Oracle Life Sciences Safety One Intake Cloud Service

User Guide

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Contents

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 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 http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.

1 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 works seamlessly with Oracle Argus Safety 8.4.1 and provides multiple options for ingesting AE documents, such as automatic uploads via API or email, or manually. These AE documents are then processed in an automated workflow, which can involve manual steps too.

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

1. A user uploads an AE document to Oracle Safety One Intake.
2. Oracle Safety One Intake checks the document. Depending on a predefined configuration, the document may require optional manual validation and grouping.
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 converts the AE data into a format compatible with Oracle Argus Safety, to which the data is transmitted.
6. Depending on whether Oracle Argus Safety is configured to accept data automatically, the data will be converted to case or will be marked for manual case acceptance.

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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 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 Oracle Argus Safety Console.

If you are responsible for user role management or would like to find out more about roles and permissions in Argus Console, see Add users and assign roles, which is part of 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 abstraction, and it allows the adverse events that don't require manual review to get to Oracle Argus Safety sooner.

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

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, click 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** from the top right corner of the page, then selecting **About Argus**.

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

Log out

- To log out, select **User menu** 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.

You possess the authority to proactively assign records to the appropriate users, to prevent any delays in the Oracle Safety One Intake processing workflow. 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 click the **Navigation Menu** ☰, located on the top-left corner of the page, and choose one of the following options:

- **Intake Worklist**
- **Intake Monitor**

> **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** in the top-right corner and select **About**.

For quick access to relevant documents and training materials, select the **User menu** 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, 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, press 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.

4 Uploading documents

Oracle Safety One Intake can ingest 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, as well as through 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. To ingest your documents, follow the steps below.

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.

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

Though you are allowed to upload documents in a variety of formats, these documents must fulfill certain criteria before they are processed automatically. Before you begin uploading documents, consider the following:

- Extraction can only work with image-based files, such as faxes or scanned documents. These can only be in DOC, DOCX, and PDF formats.
- Equally, extraction can only work on documents for which a recipe is configured. For more information on recipes and how they are configured, see Create a new recipe configuration.
- Your delegated administrator configures the maximum size for the files you upload to Oracle Safety One Intake. For more information, see Configuring Case Form (System Management).

Upload documents automatically

Oracle Safety One Intake can ingest documents automatically via email, as well as through APIs.

Oracle Safety One Intake 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.

Oracle Safety One Intake also 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.

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** button 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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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.

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.

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 5-1 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 will not change if you log out of Oracle Safety One Intake. You will 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** . 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** .
2. In the Columns window, ensure the appropriate columns are visible by checking the right side of the Select Columns panel. Columns marked as **Pinned** 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** button and choosing one of the following:

   - Country
   - Event
   - ID
   - Initial Receipt Date
   - Intake Date
   - Priority
   - Product
   - Report Type
   - Site
   - Source
   - Study
   - Type

   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 **Filter history** . 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, click the filter you would like to configure, then select one or more values from the dropdown 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.

Some of the actions which trigger an automatic refresh for the Intake Worklist are:

- 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 outlined below.

1. Make sure you are on the Intake Worklist. For more information on navigating to the Intake Worklist, see Navigating.
2. In the top right corner of the page, select **Refresh**.

6

Managing assignments

An overview of assignments management.

- 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.

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.

Want to see how to perform this task? Watch the video below.

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 assigness of your records in bulk.
- using the **Expand Details** button for each individual record.

You can have either a single individual 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 which allows you to 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, on the bottom of the page. If you receive an error message, select **View Errors** to find out about why this has happened. 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. 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 6-1 Possible assignment errors and how to fix them

Error	Why has this happened?	Actions to take
Read Only	A different user is currently working on the record.	Retry your action periodically until the record is no longer busy.
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.

Table 6-1 (Cont.) 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.

7

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.

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 7-1 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 report. • 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 report. • 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 report. 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. • 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.
Create New Record	• Whenever the document is unidentified, you can add data to a new record manually. For more information, see Manually add data to a new record.
Pending Case	• Whenever the document has been transmitted to Oracle Argus Safety and is awaiting case acceptance. For more information, see Processing pending case 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 Possible tasks related to processing your records.

1. Make sure you are on the Intake Worklist or the Intake Monitor. For more info on navigating to these pages, 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. Work with the data as required. For more information on working with the data in your documents, see Working with the data in your documents.

   > **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 on the hyperlinked 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. Mark a document as primary using the **Mark Primary** button above the panel. Repeat this action for each group from your record.

   You can identify primary records based on the **Primary** icon .

   > **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**.

> **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**.

> **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 the **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 7-2 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.

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 as 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 as 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
  On the Review Record page, you can access and review data that has been marked as Low Confidence. To begin working with Low Confidence data, follow the steps below.
- Add missing data
  If you would like to further annotate the data from the Narrative tab, follow the steps below.
- Reject a report
  As an intake processor, you can reject an entire report based on one of several criteria.
- 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.
- Processing pending case records
  Whenever a document has been transmitted to Oracle Argus Safety and is awaiting case acceptance, it receives a status of Pending Case.

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.

Table 7-3 General

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

Table 7-4 Study

Field name	Validation criteria
Study ID	N/A

Table 7-5 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 7-6 Literature

Field name	Validation criteria
Literature Reference	N/A

Table 7-7 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 7-8 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 7-9 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 7-10 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 7-11 Events

Field name	Validation criteria
Event as Reported	N/A
Event as Coded	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

Table 7-11 (Cont.) Events

Field name	Validation criteria
Outcome	N/A
Occur Country	N/A
Intensity	Non E2B field

Table 7-12 Product

Field name	Validation criteria
Product 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 7-13 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 7-14 Narrative

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

Table 7-15 References

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

Work with Low Confidence data

On the Review Record page, you can access and review data that has been marked as Low Confidence. To begin working with Low Confidence data, 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. 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. 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 by looking for the **Edited field** .

7. 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.

Add missing data

If you would like to further annotate the data from the Narrative tab, 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. 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. Make sure the **All** filter is selected for the **Show Fields** dropdown at the top.
5. Do one of the following:
   - Select a word from the narrative on the right, then begin typing.
   - Type in one of the fields on the left.

> **Note:**
>
> You can easily identify the fields you have already interacted with by looking for **Edited field** .

6. 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.

Reject a report

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

Table 7-16 Report rejection reasons

Reason	Description
Illegible or Unreadable Content	The content of the document is not decipherable.
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.

Table 7-16 (Cont.) Report rejection reasons

Reason	Description
Other	Type your own reason for marking the document as invalid. You can write up to 255 characters, including spaces.

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:
   - **Illegible or Unreadable Content**
   - **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.

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.

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

> **Note:**
>
> You can easily identify the fields you have already interacted with by looking for **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.

Processing pending case records

Whenever a document has been transmitted to Oracle Argus Safety and is awaiting case acceptance, it receives a status of Pending Case.

For more details about launching Oracle Argus Safety, see Know your basics, in the *Oracle Argus Safety User's Guide*.

8 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*

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.
- 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.

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.

> **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 8-1 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 • Pending Case • System Processing	This chart shows records that have exceeded the 24-hour compliance period, considering both manual and automatic tasks.	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 • All sites	This chart displays records that have exceeded the 24-hour compliance period, organized by site. 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 8-1 (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 8-2 Charts to explore for all records

Chart title	Chart section	What you see	What you can do
All Received by State	• In progress • Processed	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	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 • All Sites	All records received in the last 30 days, categorized by their current site. 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.
All Received by Source	• One section for each Source • Other • 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 8-3 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 – Pending Case • Grouped under System: – System Processing	All records currently in progress, grouped based on their status and necessity for intervention.	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 8-4 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.

Table 8-4 (Cont.) Charts to explore Processed

Chart title	Chart sections	What you see	What you can do
Processed Record States	• All Processed • Valid • Initial • Invalid • Not an AE • No Company Product • Other	A breakdown of all the records which have been processed, grouped based on their statuses.	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.

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.

9

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 **Expand History**.
5. Save the file to your machine.

10
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.

Table 10-1 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 10-2 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.

11 Revision history

Table 11-1 Revision history

Date	Part Number	Description
9-January-2025	F81524-04	Original version of the document.
30-January-2025	F81524-05	• Added the Revision History topic. • Added further details to two of the system errors in System errors. • Accessibility improvements for all of the images (e.g. icons, screenshots) across the publication. • Removed mention of working with duplicate records in Oracle Argus Safety from Processing pending case records.