCX, or PDF, Oracle Safety One Intake will make all the necessary adjustments in order to ensure compatibility with receiving systems.

  > ⓘ **Note**
  >
  > If the system encounters any issues during the conversion of extracted data to the E2B(R3) format, a warning file is generated, which is then embedded into the newly created E2B(R3) file.

- To documents that are compliant with the E2B(R3) format, Oracle Safety One Intake will only add information pertaining to narrative processing, such as product or event tags identified through OCR/ML extraction.

  > ⓘ **Note**
  >
  > All automated features, including OCR/ML extraction, require an additional subscription to Oracle Safety One Intake. For more information, reach out to your Oracle point of contact.

The Oracle Safety One Intake has the capability to transmit documents that require further case processing to other platforms using the following channels:

- Via email, only if the receiving system is configured appropriately. This applies to any non-Oracle Argus Safety application, as well as Oracle Argus Safety (both on-premise and cloud) applications that are older than version 8.4.1.

- Via REST API, should the recipient be an Oracle Argus Safety environment (both on-premise and cloud), version 8.4.1 or newer.

  > ⓘ **Note**
  >
  > To import E2B(R3) files received from Oracle Safety One Argus, you need to extend the existing E2B(R3) profile. For more information, see

Whenever Oracle Safety One Intake is configured to publish intake records to a sponsor-owned safety database for case processing, the system only performs tasks related to intake processing. Once intake processing has taken place, case processing is not performed within the system. This means that within the Create New Record and Review Record tasks, **Submit** is available instead of **Search**, allowing the record to be published to an external system once intake processing is complete. For more information, see [Possible tasks related to processing your records](#).

In the event that errors occur during the transmission of records to other systems, such as a temporary outage of a recipient's email service, Oracle Safety One Intake automatically assigns the Review Record task to the record. This enables users to re-submit records for transmission. For more information, see [Possible tasks related to processing your records](#).

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Export audit logs

As an intake monitor, you can export the audit log on Adverse Event (AE) data from the Intake Monitor list.

1. Make sure you are on the Intake Monitor. For more information on navigating to the Intake Monitor, see [Navigating](#).

2. At the bottom of the page, on the right, select **View All**.

3. Check the box of the records you would like to export the audit log for and select **Expand Details**.

4. From the panel on the right, select **Export History**.

5. Save the file to your machine.

12

Appendix

- **System errors**
  As you work in Oracle Safety One Intake, you may sometimes encounter system errors. To find out how to fix some of the most common errors, see the list below.

- **User role attributes**
  Use this topic to gain an overview of your role's attributes.

System errors

As you work in Oracle Safety One Intake, you may sometimes encounter system errors. To find out how to fix some of the most common errors, see the list below.

Table 12-1   System errors

Error message	What you should do
System Error Something went wrong. We have been notified of the issue and will fix it shortly. If this issue persists, contact your administrator.	You should re-attempt your action. If the error persists, make a note of the actions which have led to the error. Then contact your system administrator, providing this information.
System Error The uploaded document(s): <file name>, <file name> do not meet the required format due to syntax errors or invalid parameters. Please address these issues and upload the documents again. If this issue persists, contact your administrator.	You should review the file, check and fix its extension, then try again. If the error persists, make a note of the actions which have led to the error. Then contact your system administrator, providing this information.
Network Error The server could not be reached. Please check your connection and try again. If this issue persists, contact your administrator.	Verify your connection and make sure you are connected to the internet. Alternatively, check if any applications, such as a Virtual Private Network (VPN), have stopped working as expected. You can then re-attempt your action.
Email not imported; size limit exceeded.	You can discard the email. You can also request for the email size limit to be adjusted by contacting your administrator. For more information about email size limits and automatic email ingestion more broadly, see Modify general email settings
Document(s) not imported; size limit exceeded: <document name>.	You can discard the email. You can also request for the incoming attachment size limit to be adjusted by contacting your administrator.
Document(s) not imported; security scan failed: <document name>.	Your document has been marked as malicious. You can discard the email.
Document(s) not imported; type not supported: <document name>.	Your document is not currently supported. You can discard the email.

User role attributes

Use this topic to gain an overview of your role's attributes.

Table 12-2   User roles

User Role	Role Description
CDA (Customer Delegated admin) or Global Administrator	Responsible for the management of user access in Oracle Safety One Intake.
Intake Processor	Reviews, edits, and processes records that are unassigned, assigned to themselves, or assigned to the user group they are part of.
Workflow Manager	Ensures incoming records are assigned to the correct processing users or groups. Monitors the system queue and ensures records are efficiently assigned, to prevent delays.
System Administrator	An administrative role responsible for the configuration required for AE processing, in Oracle Argus Safety console. Users with this role are also responsible for configuring and maintaining the Oracle Safety One Intake email intake feature.