

Oracle® Health Sciences Clinical One Digital Gateway User Guide



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Preface

This preface contains the following sections:

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

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 of Oracle Health Sciences Customer Support Portal (<https://hsgbu.custhelp.com/>)
- Japanese interface of Oracle Health Sciences Customer Support Portal (<https://hsgbu-jp.custhelp.com/>)

You can also call our 24x7 help desk. For information, visit <http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html> or visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

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1

I'm new. Where do I start?

- [Get access and roles for Oracle Clinical One Digital Gateway](#)
There are several types of user roles that you need in order to perform your tasks in Oracle Clinical One Digital Gateway. Learn more about each role required in both Oracle Clinical One Platform and Oracle Health Sciences Identity and Access Management Service.
- [Bookmark your Oracle Clinical One Digital Gateway URL](#)
Bookmark the URL you receive for Oracle Clinical One Digital Gateway as it was given to you. Do not bookmark the URL after you've opened the application because it won't work.
- [Computer and browser requirements](#)

Get access and roles for Oracle Clinical One Digital Gateway

There are several types of user roles that you need in order to perform your tasks in Oracle Clinical One Digital Gateway. Learn more about each role required in both Oracle Clinical One Platform and Oracle Health Sciences Identity and Access Management Service.

- In Oracle Health IAMS you will see the following roles that are required for you to work with these applications:
 - **clinicalone-CNE**
 - **inthub-CNE**If you don't already have these roles, contact your delegated administrator.
- In Oracle Clinical One Platform, make sure you have a global user account that is assigned the **Integration Manager** global role. If you don't already have this role, contact your Oracle Clinical One Platform system administrator.

Tip:

The **Integration Viewer** global role from Oracle Clinical One Platform also lets you access Oracle Clinical One Digital Gateway, but grants read-only privileges to all areas and is mainly for monitoring purposes.

For information about the roles required for Oracle Clinical One Digital Gateway, see [Create Oracle Clinical One Digital Gateway user accounts](#).

Bookmark your Oracle Clinical One Digital Gateway URL

Bookmark the URL you receive for Oracle Clinical One Digital Gateway as it was given to you. Do not bookmark the URL after you've opened the application because it won't work.

Computer and browser requirements

System requirements

Computer	Internet browser	Resolution
Laptop or desktop computer	<ul style="list-style-type: none">Google Chrome version 42.0 or higher (recommended)Microsoft Edge version 44.18 or higher	<p>Make sure the resolution display of your computer is configured using the following values</p> <ul style="list-style-type: none">1920x1080 (recommended) for a full High Definition (HD) monitor1366x768 px or higher (standard resolution) for most non-HD computers

Using Windows 7 and Internet Explorer 11?

Starting with Oracle Clinical One Platform release 22.1, Internet Explorer 11 is no longer supported. The following instructions are still relevant for users continuing to utilize the browser.

Your security settings might prevent you from signing in. If you see a blank white page in Internet Explorer after clicking Sign In, perform the following steps in Internet Explorer to disable compatibility view.

1. In the upper-right corner, click the Tools button, and select **Compatibility View settings**.
2. Below the list of websites, make sure **Display intranet sites in Compatibility View** is **not selected**.
3. Click **Close**.
4. Close all instances of Internet Explorer.
5. Open a new instance of Internet Explorer and try signing in again.

2

Create an Oracle Health Sciences InForm to Oracle Argus Safety integration for a study

- [About the Oracle InForm to Oracle Argus Safety integration](#)
With this integration, critical data about Serious Adverse Events (SAE) is automatically sent from Oracle InForm to Oracle Argus Safety.
- [Step 1. Preparation](#)
Ready to set up this integration? Here's what you need first.
- [Step 2. Create an SFTP credential key](#)
Oracle Clinical One Digital Gateway uses a SFTP credential key to place E2B+ R2 files on the Argus SFTP server. Before you create your SFTP credential key make sure you have an account for the SFTP server.
- [Step 3. Create an integration group for the Oracle InForm study](#)
For every Oracle InForm study that you integrate, you typically have at least two integrations: a test integration and a production integration. Integration groups are a way to keep integrations grouped by study so that you can easily find and manage them.
- [Step 4. Download the Oracle InForm to Oracle Argus integration template](#)
The integration template has most of the information and settings you need to set up this integration. Download the template and then you only need to add the specifics for the study you are integrating.
- [Step 5. Create a test integration](#)
Because you'll want to test the integration before using it in production, we're going to first update the template file to create a test integration. If all goes well during testing, we will later update this file to create the production integration.
- [Step 6: Create the production integration](#)
You're almost done. You're going to download the integration file you set up and tested, update it for production, and then use it to create the production integration.

About the Oracle InForm to Oracle Argus Safety integration

With this integration, critical data about Serious Adverse Events (SAE) is automatically sent from Oracle InForm to Oracle Argus Safety.

[Watch a video overview](#) for this integration.

What does it do?

When a Serious Adverse Event (SAE) occurs during a clinical study, site users and sponsors usually have little time to process the case and report it to regulatory authorities, such as the FDA. In this short span of time, users need to enter AE/SAE data into Oracle InForm, fill out papers or generate a report, send the required documentation to the Safety team, and then Oracle Argus Safety users need to also enter the AE/SAE data in Oracle Argus Safety.

With this integration, AE/SAE data is sent directly from Oracle InForm to Oracle Argus Safety, eliminating the need for transcribing data into Oracle Argus Safety, thus enhancing the

transparency of such data to sponsor Safety personnel, and reducing the challenges of reconciling multiple databases.

What products do I need for this integration?

The following products are required to achieve this integration:

- Oracle Health Sciences Central Designer
- Oracle InForm
- Oracle InForm Publisher
- Oracle Clinical One Digital Gateway
- Standard Services Solution for Argus
- Oracle Argus Safety

For information about the supported versions for each product, see the [Oracle Health Sciences Product Compatibility Matrix](#), which is available for download as an attachment in [My Oracle Support article ID 180430.1](#).

More information

To learn more about setting up this integration, see the [Send InForm Safety Data to Argus Safety](#) infographic, which guides you through the full setup process.

Step 1. Preparation

Ready to set up this integration? Here's what you need first.

- A Oracle Clinical One Platform global user account, which requires the following roles to be able to set up this integration:
 - The **ClinicalOne_Production** or **clinicalone-CNE** role from Oracle Health Sciences Identity and Access Management Service. Your delegated administrator can create the account for you, if you don't already have an account, and assign these roles to it.
 - The **Integration Manager** global role from Oracle Clinical One Platform. Your Oracle Clinical One Platform system administrator can assign this role to your account.

For delegated administrators: How do you create this account?

- An account with write privileges for the SFTP server that your instance of Oracle Argus Safety uses. If possible, get an account with a password that won't expire. If you don't already have one, contact Health Sciences Support to request one. You need this account to create the SFTP credential key. Oracle Clinical One Digital Gateway uses the credential key so that it can place the E2B+ R2 files which contain the safety data on the SFTP server for Oracle Argus Safety.
- The path (from the server home) to a folder where Oracle Clinical One Digital Gateway should place the E2B+ R2 files for Oracle Argus Safety. Use the SFTP account to log in to the server, create necessary folders, and note their paths.

 **Tip:**

You can choose to use separate folders on the SFTP server for the test integration and production integration, but you don't have to.

- The Annotated Study Book from Oracle Central Designer for the study you are integrating.
If you plan on testing the integration on a different study than the one you intend to integrate, you will need the Annotated Study Book for that study, too. The instructions in this guide assume you are using the same study.

If you don't have these documents, request them from your Oracle Central Designer study designer.

You need them to get the codelist values from Oracle InForm which will be the source values for the codelist in the Oracle Clinical One Digital Gateway configuration file. The investigational product name (drug name) is also included in the Annotated Study Book.

Step 2. Create an SFTP credential key

Oracle Clinical One Digital Gateway uses a SFTP credential key to place E2B+ R2 files on the Argus SFTP server. Before you create your SFTP credential key make sure you have an account for the SFTP server.

1. Sign in to Oracle Clinical One Digital Gateway.
2. On the Home page, in the upper right, click **Settings**.
3. In the upper left, click **Add Credentials**.
4. Fill in the required fields:
 - **Product:** Select **Secure File Transfer Protocol (SFTP)**.
 - **Credential Key:** Enter any name for this user name and password combination. You will need to specify this key in the integration file.
 - **User Name:** Enter the user name for the SFTP server account.
 - **Password:** Enter the password for the SFTP server account.
5. Click **Save**.

Step 3. Create an integration group for the Oracle InForm study

For every Oracle InForm study that you integrate, you typically have at least two integrations: a test integration and a production integration. Integration groups are a way to keep integrations grouped by study so that you can easily find and manage them.

You can also keep other integrations that are set up for the same study, such as a Oracle Clinical One Platform to Oracle InForm integration, in this integration group.

If not already available, create an integration group for the Oracle InForm study that you are integrating.

1. On the Home page, in the upper-left, click **Create Integration Group**.
2. Enter a **Group Name**.

We recommend that you include the Oracle InForm study name in the integration group name to help identify integrations for monitoring.

3. Click **Create**.

Your new integration group appears in the list of integration groups.

 **Tip:**

You can add multiple integrations to an integration group by uploading a separate integration file for each integration.

Step 4. Download the Oracle InForm to Oracle Argus integration template

The integration template has most of the information and settings you need to set up this integration. Download the template and then you only need to add the specifics for the study you are integrating.

1. Along the top of the Home page, click **Download Integration Template**, and select **InForm to Argus**.

This downloads the integration file template.

2. Save the file locally and rename it to something specific to this integration.

You can open the integration template in any editor, but we recommend using an editor that is adequate for editing XML, such as. Notepad++, to preserve the formatting that makes the file easier to read.

Step 5. Create a test integration

Because you'll want to test the integration before using it in production, we're going to first update the template file to create a test integration. If all goes well during testing, we will later update this file to create the production integration.

- [Step 5.1: Create the test integration file](#)
- [Step 5.2: Upload the test integration file](#)
- [Step 5.3: Enable the test integration](#)
- [Step 5.4: Test the integration](#)

Step 5.1: Create the test integration file

 **Tip:**

We've provided the line numbers for where the information is in the template to help you find it. As you make updates to the template, particularly if you're adding any new lines, the line numbers may lose accuracy. If that happens, you can use the unaltered template as a reference.

Task 1 Add general information

1. Open the integration template in any editor.
We recommend using an editor that is adequate for editing XML, such as Notepad++, to preserve the formatting that makes the file easier to read.
2. Specify a company name as the value for the `CompanyName` element:

```
3 <CompanyName>your_company_name</CompanyName>
```

Where is this name used? This name is used by Oracle Clinical One Digital Gateway as part of the unique safety report ID which is visible in Oracle Clinical One Digital Gateway and in notification emails. (The safety report ID also appears as the Reference ID on the Additional Info tab in Oracle Argus Safety.)

3. Add the path to the folder on the SFTP server where you want Oracle Clinical One Digital Gateway to place the E2B+ R2 files for testing and add the credential key for the SFTP server. Add the values as shown below:

```
8 <SFTPRoot>path_from_home_to_folder</SFTPRoot>
9 <SFTPUserCredentials>SFTP_credential_key_name</SFTPUserCredentials>
```

4. Replace the constant value placeholders with the details for the study you are integrating.
 - **DTDFILEPATH** (line 315 in template): Replace this string with the full path to the DTD file on the Oracle Argus server (for example, `E:\Argus\InterchangeService\DTDFiles\lich-icsr-v2.1-services.dtd`).
 - **COMPANYNAME** (line 327 in template): Replace with the same name you used in line 3. Do not remove the surrounding dashes (-) because these act as separators between the elements that make up the Oracle Clinical One Digital Gateway safety report ID.
 - **ARGUSSTUDYNAME** (line 339 in template): The Oracle Argus Safety study ID. Must match the value in Oracle Argus Safety exactly and is case-sensitive. For testing, you can specify the ID of a test study.
 - **MEDICINALPRODUCTNAME** (line 349 in template): Replace this string with the exact trade name, as it appears on the Oracle Argus Safety license, otherwise Oracle Argus Safety won't recognize the product and the integration will be unsuccessful. This information is necessary in case the Oracle InForm study was not set up to send it, but you can specify it even if Oracle InForm does send it.
 - If the study is investigating **only one medicinal product**, on line 349 replace the string `MEDICINALPRODUCTNAME` with the exact product name.
 - If the study is investigating **multiple products**, you can use a codelist to map all product names to be used for this study. To use the codelist, uncomment line

348, update it to add the product names (as they appear on the Oracle Argus Safety license), and comment out line 349, as shown below:

```
348 <field custom-
converter="oracle.hsgbu.clinicalone.integration.impl.mapper.D
efaultCodeListMapper" custom-converter-
param="INTHUBCODELIST~DRUGSAFETYREPORT_ MEDICINALPRODUCTNAME">
349 <!-- <field custom-
converter="oracle.hsgbu.clinicalone.integration.impl.mapper.D
efaultInitializer" custom-converter-
param="MEDICINALPRODUCTNAME"> -->
350 <a>medicinalProductName[0].value</a>
351 <b>medicinalproduct.content</b>
352 </field>
```

Then, add the source and target values to the Oracle Clinical One Digital Gateway codelist (lines 102-105) based on the Oracle InForm codelist that holds the product name:

```
102 <codelist>
103 <ID>DRUGSAFETYREPORT_MEDICINALPRODUCTNAME</ID>
104 <Entry Source="" Description="Medicinal product
name" Target=""/>
<!-- Duplicate the above line for each product name
and add source and target values for each. -->
105 </codelist>
```

- If the study is **blinded**, prefix the product name with BLINDED (for example, for a product name of Drug1275, specify BLINDEDDrug1275) so that the product name isn't shown on the product name tab in Oracle Argus Safety.

Task 2 Map codelists

Edit each codelist element (starting at line 14 in the template) to add corresponding source values. The target values for Oracle Argus Safety have already been added to the template based on the standard E2B R2 codes that it expects.

Where do I get the source values? You can get the corresponding source values, which are the codes from Oracle InForm codelists, from the Annotated Study Book for the study you are integrating. The source values appear in the Code column.

Remember: If you have customized Oracle Argus Safety codelists, you must also review corresponding target values and change them from the E2B R2 standard values to the appropriate target values in customized Oracle Argus Safety codelists.

Tip:

If you are not using all available codelists, comment out the codelists that are not necessary for this integration.

1. Add the corresponding source values for the following codelists.

▲ Caution:

Oracle Argus Safety can only accept the E2B values that are already specified as target values, so do not change the target values. As an exception, if you are using custom codelists in Oracle Argus Safety and you will be mapping them appropriately, you can and should update the target values with the ones in the custom codelist.

- COUNTRY
 - GENDER
 - DRUGSAFETYREPORT_ADVERSEEVENTREPORTEDOUTCOME
 - DRUGSAFETYREPORT_ACTIONTAKEN
 - HS_YES_NO_UNKNOWN: Used to populate the Treatment Received, RelatedToStudyConduct, and PatientHasPriorHistory checkboxes on Reaction tab in Oracle Argus Safety.
 - HS_TRUE_FALSE: Used to populate the Seriousness Indicator at the case level in Oracle Argus Safety, Product level (for example, Ongoing) and Patient level indicators (for example, BreastFeedingIndicator).
 - EVENT_LEVEL_YES_NO: Used to populate the Seriousness Indicator values on the Reaction tab in Oracle Argus Safety.
 - DRUGSAFETYREPORT_DOSAGEINTERVALUNIT
 - DRUGSAFETYREPORT_SEPARATEDOSAGENUMB
 - DRUGSAFETYREPORT_DOSAGEINTERVALNUM
 - DRUGSAFETYREPORT_UNITOFMEASURE
 - DRUGSAFETYREPORT_ADMINISTRATIONROUTE
2. (Optional) If you are collecting this data in Oracle InForm and want to send it to Oracle Argus Safety, also add the corresponding source values for the following codelists:

▲ Caution:

Oracle Argus Safety can only accept the E2B values that are already specified as target values. Unless you are using a custom codelist in Oracle Argus Safety for these values, do not change the target values.

- DRUGSAFETYREPORT_QUALIFICATIONCODE
 - DRUGSAFETYREPORT_AGEGROUP
 - DRUGSAFETYREPORT_TERMHIGHLIGHTED
3. (Optional) If you are collecting this data in Oracle InForm and want to send it to Oracle Argus Safety, specify both the source and target values for the below codelists. The source column must be the value sent from Oracle InForm and the target value must be the value for the Oracle Argus Safety codelist.

- OCCUPATION
- RACE
- DRUGSAFETYREPORT_DOSAGEFORM
- DRUGSAFETYREPORT_ADVERSEEVENTSEVERITY

Task 3 Map dosage frequency

Do I need to do this? Only if you have a codelist in Oracle InForm for dosage frequency and you want to share this information to Oracle Argus Safety. For example, let's say you have a codelist in Oracle InForm for dosage frequency that saves a value of "twice a day" as "2XD," the information shared to Oracle Argus Safety would be 2XD. However, Oracle Argus Safety uses the E2B standard, which splits this information into three fields instead of just one, so the same value, 2XD in our example, needs to be mapped in three different codelists. Here's how you represent this in the integration file:

```
<DRUGSAFETYREPORT_SEPARATEDOSAGENUMB>
  <Entry Target="2" Description="Twice a day" Source="2XD" />
</DRUGSAFETYREPORT_SEPARATEDOSAGENUMB>
<DRUGSAFETYREPORT_INTERVALNUMB>
  <Entry Target="1" Description="Twice a day" Source="2XD"/>
</DRUGSAFETYREPORT_DOSAGEINTERVALNUMB>
<DRUGSAFETYREPORT_DOSAGEINTERVALUNIT>
  <Entry Target="804" Description="Day" Source = "2XD"/>
</DRUGSAFETYREPORT_DOSAGEINTERVALUNIT>
```

Task 4 Map to user-defined fields in Oracle Argus Safety

Do I need to do this? Only if you need to map any Oracle InForm fields to user-defined fields in Oracle Argus Safety.

Are there any prerequisites? Yes. If you have user-defined fields in Oracle Argus Safety that you want to populate with data from Oracle InForm, you must have created a custom data series for the field in Oracle Central Designer and use the appropriate alias name for the Oracle Argus Safety user-defined field.

The Custom Patient Fields section of the template (starting at line 891) has mappings for each of the possible user-defined fields that Oracle Argus Safety can accept and the required conversions are already applied to make sure that the target value being sent to Oracle Argus Safety is valid.

Map Oracle InForm fields to user-defined fields as necessary for your study and, if there are any entries in this section that you don't intend to use, leave them as they are, do not map them and do not delete them.

Here's an example from the template for the first custom date field in Oracle Argus Safety:

```
891 <!-- Custom Patient Fields section -->
892 <field>
      <!-- The part in bold below indicates the field type and
number for each Argus Safety user-defined field. -->
893   <a map-get-method="getSpecificCustom"
key="Cust_Patient_Dt_1">this</a>
894   <b>custpatientdt1Extension.content</b>
895 </field>
```

You have **two options for mapping these fields**:

- **Direct mapping:** This is the default mapping that is already set up and will send the value as is. Here's an example of direct mapping from the template:

```
458 <field>
459     <!-- Below line is for the InForm field whose value is sent to
Argus Safety. -->
460     <a map-get-method="getSpecificCustom"
key="Cust_General_Str_1">this</a>
461     <!-- Below line is for the target Argus Safety field where the
unaltered source value is placed. -->
         <b>custgeneralstr1Extension.content</b>
     </field>
```

You don't need to make any changes to direct mappings, unless you have a codelist in Oracle Argus Safety for the target value, in which case you need to edit the mapping to turn it into a codelist mapping (described below).

- **Codelist mapping:** Use if you need to map a custom field from Oracle InForm to a codelist value in Oracle Argus Safety. If the field uses a codelist in Oracle InForm and you want a different value than the code sent to Oracle Argus Safety, you need to add an Oracle Clinical One Digital Gateway codelist in the integration file and attach the new codelist to that custom field mapping. Here's an example where the Oracle Clinical One Digital Gateway COUNTRY codelist is used on a field to convert the source value:

```
<field custom-
converter="oracle.hsgub.clinicalone.integration.impl.mapper.DefaultCodeLis
tMapper" custom-converter-param="INTHUBCODELIST~COUNTRY">
    <!-- The part in bold below indicates the field type and number for
each Argus Safety user-defined field. -->
    <a map-get-method="getSpecificCustom" key="Cust_Patient_Dt_1">this</a>
    <b>custpatientdt1Extension.content</b>
</field>
```

Tip:

You can map multiple source values to the same target value (by adding additional rows for the additional source values), but you cannot map the same source value to multiple target values.

Task 5 (Optional) Add other mapping configurations

Do I need to do this? Only if you have particular needs for the fields that you are sharing with Oracle Argus Safety. You can use the available custom converters to automatically convert source values into target values that Oracle Argus Safety can accept or to convert them to custom values if you use custom codelists.

With custom converters, you can:

1. **Specify an alternate field** to be sent if the default field is blank: Use this converter if an already mapped Oracle InForm field (default field) can be left blank in certain situations and an alternate field would be used to record data instead.

The template already uses it to address the case when a subject experienced an adverse event while traveling outside of the country, so the source country would remain blank and the occurrence country would be specified instead. In this case, the field mapping with the converter identifies the source country to be sent whenever no occurrence country is specified.

```

        <!-- Below line is the mapping for default field -->
525   <field custom-
converter="oracle.hsgbu.clinicalone.integration.impl.mapper.Default
CodeListMapper" custom-converter-param="INTHUBCODELIST~COUNTRY">
526       <a>occurrenceCountryCode.value</a> <!-- Default InForm
field. -->
527       <b>safetyreportid.content</b>
        <!-- Above line is the field in Argus Safety that is
mapped to both the default and the alternate field. -->
528   </field>

        <!-- Use below field mapping tag to map an alternate field
to an Argus Safety field that already has a default field mapped
to it. -->
        <field custom-
converter="oracle.hsgbu.clinicalone.integration.impl.mapper.Default
NVLInitializer">
            <a>primarySourceCountryCode.value</a> <!-- Alternate
InForm field to send only if default is null. -->
            <b>safetyreportid.content</b>
            <!-- Above line is field in Argus Safety that is mapped
to both the default and the alternate field. -->
        </field>

```

- 2. Add one Oracle InForm field as a prefix to another Oracle InForm field:** Use this converter to add the value of one Oracle InForm field as a prefix to the value of another Oracle InForm field to share the resulting value with Oracle Argus Safety. Here's an example from the template that prefixes the message receiver identifier with the site's country code and uses "::" as the separator between the concatenated values:

```

541   <field custom-
converter="oracle.hsgbu.clinicalone.integration.impl.mapper.Default
Concatenator" custom-converter-param="::">
542       <a>primarysourcecountry.content</a> <!-- The value of
this field will be added as a prefix to the value of the second
field. -->
543       <b>messagereceiveridentifier.content</b> <!-- This is the
field that will be sent to Argus Safety, if mapped. -->
544   </field>

```

For example, if the primary source country was "US" and the message receiver identifier was "INFARG_01" then, according to the above mapping, "US::INFARG_01" would be the resulting value and it would be sent as the messagereceiveridentifier value.

- 3. Capitalize or lowercase product names sent from Oracle InForm to Oracle Argus Safety:** Use this converter as it is shown in the template to send product names written in capital letters to Oracle Argus Safety. To send product names in lowercase, edit the converter (line 1545 in template), and add "toLower" for the custom-converter-param parameter, as shown in the comment (line 1544 in template).

```

1544 <!-- custom-converter-param "toUpper" capitalizes all characters
and "toLower" decapitalizes all characters -->
1545     <field custom-
converter="oracle.hsgbu.clinicalone.integration.impl.mapper.CaseConverter
" custom-converter-param="toUpper">
1546         <a>this</a>
1547         <b>medicinalproduct.content</b>
1548     </field>

```

 **Note:**

By default, this case converter capitalizes all product names sent to Oracle Argus Safety.

Task 6 Configure the integration to process a partial safety case narrative from Oracle InForm

Do I need to do this? We recommend you include this tag in your integration configuration file to make sure that any partial narrative data is processed appropriately by Oracle Clinical One Digital Gateway. You should include this tag at the very end of your configuration file, after all custom converters and additional mapping elements. The tag can be set to either true or false.

```

1721     </p:Mappings>
1722 <p:Schedule>
1723 <p:retrycount>2</p:retrycount>
1724 </p:Schedule>
1725 <p:Notifications/>
<!-- Change the tag value to false, if needed -->
1726 <p:ProceedOnFailures>true</p:ProceedOnFailures>
1727 </p:Integration>

```

Task 7 Save changes to the integration file

Step 5.2: Upload the test integration file

1. Sign in to Oracle Clinical One Digital Gateway.
2. On the Home page, look for the integration group that you created for this integration.

 **Tip:**

If necessary, you can use the filters along the top to find the integration group to which you want to add the file.

3. Click the row of the integration group to expand it.
4. Click **Upload Integration File**.
If you already have integrations in this group, the button is located directly under the name of the integration group.
5. Click **InForm to Argus**.
6. In the **Upload Integration File** pop-up, fill in the fields:
 - **Title:** Enter a title for your integration. We recommend that you include the Oracle InForm study name to make monitoring easier and the word "test" so that you know this uses a test study.
 - **Study Name:** Enter the study name, exactly as it appears in the Oracle InForm URL (including case) for the study that you are integrating. Because this is a test integration, provide the name of a test study in Oracle InForm.
 - **Reattempt to send data:** Enter the number of time Oracle Clinical One Digital Gateway should try to send data before the job fails. The minimum value is 2 and this value includes the original attempt. So a setting of 2 means that Oracle Clinical One Digital Gateway will try to send data and if the original attempt fails, it will try one more time in 5 minutes. If this second attempt also fails, the job status changes to Failed and Oracle Clinical One Digital Gateway will no longer attempt to send data.
 - **Send notifications to:** Enter the email addresses of the people you want to receive email notification when this integration fails. Use a semi-colon (;) to separate multiple addresses.
7. Click **Choose File**, then find and select the integration file you want to upload.
8. Click **Upload**.

Step 5.3: Enable the test integration

When do I do this? After you upload the integration file. For the Oracle InForm to Oracle Argus Safety integration, enabling the integration is the final step so that Oracle Clinical One Digital Gateway is ready when safety case data needs to move from Oracle InForm to Oracle Argus Safety.

Why do I have to do this? Because an integration does not enable automatically after you create it. If you don't enable the integration, safety data from Oracle InForm, even if ready to be sent, can't be sent to Oracle Argus Safety.

To enable a specific integration:

1. On the Home page, click the down arrow ▼ for the integration group that you created.
It expands to show existing integrations in the group.
2. Click the toggle button one time for the integration that you want to enable.
The toggle turns blue to show that the integration is active.
Your integration is now ready.

To enable all integrations in an integration group:

1. Select the checkbox on the left of the integration group.

 **Tip:**

You can search for your integration groups using the filters in the upper right.

2. Along the top, click **Manage Integrations** and choose **Enable** from the drop-down.

All integrations in the integration group now show a blue toggle , indicating that they are enabled and ready.

When does the integration run? Because of the rare but urgent nature of safety case data, there are no scheduling settings in Oracle Clinical One Digital Gateway for when the Oracle InForm to Oracle Argus Safety integration should run. Instead, your team would have configured rules in Central Designer that trigger the sending of data. Once data is sent to Oracle Clinical One Digital Gateway, the integration runs.

 **Tip:**

You can always go back to the Manage Integrations drop-down to rename, delete, or immediately run integrations.

Step 5.4: Test the integration

1. Test the integration and make sure that it is running as expected.
If this is your first integration, work with SaaS Services.
2. When you are satisfied with the results, proceed to create the production integration based on the test integration.

Step 6: Create the production integration

You're almost done. You're going to download the integration file you set up and tested, update it for production, and then use it to create the production integration.

1. Sign in to Oracle Clinical One Digital Gateway.
2. On the Home page, click the down arrow for the integration group you created for the study.
3. Select the checkbox to the left of the test integration that you want to use as the base for this integration.
4. Along the top, click **Manage Integrations** and click **Edit Settings**.
5. In the **Edit Integration File** dialog, under **Integration File**, click the XML file name in blue to download the test integration file.
6. Save the file locally under a representative name.
7. In Oracle Clinical One Digital Gateway, click **Cancel** to close the **Edit Integration File** dialog box.

Leave Oracle Clinical One Digital Gateway as is, you will come back to it later.

8. Open the test integration file you downloaded in any text editor.
9. Change the following details that were specific to testing the integration with the values for the production integration:
 - a. **Line 8:** If you used a separate folder to place the test files, change the SFTPRoot value with the path to the folder where you want Oracle Clinical One Digital Gateway to place the E2B+ R2 files for production.
 - b. **Line 339:** If you used a test Oracle Argus Safety study ID, change the value to the production Oracle Argus Safety study ID.
10. Save your changes to the file.
11. In Oracle Clinical One Digital Gateway, with the integration group expanded, click **Upload Integration File** under the integration group name.
12. Click **InForm to Argus**.
13. In the **Upload Integration File** pop-up, fill in the fields:
 - **Title:** Enter a title for your integration. We recommend that you include the Oracle InForm study name to make monitoring easier.
 - **Study Name:** Enter the study name, exactly as it appears in the Oracle InForm URL for the production study that you are integrating.
 - **Reattempt to send data:** Enter the number of times Oracle Clinical One Digital Gateway should try to send data before the job fails. The minimum value is 2 and this value includes the original attempt. So a setting of 2 means that Oracle Clinical One Digital Gateway will try to send data and if this original attempt fails, it will try one more time in 5 minutes. If this second attempt also fails, the job status changes to Failed and Oracle Clinical One Digital Gateway will no longer attempt to send data.
 - **Send notifications to:** Enter the email addresses of the people who should know when this integration fails. If a job in the integration fails, they receive an email notification at the specified address. Use a semicolon (;) to separate multiple addresses.
14. Click **Choose File**, and then find and select the integration file you want to upload.
15. Click **Upload**.
16. Enable this integration in the same way you did for the [test integration](#).

Your integration is now ready to go. When AE/SAE data from Oracle InForm is sent to Oracle Clinical One Digital Gateway, it will process the information according to the settings in the integration file and create an E2B+ R2 file. Oracle Clinical One Digital Gateway will then use the account in the SFTP credential key to post the file on the SFTP server, where it can be picked up and brought into Oracle Argus Safety.

3

Create other integrations

- [Automate and distribute shipments using the Almac Global Depot Network](#)
This workflow applies to shipments when you use an integration with the Almac global depot network for shipments, and it applies to all types of shipments, including the initial shipment to a site, a resupply shipment that is generated automatically when resupply runs, and a manual shipment.
- [Automate and distribute shipments using Catalent Clinical Supply Services](#)
This workflow applies to shipments when you use an integration with Catalent Clinical Supply Services for shipments, and it applies to all types of shipments, including the initial shipment to a site, a resupply shipment that is generated automatically when resupply runs, and a manual shipment.
- [Automate and distribute shipments using Fisher Clinical Services](#)
This workflow applies to shipments when you use an integration with Fisher Clinical Services, and it applies to all types of shipments: the initial shipment to a site, a resupply shipment that is generated automatically when resupply runs, and a manual shipment.
- [Integrate screening and randomization data using iMednet EDC](#)
Use this web service based, two-way integration, between Mednet EDC and Oracle Clinical One Platform RTSM to integrate subject screening and randomization data.
- [Load lab results and other data into Oracle Clinical One Platform](#)
There are two types of data intake integrations available through the Oracle Clinical One Digital Gateway that can be utilized to load data into forms in Oracle Clinical One Platform.
- [Send subject and kit event data to Oracle InForm](#)
Study data from Oracle Clinical One Platform synchronizes directly in Oracle InForm.
- [Send subject event data to a third-party electronic data capture system](#)
You can send subject event data from Oracle Clinical One Platform to a third-party EDC system, based on the configuration settings you specify in the Oracle Clinical One Platform.
- [Send subject enrollment information to Veeva Vault CTMS](#)
The integration between Oracle Clinical One Platform and Veeva Vault CTMS allows you to better monitor subject enrollment information.
- [Send subject information to Oracle Siebel Clinical Trial Management System](#)
This integration allows you to get an accurate overview of your subjects' activity in the study and send the data to your clinical trial management system.
- [Track kit status and location in SmartSupplies PMD](#)
The integration between Oracle Clinical One Platform and SmartSupplies PMD lets you automatically track the status and location of kits from your clinical inventory, making sure you always have the right amount of supplies available at your sites at all times.

Automate and distribute shipments using the Almac Global Depot Network

This workflow applies to shipments when you use an integration with the Almac global depot network for shipments, and it applies to all types of shipments, including the initial shipment to a site, a resupply shipment that is generated automatically when resupply runs, and a manual shipment.

Integration user details

Integration set up includes the creation of a study level integration user account, which is assigned the Clinical supply manager template role, or a custom role that includes the same permissions. The integration user account is created using the email address of one of your organization's Clinical Supply Managers. The email address associated with the integration user receives integration notifications, which can include content resulting in unblinding. Make sure the appropriate email address is configured for the integration user account to avoid unblinding issues.

For information about how to set up this integration, contact your Oracle Project Manager.

Workflow for a shipment when you use an integration with Almac



Note:

If you need to update a shipment after the shipment request has been sent to the depot, you must contact Almac directly. If you make any updates to shipments from within Oracle Clinical One Platform, the changes won't be sent to the depot.

1. When a new shipment is raised, the status of the shipment changes to **Pending**. This activity is automated.
2. When the shipment request is sent to the depot, the status of the shipment changes to one of the following:
 - **Confirmed**, if the depot received the request.
 - **Invalid**, if an issue occurred with the request.Both status changes are automated.
3. For a confirmed shipment, after the depot fulfills the shipment, the ship date and tracking number are set, and the status of the shipment changes to **In Transit**. The setting of the ship date, tracking number, and status change are all automated.
For an invalid shipment, a clinical supply manager should cancel the shipment and do one of the following:
 - Allow the resupply process to create a new shipment the next time inventory runs.
 - Create a new manual shipment.

4. A site receives the shipment and marks the shipment as received, changing its status to **Received**.

What if an order is sent to Almac in error?

If a shipment request is sent in error or kits need to be added or removed, the clinical supply manager must contact Almac and request the shipment's cancellation. Once Almac cancels the order in their system, the shipment status changes to **Invalid** in Oracle Clinical One Platform. To allow the resupply process to create a new shipment the next time inventory runs, the clinical supply manager must also explicitly cancel the shipment in Oracle Clinical One Platform.



Note:

Almac will only be able to cancel the order if the shipment hasn't been sent yet.

Prerequisites for sending the depot order form to Almac-managed depot facilities

To make sure depot users at an Almac-managed depot facility get this email notification in their inbox, in Oracle Clinical One Platform, on the Depots tab, check that the Almac-managed depots are correctly defined and their Depot IDs match the exact names of the depot facilities. Additionally, make sure the email field for depots managed by the Almac Global Depot Network is left blank. The integration is configured to send emails to the appropriate recipients.

Automate and distribute shipments using Catalent Clinical Supply Services

This workflow applies to shipments when you use an integration with Catalent Clinical Supply Services for shipments, and it applies to all types of shipments, including the initial shipment to a site, a resupply shipment that is generated automatically when resupply runs, and a manual shipment.

Integration user details

Integration set up includes the creation of a study level integration user account, which is assigned the Clinical supply manager template role, or a custom role that includes the same permissions. The integration user account is created using the email address of one of your organization's Clinical Supply Managers. The email address associated with the integration user receives integration notifications, which can include content resulting in unblinding. Make sure the appropriate email address is configured for the integration user account to avoid unblinding issues.

For information about how to set up this integration, contact your Oracle Project Manager.

Prerequisites for clinical supply managers

1. Shipment ID prefixes created in Oracle Clinical One Platform must consist only of numbers. When you set the prefix on the Supply Settings tab, in the Shipment Settings section, choose one of the following options:
 - **Use Depot ID:** If Depot IDs have been defined using numbers only
 - **Enter Prefix:** Enter a prefix and make sure the value consists only of numbers

- **None:** If no prefix is used.
2. To make sure depot users at a Catalent-managed depot facility are notified by email about an order, in Oracle Clinical One Platform, on the Depots tab, check that the email field for depots managed by Catalent Clinical Supply Services is left blank. The integration is configured to send emails to the appropriate recipients.
 3. Catalent expects protocol values between 5 and 30 characters long, therefore the value for **Study Title** in Oracle Clinical One Platform must be defined accordingly.

Workflow for a shipment when you use an integration with Catalent Clinical Supply Services for shipments

1. When a new shipment is raised, the status of the shipment changes to **Pending** in Oracle Clinical One Platform. This activity happens both manually or automatically, depending on how the resupply conditions are set in the study.
2. When the shipment request is acknowledged by the depot, the status of the shipment changes to **Confirmed** in Oracle Clinical One Platform. This activity is automated.
3. The depot adds a ship date and a tracking number to the shipment, if available. The status of the shipment changes to **In Transit** in Oracle Clinical One Platform. These updates are automated.
4. The following updates can happen both automatically or manually, depending on how the integration is configured:
 - **If the integration is configured to support this and the courier provides the information:** Catalent Clinical Supply Services receives delivery information from the courier. The integration sets the status of the shipment to **Received** in Oracle Clinical One Platform. The status of all the kits included in the shipment automatically changes to **Available**. Additionally, the Date Received is updated in Oracle Clinical One Platform to reflect the date the integration processed the delivery file. This date may not always match the date at which the shipment is delivered by Catalent Clinical Supply Services.
 - **If the integration isn't configured to interpret the delivery as a receipt:** A site user must manually mark the shipment as **Received** in Oracle Clinical One Platform.

Note:

If you need to update (add or remove kits from a shipment) or cancel a shipment after the shipment request has been sent to the depot, you must contact Catalent Clinical Supply Services directly. If you make any updates to shipments from within Oracle Clinical One Platform, the changes won't be sent to the depot. When the shipment is marked as **Received**, this status update applies to the entire shipment and all its kits are presumed **Available**. Therefore, all the kits in the shipment, including kits added after the original request, are updated once the shipment is received.

What if an order is sent to Catalent Clinical Supply Services in error?

If a shipment request is sent in error or kits need to be added or removed, the clinical supply manager must contact Catalent Clinical Supply Services and request the

shipment's cancellation. Once Catalent Clinical Supply Services cancels the order in their system, the shipment status changes to **Invalid** in Oracle Clinical One Platform. To allow the resupply process to create a new shipment the next time inventory runs, the clinical supply manager must also explicitly cancel the shipment in Oracle Clinical One Platform.

 **Note:**

Catalent Clinical Supply Services will only be able to cancel the order if the shipment hasn't been sent yet.

Automate and distribute shipments using Fisher Clinical Services

This workflow applies to shipments when you use an integration with Fisher Clinical Services, and it applies to all types of shipments: the initial shipment to a site, a resupply shipment that is generated automatically when resupply runs, and a manual shipment.

Integration user details

Integration set up includes the creation of a study level integration user account, which is assigned the Clinical supply manager template role, or a custom role that includes the same permissions. The integration user account is created using the email address of one of your organization's Clinical Supply Managers. The email address associated with the integration user receives integration notifications, which can include content resulting in unblinding. Make sure the appropriate email address is configured for the integration user account to avoid unblinding issues.

For information about how to set up this integration, contact your Oracle Project Manager.

Workflow for a shipment when you use an integration with Fisher Clinical Services

1. When a new shipment is raised, the status of the shipment changes to **Pending**. This activity is automated.
2. For a confirmed shipment, after the depot fulfills the shipment, the ship date is set, and the status of the shipment changes to **In Transit**. The setting of the status and shipment details defined with each integration, such as shipment date, courier and tracking number, are both automated.
3. A site receives the shipment and marks the shipment as received, changing its status to **Received**.

 **Note:**

If you need to update a shipment after the shipment request has been sent to the depot, you must contact Fisher Clinical Services directly. If you make any updates to shipments from within Oracle Clinical One Platform, the changes won't be sent to the depot.

Integrate screening and randomization data using iMednet EDC

Use this web service based, two-way integration, between Mednet EDC and Oracle Clinical One Platform RTSM to integrate subject screening and randomization data.

Integration data flow

iMednet EDC to Oracle Clinical One Platform RTSM

Subjects are first screened in iMednet EDC. A schedule, configured in Oracle Clinical One Platform, calls Mednet API's to retrieve subjects who are marked *Ready for Randomization*. Screening data is returned to Oracle Clinical One Platform to automatically screen subjects.

Oracle Clinical One Platform to iMednet EDC

Once a subject has been randomized in Oracle Clinical One Platform, randomization data is returned to the iMednet EDC system.

Available events and data points

- **Available events:** Screening and Randomization.
- **Available data points for Screening:** Subject statuses, Site ID, Subject ID, and 3 other data points defined by the project team.
- **Available data points for Randomization:** Randomization date, Randomization Number, Dispensed and replaced kits, and other data points defined by the project team.

Other integration details

- Data sent to Oracle Clinical One Platform completes the screening process in which iMednet data points populate all required items in the screening visit. Other items can be present at the screening visit, but they cannot be required, or the integration will not be able to complete the screening process.
- Site ID/Name must match in both systems.
- If a subject is transferred to a new site in either system, the integration is no longer able to sync data, and jobs start failing.
- The integration in Oracle Clinical One Platform does not monitor or log any job failures once the data is sent via the Mednet APIs. The customer needs to work with Mednet to resolve any data import issues or failures. No data is stored by the integration for future retries.
- When a subject is screened in Oracle Clinical One Platform, the visit date for the screening visit defaults to the current date and time.

How can I configure this integration?

For more information about how to set up this type of integration, reach out to your Oracle project manager, or find additional details at [Access Your Data](#) under *Use a pre-built data integration*.

Load lab results and other data into Oracle Clinical One Platform

There are two types of data intake integrations available through the Oracle Clinical One Digital Gateway that can be utilized to load data into forms in Oracle Clinical One Platform.

CDISC Lab Data Intake

Load lab data into Oracle Clinical One Platform that adheres to the Clinical Data Interchange Standards Consortium (CDISC) Laboratory Data Model (LAB) standard, ensuring the data being loaded is done so in accordance with the industry's standard for transmitting electronic data related to drug development.

Data for this integration can be loaded into flat, repeating and multi-section forms assigned to a scheduled visit, unscheduled visit or cycle visit.

 **Note:**

Data loaded into hidden items does not adhere to the CDISC LAB standard.

For more information about this integration, reach out to your Oracle Customer Success Manager (CSM) or Oracle Project Manager.

Generic Data Intake

Load generic data such as subject and questionnaire data into Oracle Clinical One Platform forms.

Data for this integration can be loaded into flat and repeating forms assigned to a scheduled visit, unscheduled visit or cycle visit.

For more information about this integration, contact your Oracle Customer Success Manager (CSM) or Oracle Project Manager.

Data Intake integration overview

- Forms are created during study design that are to be populated through a data intake integration.
- The integration is configured using the integration template.
- Data files (ASCII .txt comma or pipe delimited), are placed on the Oracle sFTP server by the vendor which are picked up once detected by the Oracle Clinical One Digital Gateway.
- The Oracle Clinical One Digital Gateway validates and incrementally processes the file, then uploads the data into the appropriate forms.
- Queries are automatically raised as per the rules that have been predefined in the study design.

Data Intake integration error handling

- If data does not conform to the expected format defined for an integration or if data points do not match the options defined in Oracle Clinical One Platform such as study name,

visit, form, or subject id the job will fail and displays the appropriate error message and remediation details.

- If a Data Intake integration attempts to populate a form in a skipped visit, a visit manually skipped by a user, the import job fails, and data does not integrate. To resolve this, a user must undo the skipped visit followed by the vendor placing the file on sFTP for re-import.
- Scheduled visits can be loaded out-of-order except for branch visits. Integration jobs will fail if sending data out-of-order for any branch visit (non-cycled and cycled). For example, if a branch has Day1 -> Day2 visits then the Day2 visit cannot be loaded before Day1 is completed.

Send subject and kit event data to Oracle InForm

Study data from Oracle Clinical One Platform synchronizes directly in Oracle InForm.

For information about how to set up this integration, please reach out to your Oracle Project Manager.

All data on scheduled and unscheduled events (including unscheduled dispensation data) is sent to Oracle InForm at the intervals defined in the integration schedule. For more details on what types of data you can integrate, see below.

When integrating date fields between Oracle Clinical One Platform and Oracle InForm, make sure a date rule is created in Oracle Clinical One Platform to prevent data that is not accepted by Oracle InForm from being collected. Otherwise, the integration fails with no possible workaround. [Learn how to prevent this error and make sure your integrations with Oracle InForm won't fail.](#)

Subject event data

Type of data	Notes
Screen a subject.	You choose the data to send.
Screen fail a subject and undo screen failure	<ul style="list-style-type: none"> • For screen failure, the screen failure date and reason along with any other relevant information related to the screen failure event are sent to Oracle InForm. You can map these fields to any form you use to collect the screen failure reason. The status for the subject in Oracle InForm isn't changed. • For undo screen failure, the screen failure date is updated to blank in Oracle InForm. The status for the subject in Oracle InForm isn't changed.
Randomize a subject	You choose the data to send.
Update a form for a subject.	You choose the data to send.
Complete a subject's visit.	You choose the data to send.
Transfer a subject.	You choose the data to send.

Type of data	Notes
Withdraw a subject and undo withdrawal.	<ul style="list-style-type: none"> For subject withdrawal, the withdrawal form in Oracle InForm is updated with the withdrawal date and reason, as well as any other relevant information. For undo subject withdrawal, the completion date and other details that were sent are cleared out in Oracle InForm. Oracle Clinical One Platform retains the information in the withdrawal form.
Complete a study for a subject and undo study completion.	<ul style="list-style-type: none"> For a study completion, the completion date and any other relevant information for a subject completion event is sent to Oracle InForm. For undo study complete, the completion date and other details that were sent are cleared out in Oracle InForm. The information in the study completion form in Oracle Clinical One Platform remains.

Kit event data

Type of data	Notes
Replace a kit that was damaged or lost	Data about replaced kits and new kits that are dispensed is sent to Oracle InForm and included in a visit form. The new information includes dispensation date, original kit number and new kit number, amongst others.
Re-dispense a conserved kit.	The conserved kit number and any other relevant data can be sent to Oracle InForm and included in a visit form.

Form data

Type of data	Notes
Apply, update, or clear a data flag.	<p>In Oracle InForm, data flags correspond to the Reason Incomplete options available in the user interface for incomplete form answers. In Oracle InForm the Data Entry Flag is collected in the item comment section. Clicking the Comments icon in Oracle InForm displays the Reason Incomplete options, equivalent to those in Oracle Clinical One Platform. The Reason for Change from Oracle Clinical One Platform is featured on the Comment field above the Reason Incomplete options.</p> <p>These are the default configurations in Oracle InForm. Make sure these settings are configured appropriately, so that data flag information can be sent from Oracle Clinical One Platform to Oracle InForm.</p> <ul style="list-style-type: none"> The Require a comment setting (when entering N/A, Unknown, or Not Done) in Oracle InForm is set to No. The Display Comment Text Boxes setting is set to Yes.

Send subject event data to a third-party electronic data capture system

You can send subject event data from Oracle Clinical One Platform to a third-party EDC system, based on the configuration settings you specify in the Oracle Clinical One Platform.

For information about how to set up this integration, please reach out to your Oracle Project Manager.

Which data can Oracle Clinical One Platform share with a third-party electronic data capture system?

All event data is sent to a third-party EDC system at the intervals defined in the integration schedule.

Note:

For this type of integration, you must not apply data flags to any form fields in a Oracle Clinical One Platform study. Including data flags in an integrated study will cause integration failures.

- **Screen a subject**
You choose the data to send.
- **Screen fail a subject, and undo screen failure**

- For screen failure, the screen failure date and reason along with any other relevant information related to the screen failure event are sent to the third-party EDC system. You can map these fields to any form you use to collect the screen failure reason. The status for the subject in the third-party EDC system isn't changed.
- For undo screen failure, the screen failure date is updated to blank in the third-party EDC system. The status for the subject in the third-party EDC system isn't changed.
- **Randomize a subject**
You choose the data to send.
- **Complete a subject's visit**
You choose the data to send.
- **Withdraw a subject, and undo withdrawal**
 - For subject withdrawal, the withdrawal form in the third-party EDC system is updated with the withdrawal date and reason, as well as any other relevant information.
 - For undo subject withdrawal, the completion date and other details that were sent are cleared out in the third-party EDC system. Oracle Clinical One Platform retains the information in the withdrawal form.
- **Code break**
If a user performed a code break in Oracle Clinical One Platform, Oracle Clinical One Platform sends the date and time when the code break was performed to the third-party EDC system.
- **Kit replacement**
When a kit is replaced, the dispensed kit information is updated with the replacement kit information on the specified form and item in the third-party EDC system.

Send subject enrollment information to Veeva Vault CTMS

The integration between Oracle Clinical One Platform and Veeva Vault CTMS allows you to better monitor subject enrollment information.

For information about how to set up this integration, please reach out to your Oracle Project Manager.

What type of information can Oracle Clinical One Platform share with Veeva Vault CTMS?

For example, this integration can automatically send updates to Veeva Vault CTMS whenever a subject is screened or randomized in Oracle Clinical One Platform and their state changes accordingly.

Track kit status and location in SmartSupplies PMD

The integration between Oracle Clinical One Platform and SmartSupplies PMD lets you automatically track the status and location of kits from your clinical inventory, making sure you always have the right amount of supplies available at your sites at all times.

Integration user details

Integration set up includes the creation of a study level integration user account, which is assigned the Clinical supply manager template role, or a custom role that includes the same permissions. The integration user account is created using the email address of one of your organization's Clinical Supply Managers. The email address associated with the integration

user receives integration notifications, which can include content resulting in unblinding. Make sure the appropriate email address is configured for the integration user account to avoid unblinding issues.

For information about how to set up this integration, contact your Oracle Project Manager.

What type of information can Oracle Clinical One Platform share with SmartSupplies PMD?

This integration automatically sends updates to SmartSupplies PMD whenever one of these changes occurs in Oracle Clinical One Platform:

- A kit's status is updated
- A kit's location is updated (including kits whose location is updated from one depot to another).

Send subject information to Oracle Siebel Clinical Trial Management System

This integration allows you to get an accurate overview of your subjects' activity in the study and send the data to your clinical trial management system.

For information about how to set up this integration, please reach out to your Oracle Project Manager.

Which data can Oracle Clinical One Platform share with Oracle Siebel CTMS?

Once the integration between Oracle Clinical One Platform and Oracle Siebel CTMS is set up, you can start sending Subject Data for CTMS reports to Oracle Siebel CTMS. The report shows the current subject data for all sites within your study and does not include an audit trail of changes. For instance, you view a subject's demographic data, such as gender or date of birth, as well as some details about their last event, such as the screening date or the withdrawal date, and the reason for the withdrawal. The frequency with which the report is sent, as well as the exact information to be included in the report are set according to the study protocol.



Note:

Only subjects with completed visits are included in the report.

Need more details? Check out the Subject Data for CTMS report.

4

Monitor and manage integrations

- [Manage an integration](#)
You need to disable the integration to make changes. You can re-enable it after you finish your changes. We recommend that you do this at a time when it won't impact the integration's schedule.
- [Monitor reports and jobs for an integration](#)
Jobs for an integration might require your attention and assistance if there are any errors that prevent the integration from running properly. Follow the steps in this topic to troubleshoot any issues with your integrations.

Manage an integration

You need to disable the integration to make changes. You can re-enable it after you finish your changes. We recommend that you do this at a time when it won't impact the integration's schedule.

1. On the Home page, click the integration group row to expand it and show integrations in the group.
2. If the integration you want to edit is enabled, click the toggle one time to disable the integration.

An enabled integration has a blue toggle:



The toggle turns gray after you click it, indicating that you can now edit it:



3. Select the checkbox of the integration.
4. Along the top, click **Manage Integrations** and select **Edit Settings**.

You can edit the following details for an integration:

- Title
 - Study name
 - Number of times to attempt to send data (includes the original attempt)
 - Email addresses that should receive integration failure notifications
 - Download the current integration file or upload a new integration file.
5. Save your changes.
 6. Re-enable the integration by clicking the gray toggle  once.

Monitor reports and jobs for an integration

Jobs for an integration might require your attention and assistance if there are any errors that prevent the integration from running properly. Follow the steps in this topic to troubleshoot any issues with your integrations.

Search for a job or safety report that is failing



Tip:

Error messages may reveal integration data that can potentially be unblinding. The users who review error messages should not be blinded members of the study team.

1. On the Home page, click the row of the integration group with a failed status to expand it and see the integrations.



2. Click the row of the integration with a **Failed** status to see jobs under it.



Tip:

Use the options along the top to search or apply filters to find jobs. We recommend searching by date range as the easiest way to find a job.

3. Click the job that failed to see jobs under it.
4. Click the failed job to see details in the **Job Details** pane on the right.

Here's what each status means:

- **All:** This means you can see all jobs no matter their status.
- **Succeeded:** Only the successful jobs are shown.
- **Failed:** Only the failed jobs are shown.
- **Canceled:** Only the jobs you canceled are shown.
- **Processing:** Only the in-progress jobs are shown.
- **Blocked:** Only the blocked jobs are shown.
- **In Retry:** Only the jobs that are trying to resend data are shown.
- **Fail No Advance:** Only the jobs that have failed once, but are supposed to automatically succeed are shown. This integration runs for a certain period of time.

- **Superseded:** Only the jobs that previously had a **Fail No Advance** status and are now running properly are shown. The integration window of this job changes.
- **Fail No Retry:** This status is only applicable for the Siebel CTMS integration and indicates the job failed and no retry attempt is made.

Resend or cancel a job

▲ Caution:

For Oracle InForm to Oracle Argus Safety jobs, never cancel a job. Canceled jobs are never resent and the data would be lost.

1. On the Home page, locate the integration group that has a **Failed** job:
 - a. If you know the name of the integration that failed, you can search for it using the **Search** box in the upper right.
 - b. If you don't know the name, look for the **Failed** status to the left of the date and time.



2. Click the row of the integration that failed.



3. Find the job that you want to resend or cancel.

💡 Tip:

You can search for the job using the calendar filters along the top. For example, you can filter for **Reports** or **Jobs** using the two buttons along the top, on the right.

4. Select the checkbox for that job.
5. On the right, below **Job Details**:
 - Click **Resend** if the job isn't working
 - Click **Cancel Job** if you want to stop the job.

▲ Caution:

Never cancel an Oracle InForm to Oracle Argus Safety job.



Tip:

To see the history of a job, select the job and look in **Job Details**, on the right.

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Troubleshoot: What if...

- [An enabled integration keeps failing](#)
You'll find out about an integration failure from a notification email. Follow the steps in this topic to troubleshoot any potential issues with your integration.
- [How can I prevent integration errors with date fields between Oracle Clinical One Platform and Oracle InForm?](#)
We recommend you work with your study designer to make sure your integrations never fail due to incorrect data.
- [I can't sign in to Oracle Clinical One Digital Gateway](#)
You need an Oracle Health Sciences single sign-on account to sign in.
- [An integration manager is unable to sign in to Oracle Clinical One Digital Gateway](#)
Depending on what your role is, you'll have to make sure the user is assigned the appropriate roles in both Oracle Health Sciences Identity and Access Management Service and Oracle Clinical One Platform.
- [I want to run an integration even though one job is failing](#)
You can't do that. If a job in the integration failed, then all of the other jobs are blocked. Correct and rerun the failed job and blocked jobs will automatically run once unblocked, then you can run the integration.

An enabled integration keeps failing

You'll find out about an integration failure from a notification email. Follow the steps in this topic to troubleshoot any potential issues with your integration.

1. Check your email. When an integration fails, you receive an email notification. That email includes:
 - The safety report ID (Oracle InForm to Oracle Argus Safety) or the subject ID (Oracle Clinical One Platform to Oracle InForm and Oracle Clinical One Platform to Veeva Vault CTMS) or the job ID (Oracle Clinical One Platform to Almac, Fisher Clinical Services or SmartSupplies PMD).
 - The ID of the job that failed.
 - The name (title) of the integration.
 - The date and time (UTC) when the job status changed to Failed.
2. Check for common causes of job failure.

If you're still having trouble, contact [Health Sciences Cloud Support](#) for assistance and include the following information in the ticket:

- The integration title, the ID of the job that failed, and the time when it failed. You can get all three from the email notification.
- Name of the Oracle InForm study that needs to send safety data to Oracle Argus Safety.
- Any other details that you consider relevant.

3. After the issue is resolved, resend the job if necessary:
 - a. On the Home page, click the row of the integration group indicated in the integration failure email to expand it.
 - b. Click the safety report or job indicated in the email to see jobs under it.
 - c. Click the job that has the ID indicated in the email.
 - d. Review information in the **Job Details** pane on the right.
 - e. In the **Job Details** section on the right, click **Resend**.

How can I prevent integration errors with date fields between Oracle Clinical One Platform and Oracle InForm?

We recommend you work with your study designer to make sure your integrations never fail due to incorrect data.

For integration managers

Oracle InForm does not accept dates before the year 1800. If Oracle Clinical One Platform includes any such dates, integrations between Oracle Clinical One Platform and Oracle InForm fail without any workarounds.

How can I prevent this error?

Work with your Oracle Clinical One Platform study designer to create a rule that prevents users from entering dates earlier than 1800 in any date fields.

Remember that there is no possible workaround for this error. If Oracle Clinical One Platform allows a date value that Oracle InForm doesn't accept, the data won't be sent to Oracle InForm. Moreover, the integration will permanently fail.

I can't sign in to Oracle Clinical One Digital Gateway

You need an Oracle Health Sciences single sign-on account to sign in.

1. If you don't have a single sign-on account, contact your delegated administrator to request one.
2. If you already have a single sign-on account, but can't remember the credentials, contact your delegated administrator.
3. If you still can't sign in, ask your delegated administrator to check that you have the appropriate roles in Oracle Health Sciences Identity and Access Management Service, and your Oracle Clinical One Platform system administrator to check that you have the necessary role in Oracle Clinical One Platform.

An integration manager is unable to sign in to Oracle Clinical One Digital Gateway

Depending on what your role is, you'll have to make sure the user is assigned the appropriate roles in both Oracle Health Sciences Identity and Access Management Service and Oracle Clinical One Platform.

For delegated administrators: Make sure you've assigned them the **ClinicalOne_Production** or **clinicalone-CNE** role in Oracle Health IAMS.

For Oracle Clinical One Platform user administrators: Make sure you've assigned them the Integration Manager global role in Oracle Clinical One Platform.

I want to run an integration even though one job is failing

You can't do that. If a job in the integration failed, then all of the other jobs are blocked. Correct and rerun the failed job and blocked jobs will automatically run once unblocked, then you can run the integration.

**Note:**

This solution does not apply to the Oracle InForm to Oracle Argus Safety integration because jobs are never blocked.

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Learn more: Frequently asked questions (FAQs)

- [Can I run an integration without having credentials?](#)
We're sorry, no. It may be yet another task in the process, but credentials are mandatory for running a safe and proper integration.
- [What are the products that I can integrate using Oracle Clinical One Digital Gateway?](#)
You can integrate a variety of applications for clinical supply services, as well as EDC systems using Oracle Clinical One Platform.
- [Do you upload an integration file every time you want to create a new integration?](#)
Yes, you have to do that every time you create a new integration.
- [How do I know when a job failed?](#)
If you add your email address when you configure the integration, you are notified by email whenever an integration failure occurs. The email notification you receive contains the following details to help you identify which job failed.
- [What are the common causes of job failure?](#)
Learn more about the common causes of job failures by reading through the list of possible use cases in this topic.

Can I run an integration without having credentials?

We're sorry, no. It may be yet another task in the process, but credentials are mandatory for running a safe and proper integration.

What are the products that I can integrate using Oracle Clinical One Digital Gateway?

You can integrate a variety of applications for clinical supply services, as well as EDC systems using Oracle Clinical One Platform.

For example, you can integrate:

- Oracle InForm with Oracle Argus Safety
- Oracle Clinical One Platform with Almac
- Oracle Clinical One Platform with Fisher Clinical Services
- Oracle Clinical One Platform with Catalent Clinical Supply Services
- Oracle Clinical One Platform with SmartSupplies PMD
- Oracle Clinical One Platform with Oracle InForm
- Oracle Clinical One Platform with a third-party EDC system
- Oracle Clinical One Platform with Veeva Vault CTMS

- Oracle Clinical One Platform with Oracle Siebel Clinical Trial Management System (CTMS)

 **Note:**

The Oracle Clinical One Digital Gateway feature is included for no additional charge with the purchase of the Oracle Health Sciences InForm and Oracle Argus Safety Cloud Service. Configuration of the Oracle InForm to Oracle Argus Safety integration using Oracle Clinical One Digital Gateway may require the purchase of configuration services from Oracle.

Do you upload an integration file every time you want to create a new integration?

Yes, you have to do that every time you create a new integration.

Don't know how to create an integration file? See [Create a test integration](#) or [Create the production integration](#).

How do I know when a job failed?

If you add your email address when you configure the integration, you are notified by email whenever an integration failure occurs. The email notification you receive contains the following details to help you identify which job failed.

- The safety report ID (for Oracle InForm to Oracle Argus Safety)
- The Subject ID (for Oracle Clinical One Platform to Oracle InForm and Oracle Clinical One Platform to Veeva Vault CTMS)
- The study ID and Site ID (for both Oracle Clinical One Platform to Veeva Vault and Oracle Clinical One Platform to SmartSupplies PMD)
- The job ID (for Oracle Clinical One Platform to Almac and Oracle Clinical One Platform to Fisher Clinical Services)
- The name (title) of the integration
- The date and time (UTC) when the job status changed to Failed.

What are the common causes of job failure?

Learn more about the common causes of job failures by reading through the list of possible use cases in this topic.

1. If the status is Blocked, check to see which other jobs in this integration have failed and are blocking this job. Troubleshoot those Failed jobs and come back to the Blocked one to see if it works. (Does not apply to the Oracle InForm to Oracle Argus Safety integration.)
2. If this is the first time this job has failed, check and see if your credential key is still valid. If not valid, update the credential key and save your changes.

3. If this is the first time you run this integration, check that mappings in the integration file are set up correctly. After you fix the issue, re-upload the integration file. Don't know how to create an integration file? See [Create a test integration](#) or [Create the production integration](#).
4. If this is the first time you run an Oracle InForm to Oracle Argus Safety integration, check that the path to the folder on the SFTP server is correct.
5. If none of the above helped, in the Job Details pane on the right, click Resend for this job. It may have been only a timeout issue.