Oracle® Life Sciences Clinical One

Digital Gateway User Guide

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Contents

5 Revision history

Preface

This preface contains the following sections:

Documentation accessibility

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

Diversity and Inclusion

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

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.

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Where do I start?

Get access

Work with your Customer Delegated IAMS Administrator (CDA) and Oracle Clinical One Platform user manager, at times the same person, to gain access to Oracle Clinical One Digital Gateway.

Before you can manage integrations in Oracle Clinical One Digital Gateway, the CDA and user manager must complete the following.

1. Create an Oracle Life Sciences single sign-on (SSO) user account and assign the appropriate product roles in Oracle Life Sciences Identity and Access Management Service (IAMS).
2. Add the user account as a global user and assign the appropriate global roles in Oracle Clinical One Platform.

For additional information and to review instructions for completing these tasks, see Provide user access to Oracle Clinical One Digital Gateway.

Bookmark important URLs

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.

Browser requirements

System requirements

Computer	Internet browser	Resolution
Laptop or desktop	**Google Chrome**: • Version 119.0.6045.124 and later are supported. • **Oracle Clinical One Platform 24.2** was tested using version 127.0.6533.73 (Official Build) (64-bit). **Microsoft Edge:** • Version 119.0.2151.58 and later are supported. • **Oracle Clinical One Platform 24.2** was tested using version 126.0.2592.113 (Official build) (64-bit).	Make sure the resolution display of your computer is configured using the following values • 1920x1080 (recommended) for a full High Definition (HD) monitor • 1366x768 px or higher (standard resolution) for most non-HD computers

2

Available integrations

Clinical Trial Management Systems (CTMS)

Oracle Siebel CTMS

This section provides details about the configuration and implementation process for the two-way data integration between Oracle Clinical One Platform and Oracle's Siebel Clinical Trial Management System (CTMS).

Use these integrations to exchange data about study design, sites, subject visit data, and subject data verification information.

You are not required to configure all four of the integrations, only those you need. Start by reviewing the following topics to decide which CTMS integrations you want to use:

- Study Version Template (SVT) Integration
- Site Integration
- Subject Visit (SV) Integration
- Source Data Verification (SDV) Integration

The content of the previously listed topics includes links to the following sections, which are solely for reference.

- Shared configuration instructions
- Update an integration template

Study Version Template (SVT) Integration

This incremental integration runs on a schedule to identify study versions created in Oracle Clinical One Platform since the integration was last processed; it then creates corresponding templates in CTMS.

Integration data flow details

Table 2-1 Integration data flow details

Type of integration	Data flow	Frequency
Multiple file	One-way, from Oracle Clinical One Platform to CTMS	Scheduled

Integration overview

The SVT integration runs on a customer-defined schedule to identify study versions that have been created (for a configured study mode) since the integration was last processed. It retrieves study design metadata from Oracle Clinical One Platform, then sends the information to CTMS. The integration then imports visits, forms, and questions of type date/time and Boolean and creates a corresponding subject visit template.

- Each study version gets imported in CTMS as a subject visit template and includes an Integrated flag, which is set by the integration.
- For cycle visits and unscheduled visits, only one instance of each cycle or unscheduled visit is created in CTMS.

Monitoring the integration

The SVT integration includes the following monitoring features:

- Job monitoring is done at the study version level.

> **Note:**
>
> The integration monitors study version changes for one study mode at a time.

- Data received for multiple study versions is processed in parallel.
- Data is processed in the order the requests are received.

Integration limitations

- The forecasting information and lead days calculation (for cycle and unscheduled visits) are not included with study version details. These details can be included in the **Subject Visit Schedule** sub-integration, which is part of the Subject Visit (SV) Integration.
- The integration does not provide a delta (a list of changes) between study versions. It sends the entire study design metadata that corresponds to a study version.
- The integration does not recognize Advanced Study Version (ASV) changes applied to previous study versions and does not send them to CTMS.

Configure the integration

1. **Prerequisites**

The following prerequisites must be completed before you can configure and test the integration:

- Get access to Oracle Clinical One Digital Gateway.
- Be sure to capture your configuration decisions so you have a record of the specifications defined for this integration.
- Ask your user administrator to create the Oracle Clinical One Platform integration user:
  a. They need to create a global user and assign them to the Integration Manager and Integration Builder Global Roles.

     > **Tip:**
     >
     > Later in the process, you will need to provide the user name and password for this user when you Create Credentials. Make sure to create the user with an email address that allows you to retrieve the password.

  b. Next, the user needs to be added to the study and assigned to a study role that includes the *View Design* permission.
- The integration requires the creation of two (2) CTMS integration users, whose credentials are needed when you create credentials in Oracle Clinical One Digital Gateway and when updating the integration templates.
  – This step is a one-time setup task. You do not need to do this for each integration; two users are needed for the CTMS integration group regardless of the number of integrations you configure (SVT, SV, Site, and SDV). You can use the same credentials to configure one or all four CTMS integrations.
  – For step-by-step instructions, see Change Request (CR) creation details.
- Verify with the study designer that they have defined the visit schedule for the scheduled visits.
- Confirm the protocol exists in CTMS, and the study name matches the study title in Oracle Clinical One Platform.
- Create Credentials
- Create an Integration Group
- Download the integration templates
  For this integration download the following integration templates.
  – CTMS_SVTParentIntegration_Std.xml
  Tenant-level integration: You can configure multiple studies to use the same integration. The parent file controls this ability. For more information, see Configure a tenant-level integration.
  – CTMS_SVTSubIntegration_Std.xml

2. **Create the test integration**
   After downloading the necessary integration templates, follow these steps to configure and test the integration before using it with a production study.
   - Update the test integration template - SVT integration
   - Upload the integration template
   - Enable and disable an integration
3. **Create the production integration**

To accomplish this, you're going to download the test integration file you configured and tested, update it for production use, and then use it to create the production integration.

For step-by-step instructions, see Configure the production integration.

Manage an integration

Here are some common tasks associated with managing integrations.

- Enable and disable an integration
- Manage an integration and its jobs
- Monitor reports and jobs for an integration
- Update an existing integration

Site Integration

This cumulative integration runs on a schedule to retrieve a list of sites from CTMS (based on their status) and then imports applicable data into Oracle Clinical One Platform.

Integration data flow details

Table 2-2 Integration data flow details

Type of integration	Data flow	Frequency
Multiple file	One-way, from CTMS to Oracle Clinical One Platform.	Scheduled

Integration overview

1. The integration makes an outbound call to CTMS to retrieve a list of sites and their associated details based on status.

   Table 2-3 Site statuses available for import

Site status in CTMS	Site status in Oracle Clinical One Platform after import
Initiated	New
Enrolling	Active
Terminated	Retired

2. The CTMS response includes contact information for the Principal Investigator (Role), as defined in CTMS on the Contacts tab (Site Management – Contacts). The integration uses these details to create a Oracle Clinical One Platform Contact. If the contact already exists, the integration doesn't make any changes.
3. The response also includes information about the Site Primary account type (account type is configurable for the integration) defined in CTMS on the Accounts tab (Site Management – Accounts). The integration uses these details to create the Oracle Clinical One Platform Organization (Institution). If the organization already exists, the integration doesn't make any changes.
   - The integration uses the Site Primary address, defined in CTMS on the Accounts tab (Site Management – Accounts), to create the Primary Address for the contact and the organization created in Oracle Clinical One Platform.

- The integration uses the ship address (address is configurable for the integration), defined on the Addresses tab (Site Management – Addresses), to create the Shipping Address for the contact and the organization created in Oracle Clinical One Platform.

> **Note:**
>
> If a ship address is not defined in CTMS the Site Primary address is used as the shipping address for the contact and organization created in Oracle Clinical One Platform.

4. The integration creates the study site using the protocol name, which is also included in the CTMS response. The study site in Oracle Clinical One Platform reflects the site ID in the CTMS system, using the organization address as the primary address and the institution shipping address as the study site shipping address.
5. The following Contact and Organization details are used by Oracle Clinical One Platform to determine uniqueness when creating the study site:
   - **Contact** First Name, Last Name, Address Line 1, City, State, Country, and Zip/Postal Code. In addition to these, it is recommended that the Email and/or Phone should also match to ensure uniqueness.
   - The **Organization** Phone must also match.
6. The Upsert functionality (enabled by default) uses the unique site IDs from Oracle Clinical One Platform to determine what action to take on each site.
   - If a site does not exist, the integration creates it.
   - If a site does exist, then the information for the site is updated.
   - If an existing (already imported) site ID is updated in CTMS, a new site is created in Oracle Clinical One Platform.

Monitoring the integration

The Site integration includes the following monitoring features:

- Jobs are created and monitored at the site level.

Integration limitations

- The integration creates a job for each site it retrieves from CTMS, regardless of whether the site details have changed. The process of retrieving all sites ensures that updates to addresses and PI contacts, which CTMS does not consider to be updates in the same manner as Oracle Clinical One Platform does, get processed.
- If shipping information was not defined in CTMS, the integration uses the site address and contact information defined in Oracle Clinical One Platform for the shipping information.
- If a site's time zone is not defined in CTMS, the value in Oracle Clinical One Platform defaults to UTC, as the time zone is a required site field.

> **Note:**
>
> Time Zone can be found on the Site Info tab (Site Management—Target Site—More Info—Site Info) in CTMS.

- It is not possible to clear Prefix or Time Zone information of an existing Oracle Clinical One Platform Contact or Organization. It is only possible to update these fields after the initial import.

Configure the integration

1. **Prerequisites**
   The following prerequisites must be completed before you can configure and test the integration:
   - Get access to Oracle Clinical One Digital Gateway.
   - Be sure to capture your configuration decisions so you have a record of the specifications defined for this integration.
   - Ask your user administrator to create the Oracle Clinical One Platform integration user:
     a. They need to create a global user and assign them to the Integration Manager and Integration Builder Global Roles.

     > **Tip:**
     >
     > Later in the process, you will need to provide the user name and password for this user when you Create Credentials. Make sure to create the user with an email address that allows you to retrieve the password.

     b. Next, the user needs to be added to the study and assigned to a study role that includes the following permissions:
        - *Answer Queries*
        - *Create and Manage Sites*
        - *View Sites*
   - The integration requires the creation of two (2) CTMS integration users, whose credentials are needed when you create credentials in Oracle Clinical One Digital Gateway and when updating the integration templates.
     - This step is a one-time setup task. You do not need to do this for each integration; two users are needed for the CTMS integration group regardless of the number of integrations you configure (SVT, SV, Site, and SDV). You can use the same credentials to configure one or all four CTMS integrations.
     - For step-by-step instructions, see Change Request (CR) creation details.
   - Ensure that the values in the Oracle Clinical One Platform template codelist are accurately mapped to the full country names in CTMS. If the mappings are incorrect, the job fails with a country not found error.
   - Confirm the site numbers in CTMS match the site IDs in Oracle Clinical One Platform.
   - Create Credentials
   - Create an Integration Group
   - Download the integration templates
     For this integration download the following integration templates.
     - CTMS_TenantSiteParentIntegration_Std.xml
       Tenant-level integration: You can configure multiple studies to use the same integration. The parent file controls this ability. For more information, see Configure a tenant-level integration.

- CTMS_TenantSiteSubIntegration_Std.xml

2. **Create the test integration**
   After downloading the necessary integration templates, follow these steps to configure and test the integration before using it with a production study.
   - Update the test integration template - Site integration
   - Upload the integration template
   - Enable and disable an integration
3. **Create the production integration**
   To accomplish this, you're going to download the integration file you set up and tested, update it for production use, and then use it to create the production integration.

   For step-by-step instructions, see Configure the production integration.

Manage an integration

Here are some common tasks associated with managing integrations.

- Enable and disable an integration
- Manage an integration and its jobs
- Monitor reports and jobs for an integration
- Update an existing integration

Subject Visit (SV) Integration

This incremental integration, based on subject number, runs on a customer-defined schedule to identify Oracle Clinical One Platform subject visit, subject and visit status, and visit schedule details and imports them into CTMS.

Integration data flow details

Table 2-4 Integration data flow details

Type of integration	Data flow	Frequency
Multiple file	One-way, from Oracle Clinical One Platform to CTMS.	Scheduled

Integration overview

The integration makes a call to Oracle Clinical One Platform to retrieve a list of events that occurred in a study since the integration was last processed. The integration then sends all completed forms, questions, and subject status transitions for any subject event that occurred to CTMS. This also includes information about planned visits.

- Subject data is imported into CTMS under each site on the Subjects tab (Site Management—Subjects).
- Completed subject visit details are visible in CTMS on the Visits tab (Subject—Visits).
- All question data is visible in CTMS on the Activities tab for each visit (Subjects—Activities).

If the integration job fails to process an event, future jobs for the subject are blocked until the current job is fixed or canceled. This ensures that data stays in sync in the target system. A failed job for one subject does not block event processing for other subjects.

The integration supports the following Oracle Clinical One Platform events. The integration processes the data corresponding to these events in the order of occurrence.

> **Note:**
>
> The first row in the table below is the parent template; all others are sub-integration templates.

Table 2-5 Oracle Clinical One Platform Supported events

Event	Integration Template	Details
N/A	ClinicalOneParent.xml	This is the parent integration template. All others below are sub integration templates. ***Note**: Only one parent file is required, regardless of the number of sub-integration templates used.*
Pre-screening	NewSubjectIntegration_CTMS_SV_Std.xml	After a subject completes the pre-screening visit in Oracle Clinical One Platform, the integration sends subject information to CTMS, including the visit complete date. ***Note**: The Visit Complete date in Oracle Clinical One Platform is equivalent to the Encounter Date in CTMS.* After screening, the integration updates the encounter date in CTMS to the screening date.
Screening Screen fail Undo Screen fail	ScreeningIntegration_CTMS_SV.xml	A subject with the same subject number and a status of Screening is created in CTMS after the subject is screened in Oracle Clinical One Platform. ***Note**: Undo events restore subjects to their previous status.*
Enrolling	EnrollIntegration_CTMS_SV.xml	This is for your non-randomization studies. Once a subject completes the screening visit in Oracle Clinical One Platform, CTMS receives the Enrolled status.
Change Subject Number	ChangeSubjectNumberIntegration_CTMS_SV.xml	After you update a subject number in Oracle Clinical One Platform, the integration sends the new subject number to CTMS.
Randomization	RandomizationIntegration_CTMS_SV.xml • This template must include the randomization visit ID. • For a study with multiple randomization visits, you must create one template per visit.	After a subject completes the randomization visit in Oracle Clinical One Platform, the integration sends the updated status and randomization details to CTMS, which include the randomization date, randomization number, and cohort name.

Table 2-5 (Cont.) Oracle Clinical One Platform Supported events

Event	Integration Template	Details
Subject Withdrawal Undo Withdrawal	SubjectWithdrawIntegration_CTMS_SV.xml	When you withdraw or undo a withdrawal for a subject in Oracle Clinical One Platform, the integration sends the updated status to CTMS.
Subject Completion Undo Completion	SubjectCompleteIntegration_CTMS_SV.xml	When you mark a subject complete or undo subject completion in Oracle Clinical One Platform, the integration sends the updated status to CTMS.
Subject Transfer	SubjectTransferIntegration_CTMS_SV.xml	After you transfer a subject in Oracle Clinical One Platform, the integration sends the updated status to CTMS. You can send this event to CTMS either before or after a subject has undergone screening in Oracle Clinical One Platform.
Visit Dump	VisitDataDumpIntegration_CTMS_SV.xml	Use this template to send visit details and question data for all forms in a completed visit from Oracle Clinical One Platform to CTMS. You can configure the visit dump sub-integration to send clinical items imported via the Study Version Template (SVT) integration, which are enabled for integration in the CTMS item library. These items are marked in CTMS with a completion date. When question data or a visit date are cleared or deleted for a completed Oracle Clinical One Platform visit, the corresponding visits should also be cleared in CTMS. This ensures activities corresponding to an incomplete visit are updated in CTMS and the completed date is cleared. This should be done so that the payment cannot be done for such questions and visits. When subsequent updates are made in Oracle Clinical One Platform, the integration will send the visit dump payload for all activities within a visit. This template also processes Oracle Clinical One Platform visit date changes and sends the updated visit date to CTMS. The integration updates both the visit's completed date and the completion date of the Boolean items, which are part of the CTMS item library, when a visit date changes.

Table 2-5 (Cont.) Oracle Clinical One Platform Supported events

Event	Integration Template	Details
Visit Schedule	VisitScheduleIntegration_CTMS_SV_Std.xml	A subject's visit schedule can change based on previous visits, the treatment arm assigned, or completion of a form question by selecting a specific answer. The sub-integration retrieves: • The VisitComplete date for the configured visits. • Data updates for a configured visit, form, or question. ***Note**: You can configure a generic visit ID, such as "00000000000000000000000000000", for a form question. In this case, the integration processes the visit complete event and data update event from all of the visits where this form question exists. Configure the corresponding event IDs in the integration template if you need to process events from specific visits.* • The data that pertains to Screen Fail / Undo Screen Fail, Withdraw / Undo Withdraw, and Subject Complete / Undo Subject Complete events. Once received, the integration sends the projected visit dates and matching visit names to CTMS. The integration also sends the information required for planning and forecasting and marks them as planned in CTMS. • For **cycle visits**, the integration sends the visit name concatenated with the branch name and the event instance number. • Due to the dynamic nature of the **branch visits**, which control how a subject progresses in a Oracle Clinical One Platform study, CTMS creates branch visit instances on the fly when the data is received. • For **unscheduled visits**, the integration includes the event instance number from Oracle Clinical One Platform. CTMS dynamically creates these visits.

Integration limitations

- The integration cannot be configured at the tenant level.
- All dates are in UTC time zone.
- The sub integration generates a list of future visits based on the subject's current state in the study. The list of future visits is not based on the current event that the integration is handling.

For example, if a subject was screened, randomized, and completed Visit1 and all the events were picked in a single job, only the next visits from Visit1 would be selected as Planned in CTMS and the Screening, Rand, and Visit1 visits would show as Completed in CTMS.

- If the question used to determine a branch or treatment arm for a subject is changed after the initial branch has started, the integration returns data from both branches.
  For example, if the user initially selects Branch1 and enters data, then subsequently changes the option to Branch2, the integration returns started visits from Branch1 and Branch2.
- Subject Visit information for Adverse Events is not sent.

Configure the integration

1. **Prerequisites**
   The following prerequisites must be completed before you can configure and test the integration:
   - Get access to Oracle Clinical One Digital Gateway.
   - Be sure to capture your configuration decisions so you have a record of the specifications defined for this integration.
   - Ask your user administrator to create the Oracle Clinical One Platform integration user:
     a. They need to create a global user and assign them to the Integration Manager and Integration Builder Global Roles.

     > **Tip:**
     >
     > Later in the process, you will need to provide the user name and password for this user when you Create Credentials. Make sure to create the user with an email address that allows you to retrieve the password.

     b. Next, the user needs to be added to the study and assigned to a study role that includes the following permissions:
        - *Edit Supply Settings, Blinded Groups, Label Groups and Resupply Strategies (Unblind)*
        - *Integrate Subject Data*
        - *View Form Data for Subjects*
   - The integration requires the creation of two (2) CTMS integration users, whose credentials are needed when you create credentials in Oracle Clinical One Digital Gateway and when updating the integration templates.
     - This step is a one-time setup task. You do not need to do this for each integration; two users are needed for the CTMS integration group regardless of the number of integrations you configure (SVT, SV, Site, and SDV). You can use the same credentials to configure one or all four CTMS integrations.
     - For step-by-step instructions, see Change Request (CR) creation details.
   - Confirm the sites in CTMS are active and are associated with an approved study version.
   - Confirm the study version for the site in CTMS and the site in Oracle Clinical One Platform match.
   - Create Credentials

- Create an Integration Group
- Download the integration templates
  For this integration download the following integration templates.
  - ClinicalOneParent.xml
  - Refer to the table above for a list of available sub-integration templates.

2. **Create the test integration**
   After downloading the necessary integration templates, follow these steps to configure and test the integration before using it with a production study.
   - Update the test integration template - SV integration
   - Upload the integration template
   - Enable and disable an integration
3. **Create the production integration**
   To accomplish this, you're going to download the integration file you set up and tested, update it for production use, and then use it to create the production integration.

   For step-by-step instructions, see Configure the production integration.

Manage an integration

Here are some common tasks associated with managing integrations.

- Enable and disable an integration
- Manage an integration and its jobs
- Monitor reports and jobs for an integration
- Update an existing integration

Source Data Verification (SDV) Integration

This integration generates a cumulative list of subjects selected for Source Data Verification (SDV) in a Oracle Clinical One Platform study, as well as an incremental list of verified visits, and sends this data to CTMS.

Integration data flow details

Table 2-6 Integration data flow details

Type of integration	Data flow	Frequency
Multiple file	One-way, from Oracle Clinical One Platform to CTMS.	Scheduled

Integration overview

This integration generates a cumulative list of subjects selected for SDV in a Clinical One Platform study based on a customer-defined schedule. The integration also sends incremental information regarding SDV status changes at the visit level. The integration sends only the first SDV performed for a visit to CTMS.

Once the integration process completes,

- In CTMS, the Subjects tab (Site Management—Subjects—SDV Required column) stores subject data from Oracle Clinical One Platform.

- In CTMS, the CRF Tracking tab (Site Management—CRF Tracking tab—Source Verified and Source Verified Date columns) stores the subject visit verification data.

Integration limitations

- Subject Data Verification information for Adverse Events is not sent.

Configure the integration

1. **Prerequisites**
   The following prerequisites must be completed before you can configure and test the integration:
   - Get access to Oracle Clinical One Digital Gateway.
   - Be sure to capture your configuration decisions so you have a record of the specifications defined for this integration.
   - Ask your user administrator to create the Oracle Clinical One Platform integration user:
     a. They need to create a global user and assign them to the Integration Manager and Integration Builder Global Roles.

     > **Tip:**
     >
     > Later in the process, you will need to provide the user name and password for this user when you Create Credentials. Make sure to create the user with an email address that allows you to retrieve the password.

     b. Next, the user needs to be added to the study and assigned to a study role that includes the following permissions:
        - *Answer Queries*
        - *Integrate Subject Data*
        - *Perform Source Data Verification and Reconcile Inventory*
   - The integration requires the creation of two (2) CTMS integration users, whose credentials are needed when you create credentials in Oracle Clinical One Digital Gateway and when updating the integration templates.
     - This step is a one-time setup task. You do not need to do this for each integration; two users are needed for the CTMS integration group regardless of the number of integrations you configure (SVT, SV, Site, and SDV). You can use the same credentials to configure one or all four CTMS integrations.
     - For step-by-step instructions, see Change Request (CR) creation details.
   - Confirm the study versions for sites in CTMS and in Oracle Clinical One Platform match.
   - Confirm the source data verification setting in Oracle Clinical One Platform is configured to allow for source data verification in a study.
   - Create Credentials
   - Create an Integration Group
   - Download the integration templates
     For this integration download the following integration templates.
     - CTMS_SDVParentIntegration_Std.xml

Tenant-level integration: You can configure multiple studies to use the same integration. The parent file controls this ability. For more information, see Configure a tenant-level integration.

- CTMS_SDVSubIntegration_Std.xml

2. **Create the test integration**
   After downloading the necessary integration templates, follow these steps to configure and test the integration before using it with a production study.
   - Update the test integration template - SDV integration
   - Upload the integration template
   - Enable and disable an integration
3. **Create the production integration**
   To accomplish this, you're going to download the integration file you set up and tested, update it for production use, and then use it to create the production integration.

   For step-by-step instructions, see Configure the production integration.

Manage an integration

Here are some common tasks associated with managing integrations.

- Enable and disable an integration
- Manage an integration and its jobs
- Monitor reports and jobs for an integration
- Update an existing integration

Shared configuration instructions

The following sections apply to all CTMS integrations.

- Change Request (CR) creation details
- Create Credentials
- Create an Integration Group
- Download the integration templates
- Upload the integration template
- Enable and disable an integration
- Configure the production integration
- Configure a tenant-level integration
- Update an existing integration

Change Request (CR) creation details

Follow these steps to request the creation of two (2) CTMS integration users. Use the credentials of one user to configure the test integration and the other to configure the production instance.

The username and password for each user are provided after each ticket closes, enabling you to create credentials and update the integration templates.

1. Log into Oracle Life Sciences Support Cloud.

2. Select **Create Request** in the upper right, then select **Change Request**.
3. Select the **Make a post go live change** tile.
4. Complete the following fields.

Table 2-7 Change Request field completion details

Field	Details
Summary	Oracle Siebel CMTS integration setup for <enter customer name> in <enter UAT or PROD>.
Severity	Medium
Description	I am requesting the implementation of Oracle related tasks for the Oracle Siebel Clinical Trial Management (CTMS) integration for <enter customer name> in <enter UAT or PROD>. When complete please provide the username and password for the CTMS integration user.
Category	Change—Cloud Environment > Application > Configuration > Change
Oracle Internal	No
Customer	Select your company
Product	Siebel CTMS
Business Service	Select the applicable environment. **Example**: abc123—uat—siectms **or** abc123—siectms
Environment	Select UAT **or** Prod/Live
Implementation Window	As Soon As Possible
Action	Other
sFTP Path	Select the box to the left of *Tick if sFTP is not applicable for this request*.
Date Required By	Select the next available week day from the calendar.
Additional Contacts	Enter the email addresses, separated by a semicolon, of anyone that needs to be notified of updates to this ticket.

5. Select **Submit** in the upper right.

Create Credentials

Credentials are required for all CTMS integrations in order to pull and post data from CTMS and Oracle Clinical One Platform.

Each integration requires the creation of two sets of credentials; one for Oracle Clinical One Platform and the other for CTMS.

> **Note:**
>
> For CTMS credentials, you will create one for testing purposes and another for the production integration. The table below provides additional details.

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 **Create Credentials**.
4. Fill in the required fields.

Table 2-8 Create Credentials fields and details

Field	Details for Oracle Clinical One Platform credentials	Details for CTMS credentials
Product	Select **Clinical One - Oracle Life Sciences**.	Select **CTMS**
Credential Key	Enter a unique value, such as **C1userForCTMS**.	Enter a unique value, such as **CTMSAPIUserUAT** for testing purposes or **CTMSAPIUserProd** for the production integration.
User Name	Enter the user name for the Oracle Clinical One Platform integration user you had created as a prerequisite.	Enter the user name for the CTMS integration user you had created as a prerequisite. ***Note**: Use the UAT user name when you configure the test integration and the prod user name when configuring the production integration.*
Password	Enter the password for the Oracle Clinical One Platform integration user you had created as a prerequisite.	Enter the password for the CTMS integration user you had created as a prerequisite. ***Note**: Use the UAT password when you configure the test integration and the prod password when configuring the production integration.*

5. Click **Save**.

The next step is to Create an Integration Group.

Create an Integration Group

Integration groups allow you to organize integrations, for example, by study, making it simple to find and manage them.

1. Sign in to Oracle Oracle Clinical One Digital Gateway.
2. On the home page, in the upper-left click **Create Integration Group**.
3. Enter a **Group Name**.

> **Note:**
>
> We recommend including the Oracle Clinical One Platform study name in the integration group name, making it easier to identify integrations for monitoring.

4. Click **Create**.

Now it's time to Download the integration templates.

Download the integration templates

Each integration requires the use of one parent integration template and one sub-integration template. The one exception is the Subject Visit integration, which includes sub-integration templates for each Oracle Clinical One Platform event, such as pre-screen, screen, and enroll, among others.

1. Sign in to Oracle Oracle Clinical One Digital Gateway.

2. On the top of the home page, click **Download Integration Template**, select **Other**, and finally, select the applicable templates.

Table 2-9 Integration templates needed based integration type

Integration type	Parent template	Sub-integration template
Study Version Template (SVT) integration	CTMS_SVTParentIntegration_Std.xml	CTMS_SVTSubIntegration_Std.xml
Site integration	CTMS_SiteParentIntegration_Std.xml	CTMS_SiteSubIntegration.xml
Subject Visit (SV) integration	ClinicalOneParent.xml	For a list of available templates, see Subject Visit (SV) Integration.
Source Data Verification (SDV) integration	CTMS_SDVParentIntegration_Std.xml	CTMS_SDVSubIntegration_Std.xml

3. Save the files locally and rename them to something specific to the study and/or integration.
4. The next step is to update the integration template. Select the appropriate option below.
   - Update the test integration template - SVT integration
   - Update the test integration template - Site integration
   - Update the test integration template - SV integration
   - Update the test integration template - SDV integration

Upload the integration template

Follow the steps below to upload the integration templates to Oracle Clinical One Digital Gateway.

1. If you have not done so already, Create an Integration Group.
2. If you have already created the integration group, navigate to the home page and click the down arrow (⌄) to expand it. Click **Upload Integration File**, followed by **Other**.
3. Complete the following fields, then click **Next**.

Table 2-10 Upload Integration File - Settings

Setting	Details
Category	Select **CTMS**

Table 2-10 (Cont.) Upload Integration File - Settings

Setting	Details
Integration Type	For a tenant-level integration, choose the option prefixed with MultiStudy. For more information, see Configure a tenant-level integration. • For the Subject Visit (SV) integration select **CTMS Visit Dump** **Note:** This integration does not support tenant-centric integrations. • For the Study Version Template (SVT) integration select **CTMS SVT** or **MultiStudy CTMS SVT** • For the Site integration select **CTMS Site** or **MultiStudy CTMS Site** • For the Source Data Verification (SDV) integration select **CTMS SDV** or **MultiStudy CTMS SDV**
Title	Enter a unique title for the integration.
Description	In a few words describe the integrations use.
Job Start Date	Click the calendar icon to select a date when the integration should start running.
Days When to Send Data	Click All or select the specific days when the integration should run.
Send Data	If **At** is selected (for Days when to Send Data), enter the time when the integration should run. If **Every** is selected, enter the interval at which the integration should run.
Data Transfer Options	Determine if you want to **Transfer all data** or **Only transfer data from specific date**.
Reattempt to Send Data	Use the up and down arrows to select the number of times a failed integration job should be reattempted; the minimum is two (2). If the last attempt fails, the status remains Failed, and resiliency takes over. **Automatic Recovery, also referred to as Resiliency** Oracle Clinical One Digital Gateway ensures that jobs impacted by a service interruption, for example, a server shutdown or an unexpected outage, are automatically recovered without manual intervention. ***Note**: Resiliency is disabled for the Site integration, as it is cumulative by nature. The next successful run ensures the systems are in sync.* • Jobs in a **Processing** or **Retry** state for over one (1) hour are considered stuck and are automatically re-attempted. • Jobs that have been in a **Failed** state for over four (4) hours are also automatically re-attempted.
Send Notifications to	Enter email addresses, separated by a semicolon, of those users that should receive failure notifications.

4. Select the parent file and the sub-integration files, then click **Upload**.

The next step is to enable the integration. For more information, see Enable and disable an integration

Enable and disable an integration

Follow the steps below to enable and disable your integrations.

1. On the home page, on the right side, click the down arrow ( ) to expand the integration group where the integration was created.
2. Click the toggle button ( ) one time for the integration that you want to enable. The toggle turns blue ( ), indicating that the integration is active.
3. To disable an integration, click the (blue) toggle one time. The toggle turns gray.

To enable all integrations in an integration group:

1. Select the checkbox to 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 active.

Once testing is complete you can Configure the production integration.

Configure the production integration

Now that testing is complete, follow the steps below to configure and implement the production integration.

1. Start by opening the parent and sub-integration templates that were used to test the integration.

> **Note:**
>
> If you did not retain the templates, see Update an existing integration for instructions on how to download the templates.

2. Update the integrations templates. You can refer to Update an integration template to see where the updates need to be applied.
   - In the parent and sub-integration templates for the SVT, SV, and SDV integrations, update the XML element <Mode>**test**</Mode> to <Mode>**active**</Mode>.

> **Note:**
>
> For the Site integration this element is included in the sub-integration template.

   - In the sub-integration templates for the SVT, SV, and SDV integrations, update the <CtmsUserName> XML element from the UAT value to the production one.

> **Note:**
>
> For the Site integration this element is included in the parent template.

3. Save your updates.
4. Next Upload the integration template.
5. The last step is to enable the integration. For more information, see Enable and disable an integration.

Configure a tenant-level integration

With a tenant-level integration, you list numerous studies in a single integration template, removing the need to create integrations at the study level.

Each parent integration template contains a section where you can list multiple studies.

```
<!--  Uncomment below and add studies for tenant enabled integration...
<!-- <p:Studies></p:Studies> -->
```

1. **Configure a tenant-level integration - new integration**
   a. Download the parent integration template. For more information, see Download the integration templates.
   b. Open the parent file and uncomment the row by removing the leading and trailing characters, resulting in the following format.

      ```
      <p:Studies></p:Studies>
      ```

   c. Add the appropriate details, separating studies using a comma.
      - For the **SVT** and **SDV integrations**, the format is the Oracle Clinical One Platform study GUID followed by the CTMS study name.

        > **Note:**
        >
        > The study GUID is located on the **General** tab under **Study Settings**. For more information, see Open the study's settings.

        ```
        <p:Studies>ClinicalOneStudyAGUID:CTMSStudyNameA,ClinicalOneStudyBGUI
        D:CTMSStudyNameB</p:Studies>
        ```

      - For the **Site integration**, the format is the CTMS study name followed by the Oracle Clinical One Platform study GUID.

        ```
        <p:Studies>CTMSStudyNameA:ClinicalOneStudyAGUID,CTMSStudyNameB:Clini
        calOneStudyBGUID</p:Studies>
        ```

   d. Save your changes, then Upload the integration template.
2. **Configure a tenant-level integration - existing production integration**
   a. Review Update an existing integration to locate and download the integration template to be updated.
   b. After downloading the template, follow the instructions starting at 1b. above.

Update an existing integration

Follow these steps to update the settings and the integration templates for an existing integration.

1. From the home page, click the down arrow (⌄) to the right to expand the integration group where the integration you need to update was created.
2. Disable the integration. For more information, see Enable and disable an integration.
3. Click the arrow to the right of the integration.
4. Click **Edit Integration Files** in the upper left.

   The **Edit Integration File** dialog window opens.
5. Update the settings if applicable, or scroll down to the bottom of the window to update an integration template.
6. Click the download icon ( ) to the right of the **Integration File** field, and save the file locally.
7. Update the necessary elements in the file.
8. From the **Edit Integration File** dialog window, click **Replace File**.
9. Select the updated integration file, then click **Upload**.
10. Finally, enable the integration. For more information, see Enable and disable an integration.

Update an integration template

Refer to the sections below to learn how to update the integration template for each integration.

- Update the test integration template - SVT integration
- Update the test integration template - Site integration
- Update the test integration template - SV integration
- Update the test integration template - SDV integration

Update the test integration template - SVT integration

You want to test the integration before using it in production, so you're going to first update the templates to create a test integration. After testing is complete, you will update the templates to establish the production integration.

Use the table below to update the parent and sub-integration templates for the SVT integration.

Table 2-11 SVT integration xml elements that require updates (Parent file: CTMS_SVTParentIntegration_Std.xml)

XML element	Details
StudyId	Enter the Oracle Clinical One Platform study GUID. You can locate the GUID on the **General** tab under **Study Settings**. For more information, see Open the study's settings. ***Note:*** *If you are configuring this as a tenant-level integration, do not update this element and see,* Configure a tenant-level integration*.*
Mode	If your intention is to test the integration, enter **test**. ***Note****: The mode aligns with the Oracle Clinical One Platform study container. You will update this to* ***active*** *when you're ready to* Configure the production integration.
C1UserCredentials	Enter the Oracle Clinical One Platform credential key name. For more information, see Create Credentials.
C1UserName	Enter the user name for the Oracle Clinical One Platform integration user created as a prerequisite. For more information, see Study Version Template (SVT) Integration.

Table 2-12 SVT integration xml elements that require updates (Sub integration file: CTMS_SVTSubIntegration_Std.xml)

XML element	Details
StudyId	Enter the Oracle Clinical One Platform study GUID. If you are configuring this as a tenant-level integration, do not update this element.
Mode	If your intention is to test the integration, enter **test**. ***Note****: The mode aligns with the Oracle Clinical One Platform study container. You will update this to* ***active*** *when you're ready to* Configure the production integration.
C1UserCredentials	Enter the Oracle Clinical One Platform credential key name. For more information, see Create Credentials.
C1UserName	Enter the user name for the Oracle Clinical One Platform integration user created as a prerequisite. For more information, see Study Version Template (SVT) Integration.
CtmsUserName	Enter the user name for the UAT CTMS integration user created as a prerequisite. For more information, see Study Version Template (SVT) Integration. ***Note****: For the test integration, enter the user name created in the UAT Change Request (CR), and when the time comes, update this value to the user name created in the Production Change Request (CR).*
APIUserCredentials	Enter the CTMS credential key name. For more information, see Create Credentials.

The next step is to Upload the integration template.

Update the test integration template - Site integration

You want to test the integration before using it in production, so you're going to first update the templates to create a test integration. After testing is complete, you will update the templates to establish the production integration.

Use the table below to update the parent and sub-integration templates for the Site integration.

Table 2-13 Site integration xml elements that require updates (Parent file: CTMS_TenantSiteParentIntegration_Std.xml)

XML element	Details
CtmsStudyName	Enter the CTMS study name. ***Note:*** *If you are configuring this as a tenant-level integration, do not update this element and see,* Configure a tenant-level integration*.*
CtmsUserCredentials	Enter the CTMS credential key. For more information, see Create Credentials.
CtmsUserName	Enter the user name for the UAT CTMS integration user created as a prerequisite. For more information, see Site Integration. ***Note****: For the test integration, enter the user name created in the UAT Change Request (CR), and when the time comes, update this value to the user name created in the Production Change Request (CR).*
CtmsSiteAddressKeyName	The default value is `Site Primary`. To change this value, select another option from the **Type** dropdown on the Site Management - Accounts tab in CTMS. The details of this account are used in the creation of the Oracle Clinical One Platform organization. For more information, review the integration overview in the Site Integration chapter.
CtmsPIContactRole	The default value is `Principal Investigator`. To change this value, select another option from the **Role** dropdown on the Site Management - Contacts tab in CTMS. The details of this account are used in the creation of the Oracle Clinical One Platform contact. For more information, review the integration overview in the Site Integration chapter.
CtmsShippingContactRoles	The default value is `Pharmacist`. Multiple values can be entered, separated by a comma. These values are defined on the Management - Contacts tab in CTMS. The details associated with these accounts are used in the creation of the Oracle Clinical One Platform shipping addresses. For more information, review the integration overview in the Site Integration chapter.

Table 2-14 Site integration xml elements that require updates (Sub integration file: CTMS_TenantSiteSubIntegration_Std.xml)

XML element	Details
StudyId	Enter the Oracle Clinical One Platform study GUID. You can locate the GUID on the **General** tab under **Study Settings**. For more information, see Open the study's settings If you are configuring this as a tenant-level integration, do not update this element.
Mode	If your intention is to test the integration, enter **test**. ***Note****: The mode aligns with the Oracle Clinical One Platform study container. You will update this to* ***active*** *when you're ready to* Configure the production integration.
C1UserCredentials	Enter the Oracle Clinical One Platform credential key name. For more information, see Create Credentials.
C1UserName	Enter the user name for the Oracle Clinical One Platform integration user created as a prerequisite. For more information, see Site Integration.
StatusUpdate	Change to **true** if you want to integrate site status changes.

The next step is to Upload the integration template.

Update the test integration template - SV integration

You want to test the integration before using it in production, so you're going to first update the templates to create a test integration. After testing is complete, you will update the templates to establish the production integration.

Use the details in the table below to update the parent integration template for the SV integration.

Table 2-15 SV integration xml elements that require updates (Parent file: ClincalOneParent.xml)

XML element	Details
StudyId	Enter the Oracle Clinical One Platform study GUID. You can locate the GUID on the **General** tab under **Study Settings**. For more information, see Open the study's settings
Mode	If your intention is to test the integration, enter **test**. ***Note**: The mode aligns with the Oracle Clinical One Platform study container. You will update this to **active** when you're ready to* Configure the production integration.
UserName	Enter your organization's ShortOrgID and the user name for the Oracle Clinical One Platform integration user created as a prerequisite. For more information, see Subject Visit (SV) Integration. Use the following format when updating the integration template. `<UserName>ShortOrgID.Username</UserName>` For information about how to obtain your ShortOrgID, see How do I find my company's ShortOrgId?.

Use the details in the table below to update the following sub-integration templates:

- NewSubjectIntegration_CTMS_SV_Std.xml
- VisitScheduleIntegration_CTMS_SV_Std.xml

Table 2-16 SV integration xml elements that require updates (sub-integration files)

XML element	Details
StudyId	Enter the Oracle Clinical One Platform study GUID.
Mode	If your intention is to test the integration, enter **test**. ***Note**: The mode aligns with the Oracle Clinical One Platform study container. You will update this to **active** when you're ready to* Configure the production integration.
C1UserCredentials	Enter the Oracle Clinical One Platform credential key name. For more information, see Create Credentials.
C1UserName	Enter the user name for the Oracle Clinical One Platform integration user created as a prerequisite. For more information, see Subject Visit (SV) Integration.
APIUserCredentials	Enter the CTMS credential key name. For more information, see Create Credentials.

Table 2-16 (Cont.) SV integration xml elements that require updates (sub-integration files)

XML element	Details
CtmsUserName	Enter the user name for the UAT CTMS integration user created as a prerequisite. For more information, see Subject Visit (SV) Integration. ***Note**: For the test integration, enter the user name created in the UAT Change Request (CR), and when the time comes, update this value to the user name created in the Production Change Request (CR).*

Use the details in the table below to update the following sub-integration templates:

- ScreeningIntegration_CTMS_SV_Std.xml
- RandomizationIntegration_CTMS_SV_Std.xml
- SubjectWithdrawIntegration_CTMS_SV_Std.xml
- SubjectCompleteIntegration_CTMS_SV_Std.xml
- SubjectTransferIntegration_CTMS_SV_Std.xml
- ChangeSubjectNumberIntegration_CTMS_SV_Std.xml

Table 2-17 SV integration xml elements that require updates (sub-integration files)

XML element	Details
StudyId	Enter the Oracle Clinical One Platform study GUID.
Mode	If your intention is to test the integration, enter **test**. ***Note**: The mode aligns with the Oracle Clinical One Platform study container. You will update this to **active** when you're ready to* Configure the production integration.
UserName	Enter the user name for the Oracle Clinical One Platform integration user created as a prerequisite. For more information, see Subject Visit (SV) Integration.

Table 2-17 (Cont.) SV integration xml elements that require updates (sub-integration files)

XML element	Details

RefName and Id	These elements are only applicable to the RandomizationIntegration_CTMS_SV_Std.xml integration template.
	• **RefName**: Enter the visit title.
	To get the visit title, open your study in design mode, then click on the visit under the Scheduled Visits side panel. Use the value to the right at the top of the window.
	 
	• **Id**: Enter the visit GUID.
	Use the Get visit information API to retrieve information about visits and the visit schedule, including the GUID. For more information, see the Get visit information API.
	Refer to the following example if you need to configure multiple randomization visits.
	
	`<Visit>`
	`<RefName>Randomization_1</RefName>`
	`<Id>123456789</Id>`
	`</Visit>`
	`<Visit>`
	`<RefName>Randomization_2</RefName>`
	`<Id>987654321</Id>`
	`</Visit>`

APIUserCredentials	Enter the CTMS credential key name. For more information, see Create Credentials.
CtmsUserName	Enter the user name for the UAT CTMS integration user created as a prerequisite. For more information, see Subject Visit (SV) Integration. ***Note**: For the test integration, enter the user name created in the UAT Change Request (CR), and when the time comes, update this value to the user name created in the Production Change Request (CR).*

Use the details in the table below to update the following sub-integration template:

- VisitDataDumpIntegration_CTMS_SV_Std.xml

Table 2-18 SV integration xml elements that require updates (sub-integration files)

XML element	Details
StudyId	Enter the Oracle Clinical One Platform study GUID.
Mode	If your intention is to test the integration, enter **test**. ***Note**: The mode aligns with the Oracle Clinical One Platform study container. You will update this to **active** when you're ready to* Configure the production integration.
C1UserCredentials	Enter the Oracle Clinical One Platform credential key name. For more information, see Create Credentials.

Table 2-18 (Cont.) SV integration xml elements that require updates (sub-integration files)

XML element	Details
C1UserName	Enter the user name for the Oracle Clinical One Platform integration user created as a prerequisite. For more information, see Subject Visit (SV) Integration.
APIUserCredentials	Enter the CTMS credential key name. For more information, see Create Credentials.
CtmsUserName	Enter the user name for the UAT CTMS integration user created as a prerequisite. For more information, see Subject Visit (SV) Integration. ***Note**: For the test integration, enter the user name created in the UAT Change Request (CR), and when the time comes, update this value to the user name created in the Production Change Request (CR).*
CtmsStudyName	Enter the study name as defined in CTMS.

The next step is to Upload the integration template.

Update the test integration template - SDV integration

You want to test the integration before using it in production, so you're going to first update the templates to create a test integration. After testing is complete, you will update the templates to establish the production integration.

Use the table below to update the parent and sub-integration templates for the SDV integration.

Table 2-19 SDV integration xml elements that require updates (Parent file: CTMS_SDVParentIntegration_Std.xml)

XML element	Details
StudyId	Enter the Oracle Clinical One Platform study GUID. You can locate the GUID on the **General** tab under **Study Settings**. For more information, see Open the study's settings ***Note:** If you are configuring this as a tenant-level integration, do not update this element and see,* Configure a tenant-level integration*.*
Mode	If your intention is to test the integration, enter **test**. ***Note**: The mode aligns with the Oracle Clinical One Platform study container. You will update this to **active** when you're ready to* Configure the production integration.
C1UserCredentials	Enter the Oracle Clinical One Platform credential key name. For more information, see Create Credentials.
C1UserName	Enter the user name for the Oracle Clinical One Platform integration user created as a prerequisite. For more information, see Source Data Verification (SDV) Integration.

Table 2-20 SDV integration xml elements that require updates (Sub integration file: CTMS_SDVSubIntegration_Std.xml)

XML element	Details
StudyId	Enter the Oracle Clinical One Platform study GUID. If you are configuring this as a tenant-level integration, do not update this element.
Mode	If your intention is to test the integration, enter **test**. ***Note**: The mode aligns with the Oracle Clinical One Platform study container. You will update this to **active** when you're ready to* Configure the production integration.
C1UserCredentials	Enter the Oracle Clinical One Platform credential key name. For more information, see Create Credentials.
C1UserName	Enter the user name for the Oracle Clinical One Platform integration user created as a prerequisite. For more information, see Source Data Verification (SDV) Integration.
APIUserCredentials	Enter the CTMS credential key name. For more information, see Create Credentials.
CtmsUserName	Enter the user name for the UAT CTMS integration user created as a prerequisite. For more information, see Source Data Verification (SDV) Integration. ***Note**: For the test integration, enter the user name created in the UAT Change Request (CR), and when the time comes, update this value to the user name created in the Production Change Request (CR).*

The next step is to Upload the integration template.

Subject Data for Oracle Siebel CTMS Report

Thanks to this seamless integration, you can now obtain a precise and up-to-date overview of your subjects' study activity, a crucial aspect of effective clinical trial management, and effortlessly transfer this data to your clinical trial management system.

With this integration, you can send data from the **Subject Data for CTMS report** to Oracle Siebel CTMS. This report includes data for subjects from all sites who have completed visits. The report does not include an audit trail of changes.

> **Note:**
>
> For more information, see the Subject Data for CTMS report.

- A job created as part of the integration setup generates the Subject Data for CTMS report and automatically places the pipe-delimited file on the Oracle sFTP server for Oracle Siebel CTMS to consume.

> **Note:**
>
> The default naming convention for the file is <Protocol>_<ENV>_ORACLE_<MMDDYYYY>.txt

- The frequency with which the integration sends report data and when that process begins is configurable and defined in the Oracle Clinical One Digital Gateway.
- The following subject data points are the only ones that can be mapped for this integration. These fields can be spread across multiple forms or on the same form but must exist in the same visit.
  - Initials
  - Date of Birth
  - Gender
  - Informed Consent Date

If you require a more robust CTMS integration, see Oracle's Siebel Clinical Trial Management System (CTMS), which allows you to integrate site, study version, subject visit, and source data verification (SDV) data between Oracle Clinical One Platform and Oracle Siebel CTMS.

Configuration Service details for this integration

B92664: Oracle Life Sciences Clinical One Digital Gateway Configuration Service, up to 40 Data Points.

> **Note:**
>
> For more information, see Oracle Life Sciences Cloud Consulting Professional Services, Service Descriptions and Metrics.

Reach out to your Oracle point of contact if more information is needed.

Veeva Vault CTMS

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

Configuration Service details for this integration

B92664: Oracle Life Sciences Clinical One Digital Gateway Configuration Service, up to 40 Data Points.

> **Note:**
>
> For more information see, Oracle Life Sciences Cloud Consulting Professional Services, Service Descriptions and Metrics.

Reach out to your Oracle point of contact if more information is needed.

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.

Data Collection

- Data Intake integration
  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.
- Medrio Integration
  An integration that allows you to import subject data from an external application into Oracle Clinical One Platform, using the Oracle Clinical One Digital Gateway web service, in a standard ODM format.
- Multi-IWR Integration
  A near real-time integration that allows you to import subject data sent by an external IVR system, in a standard ODM format, to an Oracle Clinical One Platform study using the Oracle Clinical One Digital Gateway web service.
- ObvioHealth Integration
  An integration that allows you to import subject data from an external application into Oracle Clinical One Platform, using the Oracle Clinical One Digital Gatewayweb service, in a standard ODM format.

Data Intake integration

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.

Configuration Service details for these integrations

B92664: Oracle Life Sciences Clinical One Digital Gateway Configuration Service, up to 40 Data Points.

> **Note:**
>
> For more information see, Oracle Life Sciences Cloud Consulting Professional Services, Service Descriptions and Metrics.

Reach out to your Oracle point of contact if more information is needed.

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.

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.

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.

Medrio Integration

An integration that allows you to import subject data from an external application into Oracle Clinical One Platform, using the Oracle Clinical One Digital Gateway web service, in a standard ODM format.

Configuration Service details for this integration

B92664: Oracle Life Sciences Clinical One Digital Gateway Configuration Service, up to 40 Data Points.

> **Note:**
>
> For additional details see, Oracle Life Sciences Cloud Consulting Professional Services, Service Descriptions and Metrics.

If more information is needed, reach out to your Oracle point of contact.

Overview

Medrio collects patient data via a proprietary application. This data is then converted into the ODM format. Oracle Clinical One Digital Gateway ingests this data through the Medrio integration. The frequency and granularity of the data which is imported through the integration with Oracle Clinical One Digital Gateway depends on the architecture and implementation of the Medrio web service client. The mapping and conversion of data to the format of corresponding visits, forms, and other items in Oracle Clinical One Platform also depends on the implementation of the ObvioHealth web service client.

> **Note:**
>
> This integration is an extension of the Multi-IWR integration. For more information, see Multi-IWR Integration.
> Review the sections below to gain a complete understanding of this offering.

- Features and Limitations
- Workflow and supported events
- About the external REST API call

Features and Limitations

Features

- Provides the ability to monitor jobs by subject.
- Allows for parallel processing of subject data.
- Includes email notifications sent for failed jobs.
- Data is processed in the order requests are received.

> **Note:**
>
> If the current job is in a failed status, new jobs for the same subject remain in a blocked status until the failed job either succeeds or is canceled.

- Has the ability to create subjects in Oracle Clinical One Platform.

Limitations for visits, forms, and items

- Data upsert into frozen items is not supported.

> **Note:**
>
> An upsert is a database operation that updates an existing row if a specified value already exists in a table, and inserts a new row if the specified value doesn't already exist.

- Importing data into dynamic visits, forms, or other items is not supported.

- Importing data into two-section forms is not supported.

Limitations for subjects

- Data relating to subject status changes is not supported.

Limitations for repeating forms

- Deleting a row on a repeating form is not supported.
- Only those rows inserted through the integration for, Screening, VisitComplete, and AdverseEvent can be updated.
- Updating or deleting manually added rows for repeating forms is not supported.
- The data value for items defined as the primary identifier(s) cannot be updated.

Limitations for branch visits

- Branch visits are added in sequence starting from instance 1; Design settings of cycle start are not taken into account.
- Partial dates cannot be used as visit start date values.

Workflow and supported events

1. Events completed in the external Medrio system trigger calls to a REST API-enabled web service.
   The supported events are:

   > **Note:**
   >
   > Events depend on the source system design. The integration needs to be configured based on how the source system bundles and sends the data.

   - Create a subject
   - Screen a subject
   - Update the status for a subject
   - Insert, update and delete data in Visits-Form-Items (static repeating, flat and two-section forms).
     - Supported item types include text, date, check box (single and multi-select), radio control, and dropdown.
   - Update the status of a visit
   - Update visit date (all visit types are supported).
     - For cycle visits, the visit date should not be used as a repeat key if updates are expected.
   - Visit completion
   - Withdrawal or completion of a subject
   - Create Adverse Event entries
2. The web service validates the data, then triggers the parent integration (a specific integration configuration), which controls the entire integration process.

3. The parent integration calls the appropriate event processing sub-integration configuration. The available sub-integration configuration templates are:

Sub-integration	Description
Screening	Handles the creation of a subject, subject screening activities, and data updates for the screening visit.
Visit completion	Handles the creation and completion of scheduled and unscheduled visits and data upserts for visits.
Subject Withdrawal or Completion	Handles subject state updates.
Adverse event	Handles the creation of log entries in an Adverse event.
Subject number update	Handles updates to a subject number after the subject is created.
Clear data	Supports the Clear Data feature for Oracle Clinical One Platform.

4. The triggered sub-integration reads the data, then groups it by subject and visits, allowing the integration to process data for multiple subjects in parallel.
5. Subject data is transformed per the Oracle Clinical One Platform study design.
6. Clinical One API calls are made to update the subject status and insert or update the data in the respective visit, form, and item.

About the external REST API call

The Medrio integration uses a configuration which is identical to that of Multi-IWR. To learn how to configure Medrio's external REST API call, see About the external REST API call.

Multi-IWR Integration

A near real-time integration that allows you to import subject data sent by an external IVR system, in a standard ODM format, to an Oracle Clinical One Platform study using the Oracle Clinical One Digital Gateway web service.

Configuration Service details for this integration

B92664: Oracle Life Sciences Clinical One Digital Gateway Configuration Service, up to 40 Data Points.

> **Note:**
>
> For additional details see, Oracle Life Sciences Cloud Consulting Professional Services, Service Descriptions and Metrics.

If more information is needed, reach out to your Oracle point of contact.

Overview

The integration aims to minimize or eliminate duplicate data entry, ensuring consistency between the two systems.

This integration can generally integrate with any data source system that involves persisting patient data into a Clinical One Platform study.

Review the sections below to gain a complete understanding of this offering.

Features and Limitations

Features

- Provides the ability to monitor jobs by subject.
- Allows for parallel processing of subject data.
- Includes email notifications sent for failed jobs.
- Data is processed in the order requests are received.

> **Note:**
>
> If the current job is in a failed status, new jobs for the same subject remain in a blocked status until the failed job either succeeds or is canceled.

Limitations

Limitations for visits, forms, and items

- Data upsert into frozen items is not supported.

> **Note:**
>
> An upsert is a database operation that updates an existing row if a specified value already exists in a table, and inserts a new row if the specified value doesn't already exist.

- Deleting a row on a repeating form is not supported.

Limitations for repeating forms

- Only those rows inserted through the integration for, Screening, VisitComplete, and AdverseEvent can be updated.
- Updating or deleting manually added rows for repeating forms is not supported.
- The data value for items defined as the primary identifier(s) cannot be updated.

Limitations for branch visits

- Branch visits are added in sequence starting from instance 1; Design settings of cycle start are not taken into account.
- Partial dates cannot be used as visit start date values.

Workflow and supported events

1. Events completed in the external IWR system trigger calls to a REST API-enabled web service.
   The supported events are:

> **Note:**
>
> Events depend on the source system design. The integration needs to be configured based on how the source system bundles and sends the data.

- Create a subject
- Screen a subject
- Update the status for a subject
- Insert, update and delete data in Visits-Form-Items (static repeating, flat and two-section forms).
  - Supported item types include text, date, check box (single and multi-select), radio control, and dropdown.
- Update the status of a visit
- Update visit date (all visit types are supported).
  - For cycle visits, the visit date should not be used as a repeat key if updates are expected.
- Visit completion
- Withdrawal or completion of a subject
- Create Adverse Event entries

2. The web service validates the data, then triggers the parent integration (a specific integration configuration), which controls the entire integration process.
3. The parent integration calls the appropriate event processing sub-integration configuration. The available sub-integration configuration templates are:

Sub-integration	Description
Screening	Handles the creation of a subject, subject screening activities, and data updates for the screening visit.
Visit completion	Handles the creation and completion of scheduled and unscheduled visits and data upserts for visits.
Subject Withdrawal or Completion	Handles subject state updates.
Adverse event	Handles the creation of log entries in an Adverse event.
Subject number update	Handles updates to a subject number after the subject is created.
Clear data	Supports the Clear Data feature for Oracle Clinical One Platform.

4. The triggered sub-integration reads the data, then groups it by subject and visits, allowing the integration to process data for multiple subjects in parallel.
5. Subject data is transformed per the Oracle Clinical One Platform study design.
6. Clinical One API calls are made to update the subject status and insert or update the data in the respective visit, form, and item.

About the external REST API call

The IWR system makes Rest API POST calls to `ib-ext-svc`. Each call contains a request body, which is expected to be data wrapped in an `<IRTdata>` element, in ODM XML format.

You must construct your ODM according to your integration configuration, the event type and the clinical data you want to map. Additionally, each external IWR system can choose to fit one of two different patterns to map IRTData into Oracle Clinical One Platform.

To learn more about these patterns of payload types and get additional details on how to construct the ODM and push data to integrate, see the Integrate data into Clinical One via Digital Gateway use case in the *REST API guide for the Clinical One Platform*.

ObvioHealth Integration

An integration that allows you to import subject data from an external application into Oracle Clinical One Platform, using the Oracle Clinical One Digital Gatewayweb service, in a standard ODM format.

Configuration Service details for this integration

B92664: Oracle Life Sciences Clinical One Digital Gateway Configuration Service, up to 40 Data Points.

> **Note:**
>
> For additional details see, Oracle Life Sciences Cloud Consulting Professional Services, Service Descriptions and Metrics.

If more information is needed, reach out to your Oracle point of contact.

Overview

ObvioHealth collects patient data via a proprietary application. This data is then converted into the ODM format. Oracle Clinical One Digital Gateway ingests this data through the ObvioHealth integration. The frequency and granularity of the data which is imported through the integration with Oracle Clinical One Digital Gateway depends on the architecture and implementation of the ObvioHealth web service client. The mapping and conversion of data to the format of corresponding visits, forms, and other items in Oracle Clinical One Platform also depends on the implementation of the ObvioHealth web service client.

> **Note:**
>
> This integration is an extension of the Multi-IWR integration. For more information, see Multi-IWR Integration.

Review the sections below to gain a complete understanding of this offering.

- Features and Limitations
- Workflow and supported events
- About the external REST API call

Features and Limitations

Features

- Provides the ability to monitor jobs by subject.

- Allows for parallel processing of subject data.
- Includes email notifications sent for failed jobs.
- Data is processed in the order requests are received.

> **Note:**
>
> If the current job is in a failed status, new jobs for the same subject remain in a blocked status until the failed job either succeeds or is canceled.

- Has the ability to create subjects in Oracle Clinical One Platform.

Limitations for visits, forms, and items

- Data upsert into frozen items is not supported.

> **Note:**
>
> An upsert is a database operation that updates an existing row if a specified value already exists in a table, and inserts a new row if the specified value doesn't already exist.

- Importing data into unscheduled and cycle visits is not supported.
- Importing data into dynamic visits, forms, or other items is not supported.
- Importing data into two-section forms is not supported.

Limitations for repeating forms

- Deleting a row on a repeating form is not supported.
- Only those rows inserted through the integration for, Screening, VisitComplete, and AdverseEvent can be updated.
- Updating or deleting manually added rows for repeating forms is not supported.
- The data value for items defined as the primary identifier(s) cannot be updated.

Limitations for subjects

- All imported subjects will be created in a single site in Oracle Clinical One Platform, as ObvioHealth does not support multiple sites.
- Patient transfers are not reflected in the data transmitted through the integration with Oracle Clinical One Digital Gateway.
- Data relating to subject status changes is not supported.

Limitations for branch visits

- Branch visits are added in sequence starting from instance 1; Design settings of cycle start are not taken into account.
- Partial dates cannot be used as visit start date values.

Workflow and supported events

1. Events completed in the external ObvioHealth system trigger calls to a REST API-enabled web service.
   The supported events are:

   > **Note:**
   >
   > Events depend on the source system design. The integration needs to be configured based on how the source system bundles and sends the data.

   - Create a subject
   - Screen a subject
   - Update the status for a subject
   - Insert, update and delete data in Visits-Form-Items (static repeating, flat and two-section forms).
     - Supported item types include text, date, check box (single and multi-select), radio control, and dropdown.
   - Update the status of a visit
   - Update visit date (all visit types are supported).
     - For cycle visits, the visit date should not be used as a repeat key if updates are expected.
   - Visit completion
   - Withdrawal or completion of a subject
   - Create Adverse Event entries
2. The web service validates the data, then triggers the parent integration (a specific integration configuration), which controls the entire integration process.
3. The parent integration calls the appropriate event processing sub-integration configuration.
   The available sub-integration configuration templates are:

Sub-integration	Description
Screening	Handles the creation of a subject, subject screening activities, and data updates for the screening visit.
Visit completion	Handles the creation and completion of scheduled and unscheduled visits and data upserts for visits.
Subject Withdrawal or Completion	Handles subject state updates.
Adverse event	Handles the creation of log entries in an Adverse event.
Subject number update	Handles updates to a subject number after the subject is created.
Clear data	Supports the Clear Data feature for Oracle Clinical One Platform.

4. The triggered sub-integration reads the data, then groups it by subject and visits, allowing the integration to process data for multiple subjects in parallel.
5. Subject data is transformed per the Oracle Clinical One Platform study design.

6. Clinical One API calls are made to update the subject status and insert or update the data in the respective visit, form, and item.

About the external REST API call

The ObvioHealth integration uses a configuration which is identical to that of Multi-IWR. To learn how to configure ObvioHealth's external REST API call, see About the external REST API call.

Oracle Life Sciences InForm to Oracle Argus Safety

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 Life 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 Life 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 that 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\ich-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.DefaultC
odeListMapper" custom-converter-
param="INTHUBCODELIST~DRUGSAFETYREPORT_MEDICINALPRODUCTNAME">
349   <!-- <field custom-
converter="oracle.hsgbu.clinicalone.integration.impl.mapper.DefaultI
nitializer" 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 Include the correct SpecialKeyCodeListMapper
To ensure that code lists that contain commas are properly sent from Oracle InForm to Oracle Argus Safety, include this specific mapper in your integration file. This determines the integration to properly send out data related to code lists even when these code lists contain commas in their values.

> **Note:**
>
> For an existing integration, make sure that you update your configuration file with the new code list mapper. Then, re-upload the configuration file in Oracle Clinical One Digital Gateway.

```
<mapping map-null="false" wildcard="false" trim-strings="true" type="one-way"
map-id="PrimaryCountryCodeMap">
                <class-
a>oracle.hsgbu.infpub.ebm.com.oracle.xmlns.informtosafety.drugsafetyreport.v1.
ReportDrugSafetyReportType</class-a>
                <class-b>oracle.hsgbu.argus.e2b.r2.Safetyreportext</class-b>
            <field custom-
converter="oracle.hsgbu.clinicalone.integration.impl.mapper.SpecialKeyCodeList
Mapper" custom-converter-param="INTHUBCODELIST~COUNTRY">
                    <a>primarySourceCountryCode.value</a>
                    <b>safetyreportid.content</b>
                </field>
            </mapping>
                    <mapping map-null="false" wildcard="false" trim-
strings="true" type="one-way" map-id="IchicsrSafetyReportGenericMap">
                <class-
a>oracle.hsgbu.infpub.ebm.com.oracle.xmlns.informtosafety.drugsafetyreport.v1.
ReportDrugSafetyReportType</class-a>
                <class-b>oracle.hsgbu.argus.e2b.r2.Safetyreportext</class-b>
                <field map-id="IchicsrSafetyReportPrimarySourceMap">
                    <a>drugSafetyReportPrimarySource</a>
                    <b>primarysource</b>
                    <a-
hint>oracle.hsgbu.infpub.ebm.com.oracle.xmlns.informtosafety.drugsafetyreport.
v1.DrugSafetyReportPrimarySourceType</a-hint>
                    <b-hint>oracle.hsgbu.argus.e2b.r2.Primarysource</b-hint>
                </field>
                <field custom-
converter="oracle.hsgbu.clinicalone.integration.impl.mapper.SpecialKeyCodeList
Mapper" custom-converter-param="INTHUBCODELIST~COUNTRY">
                    <a>primarySourceCountryCode.value</a>
                    <b>primarysourcecountry.content</b>
                </field>
                        <field custom-
converter="oracle.hsgbu.clinicalone.integration.impl.mapper.SpecialKeyCodeList
Mapper" custom-converter-param="INTHUBCODELIST~COUNTRY">
                    <a>occurrenceCountryCode.value</a>
                    <b>occurcountry.content</b>
                </field>
```

Task 4 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 5 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.clnicalone.integration.impl.mapper.DefaultCodeList
Mapper" 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 6 (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.DefaultCodeLis
tMapper" 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.DefaultNVLInit
ializer">
         <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.DefaultConcate
nator" 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 7 Configure the integration to process a partial safety case narrative from Oracle InForm

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 8 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.

Randomization & Trial Supply Management (RTSM)

Supply Systems

- Almac Global Depot Network
  This workflow applies to shipments when you use an integration with the Almac global depot network, 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.
- Catalent Clinical Supply Services
  This workflow applies to shipments when you use an integration with Catalent Clinical Supply Services. 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.
- Fisher Clinical Services
  This workflow applies to shipments when you use an integration with Fisher Clinical Services. 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.
- Sharp ERP Shipment
  This integration is used to synchronize shipment and tracking data between Sharp's Supply Management system and Oracle Life Sciences Clinical One Platform RTSM.

- 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.

Almac Global Depot Network

This workflow applies to shipments when you use an integration with the Almac global depot network, 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.

Configuration Service details for this integration

B92664: Oracle Life Sciences Clinical One Digital Gateway Configuration Service, up to 40 Data Points.

For more information see, Oracle Life Sciences Cloud Consulting Professional Services, Service Descriptions and Metrics.

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.

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.

> **WARNING:**
>
> 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, reach out to your Oracle point of contact.

What information can be integrated?

This integration includes request and response components. You only need to implement what is necessary for your organization.

Available events:

- Shipment requests
- Automated shipment response - **Confirmed**
- **In Transit** status

Available data points:

- For request:
  - Shipping site address
  - Site contact information
  - Site investigator information
  - Shipment order details
- For response:
  - Shipment order
  - Tracking number and Shipment date
  - Shipment status

Things to consider for shipments when you use an integration with Almac

The integration with Almac Global Depot Network only supports one kit type per lot. If your study uses non-serialized kits, a kit type must be mapped to an individual lot number. To update the configuration of your integration with Almac Global Depot Network, reach out to your Oracle point of contact.

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

If a shipment request is sent in error or kits need to be added or removed, the clinical supply manager must contact the organization managing the depot and request the shipment's cancellation. Once the organization managing the depot cancel the order in their system, the shipment status changes to **Invalid** in Oracle Clinical One Platform.

> **Note:**
>
> The organization managing the depot can only cancel an order if the shipment has not been sent yet. 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.

Table 2-21 Status details

Status	Details
Pending	The status changes automatically to **Pending** when a new shipment is raised.

Table 2-21 (Cont.) Status details

Status	Details
Confirmed or **Invalid**	The status changes automatically to **Confirmed** or **Invalid** when a shipment request is sent to the depot. • **Confirmed**: indicates the depot received the request. • **Invalid**: indicates an issue occurred with the request. ***Note**: For an invalid shipment, a clinical supply manager should cancel the request 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.*
In Transit	The status changes to **In Transit** after the depot fulfills the shipment for a **Confirmed** request. The ship date and tracking number are also set automatically.
Received	Once the site receives the shipment, the set the status to **Received** manually.

Catalent Clinical Supply Services

This workflow applies to shipments when you use an integration with Catalent Clinical Supply Services. 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.

Configuration Service details for this integration

B92664: Oracle Life Sciences Clinical One Digital Gateway Configuration Service, up to 40 Data Points.

For more information see, Oracle Life Sciences Cloud Consulting Professional Services, Service Descriptions and Metrics.

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

To make sure depot users at a Catalent-managed depot facility get this email notification in their inbox, in Oracle Clinical One Platform, on the **Depot** 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. Further, in order for the integration to run as expected, ensure shipment ID prefixes consist only of numbers. When setting the prefix on the **Supply Settings** tab, in the **Shipment Settings** section, choose one of the following options:

- **Use depot ID**: depot IDs have been defined using numbers only
- **Enter prefix**: enter a prefix and make sure the values consists only of numbers
- **None**: if no prefix is used

Finally, in Oracle Clinical One Platform, make sure the value for **Study Title** is between 5 and 30 characters long.

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.

> **WARNING:**
>
> 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, reach out to your Oracle point of contact.

What information can be integrated?

This integration includes request and response components. You only need to implement what is necessary for your organization.

Available events:

- Shipment requests
- Automated shipment response - **Confirmed**
- **In Transit**
- **Received**

Available data points:

- For request:
  - Shipping site address
  - Site contact information
  - Site investigator information
  - Shipment depot and order details
- For response:
  - Shipment order
  - Tracking number
  - Shipment date, status, and delivery

Things to consider for shipments when you use an integration with Catalent Clinical Supply Services

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.

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.

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

Table 2-22 Status details

Status	Details
Pending	The status of a shipment changes automatically to **Pending** when a new shipment is raised.
Confirmed or **Invalid**	The status changes automatically to **Confirmed** or **Invalid** when a shipment request is sent to the depot. • **Confirmed**: indicates the depot received the request • **Invalid**: indicates an issue occurred with the request ***Note**: For an invalid shipment, a clinical supply manager should cancel the request 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.*
In Transit	The status changes to **In Transit** after the depot fulfills the shipment for a **Confirmed** request. The shipping date and tracking number are also set automatically.
Available or **Received**	Once the site receives the order, one of the following can happen: • 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.

Fisher Clinical Services

This workflow applies to shipments when you use an integration with Fisher Clinical Services. 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.

Configuration Service details for this integration

B92664: Oracle Life Sciences Clinical One Digital Gateway Configuration Service, up to 40 Data Points.

For more information see, Oracle Life Sciences Cloud Consulting Professional Services, Service Descriptions and Metrics.

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

In order for the integration to run as expected, ensure shipment ID prefixes consist only of numbers. When setting 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
- **None**: if no prefix is used.

Integration user details

Integration setup includes the creation of a study-level integration user account, which is assigned to 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.

> **Note:**
>
> 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, reach out to your Oracle point of contact.

What information can be integrated?

This integration includes request and response components. You only need to implement what is necessary for your organization.

Available events:

- Shipment requests
- Automated shipment response - **Date Shipped**
- Courier for **In Transit** status

Available data points:

- For request:
  - Shipping site address

  - Site contact information
  - Site investigator information
  - Shipment order details
- For response:
  - Shipment order
  - Tracking number
  - Shipment date and status

Things to consider for shipments when you use an integration with Fisher Clinical Services

If a shipment request is sent in error or kits need to be added or removed, the clinical supply manager must contact Fisher Clinical Services and request the shipment's cancellation. Once Fisher Clinical Services cancels the order in their system, the shipment status changes to **Invalid** in Oracle Clinical One Platform.

> **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.

Table 2-23 Status details

Status	Details
Pending	The status of a shipment changes automatically to **Pending** when a new shipment is raised.
In Transit or **Confirmed**	The status changes to **In Transit** after the depot fulfills the shipment for a **Confirmed** request. The ship date and tracking number are also set automatically.
Received	Once the site receives the order and marks it as received, the status changes to **Received**.

Sharp ERP Shipment

This integration is used to synchronize shipment and tracking data between Sharp's Supply Management system and Oracle Life Sciences Clinical One Platform RTSM.

Configuration Service details for this integration

B92664: Oracle Life Sciences Clinical One Digital Gateway Configuration Service, up to 40 Data Points.

> **Note:**
>
> For more information see, Oracle Life Sciences Cloud Consulting Professional Services, Service Descriptions and Metrics.

Reach out to your Oracle point of contact if more information is needed.

Integration components

- **Shipment Request**: Retrieves shipment event information from Oracle Life Sciences Clinical One Platform generated since the last run. The data is then translated per the Sharp ERP requirements and placed on the Oracle sFTP server, where Sharp's ERP Supply Management System retrieves it.
- **Shipment Response (or Shipment Dispatch)**: Imports shipment tracking information into Oracle Life Sciences Clinical One Platform RTSM sent by the Sharp ERP Supply Management System.

Integration details

- **Data Flow:** Bi-directional
- **Mode:** sFTP
- **File Type:** XML

Supported events

- Shipment Requests
- Shipment Response: Date Shipped, Courier for In Transit status.

Supported data points

- Shipment Requests: shipping site address, site contact information, site investigator information, shipment order details, lot number, and kit type.
- Shipment Response: shipment order, tracking number and ship date, and shipment status.

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.

Configuration Service details for this integration

B92664: Oracle Life Sciences Clinical One Digital Gateway Configuration Service, up to 40 Data Points.

For more information see, Oracle Life Sciences Cloud Consulting Professional Services, Service Descriptions and Metrics.

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.

For information about how to set up this integration, reach out to your Oracle point of contact.

> **WARNING:**
>
> Make sure the appropriate email address is configured for the integration user account to avoid unblinding issues.

What information can be integrated?

As it only includes request components, this integration sends updates to SmartSupplies PMD whenever one of the events it supports takes place.

Available events:

- Kit status changes at depots and sites.
- Kit request transfer from depot to depot.
- Kit receipt transfer from depot to depot.

> **Note:**
>
> As it only includes request components, this integration sends updates to SmartSupplies PMD whenever one of the vents supported by the integration takes place.

Available data points:

- Kit number
- Lot number and Status
- Source and Destination depot
- Shipment date
- Expected date
- Kit and Lot

Workflow for a shipment when you use an integration with SmartSupplies PMD

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

EDC Systems

- Oracle Clinical One Platform to Oracle InForm
  Integrate study data from Oracle Clinical One Platform with Oracle InForm.
- 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.

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

Oracle Clinical One Platform to Oracle InForm

Integrate study data from Oracle Clinical One Platform with Oracle InForm.

Configuration service details for this integration

B92665: Oracle Life Sciences Clinical One Digital Gateway Configuration Service, up to 70 Data Points.

> **Note:**
>
> For more information, see Oracle Life Sciences Cloud Consulting Professional Services, Service Descriptions and Metrics.

If you require more information, reach out to your Oracle point of contact.

Integration details

The following guidelines are required for a successful integration:

- The site ID and site name must match in both systems.
  Sites for Oracle Clinical One Platform studies are created under **Study Settings** in the user interface. For Oracle InForm studies, sites are created in the Oracle InForm User Management Tool (UMT).

  > **Note:**
  >
  > The integration does not integrate site details between the two systems. Sites must be created for each system as defined above.

- 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 the **Subject event data** section below.

Subject events and data

You can integrate data for the following subject events:

Subject event data	Details
Clear a visit date	If you don't want to integrate clear visit date events, you can update the integration template. ***Warning**: The integration does not verify the setting. If the date and time components are enabled, the integration fails, and the update is sent to Oracle InForm.* • By default, the visit date is cleared in Oracle InForm as long as the **Date Time Properties** for the visit date item are configured correctly in Oracle Central Designer. • In Oracle Central Designer, ensure the **Required** option is disabled for all date and time components under the **Date Time Component Setting** section.
Screen a subject	You choose the data to send from Oracle Clinical One Platform to Oracle InForm.
Screen fail a subject, undo a subject's screen failure, or update a user's screen failure date and reason	• For the screen failure event, the screen failure user-entered date and reason are sent to Oracle InForm, along with any other relevant information related to the screen failure event. 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 undoing a subject's 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 from Oracle Clinical One Platform to Oracle InForm.
Update a form for a subject	You choose the data to send from Oracle Clinical One Platform to Oracle InForm.
Complete a subject's visit	You choose the data to send from Oracle Clinical One Platform to Oracle InForm.
Transfer a subject	You choose the data to send from Oracle Clinical One Platform to Oracle InForm.
Withdraw a subject, undo a subject's withdrawal, or update a subject's withdrawal date and reason	***Note**: Data related to these events can also be sent for subjects who failed screening. This is dependent on the study setting Screen Failed Subjects.* • For the withdrawal event, the withdrawal user-entered date and reason are updated in the withdrawal form in Oracle InForm, as well as any other relevant information. • For the undo withdrawal event, the withdrawal date and other details that were initially sent are cleared out in Oracle InForm. Oracle Clinical One Platform retains the information in the withdrawal form. A subject's status in Oracle InForm is updated to *Enrolled*. • In the Oracle Clinical One Platform, if a user manually clears question fields in the resurfaced withdrawal visit, no job failures occur for this action. Jobs associated with the clear event should succeed in Oracle Clinical One Digital Gateway. • In the Oracle Clinical One Platform, if a user manually updates question fields in the resurfaced withdrawal visit, the updated values integrate into Oracle InForm without any jobs failing.

Subject event data	Details
Complete a study for a subject, undo a subject's study completion, or update a subject's study completion date	***Note**: Data related to these events can also be sent for subjects who failed screening. This is dependent on the study setting Screen Failed Subjects.* • For a subject's study completion event, the completion user-entered date and reason, as well as any other relevant information for a subject's completion event is sent to Oracle InForm. • For the undo study complete event, the completion date and other details that were sent are cleared out in Oracle InForm. Oracle Clinical One Platform retains the information in the completion form. A subject's status in Oracle InForm is updated to *Enrolled*. • In the Oracle Clinical One Platform, if a user manually clears question fields in the resurfaced completion visit, no job failures occur for this action. Jobs associated with the clear even should succeed in Oracle Clinical One Digital Gateway. • In the Oracle Clinical One Platform, if a user manually updates question fields in the resurfaced completion visit, the updated values integrate into Oracle InForm without any jobs failing.

Dispensation and kit data

> **Note:**
>
> Contact your Oracle point of contact if your study uses non-serialized kits and you would like to send data about non-serialized inventory to Oracle InForm.

You can integrate data for the following dispensation or kit-related events:

Type of data	Details
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 form. The new information includes dispensation date, original kit number, and new kit number, along with other details.
Re-dispense a conserved kit	The conserved kit number and any other relevant data can be sent to Oracle InForm and included in a form.

Form data

You can integrate data for the following form-related events:

Type of data	Details
Apply, update, or clear a data flag	Data flags correspond to the *Reason Incomplete* options available in Oracle InForm 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. 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. • The Require a comment setting (when entering Not Applicable, Unknown, or Not Done) in Oracle InForm is set to No. • The Display Comment Text Boxes setting is set to Yes.

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.

Configuration Service details for this integration

B92665: Oracle Life Sciences Clinical One Digital Gateway Configuration Service, up to 70 Data Points.

> **Note:**
>
> For more information see, Oracle Life Sciences Cloud Consulting Professional Services, Service Descriptions and Metrics.

Reach out to your Oracle point of contact if more information is needed.

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.

Outbound subject data integration

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

Configuration Service details for this integration

B92665: Oracle Life Sciences Clinical One Digital Gateway Configuration Service, up to 70 Data Points.

> **Note:**
>
> For more information see, Oracle Life Sciences Cloud Consulting Professional Services, Service Descriptions and Metrics.

If you require more information, reach out to your Oracle point of contact.

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

> **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.

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

Type of data	Details
Screen a subject	You choose the data to send from Oracle Clinical One Platform to the third-party EDC system.

Type of data	Details
Screen fail a subject, undo a subject's screen failure, or update a user's screen failure date and reason	• 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. In the third-party EDC system, the subject's status isn't changed. • For undo screen failure, the screen failure date is updated to blank in the third-party EDC system. In the third-party EDC system, the subject's status isn't changed.
Randomize a subject	You choose the data to send from Oracle Clinical One Platform to the third-party EDC system. Data for these events can be sent for subjects who failed screening, as well.
Complete a study for a subject, undo a subject's study completion, or update a subject's study completion date	• For a subject's study completion event, the completion user-entered date and reason, as well as any other relevant information for a subject's completion event, is sent to the third-party EDC system. • For the undo study complete event, the completion date and other details that were sent to the third-party EDC system are cleared. In the third-party EDC system, the subject's status isn't changed. • In the Oracle Clinical One Platform, if a user manually clears question fields in the resurfaced study completion visit, no job failures occur for this action. Jobs associated with the clear event should succeed in Oracle Clinical One Digital Gateway. • In the Oracle Clinical One Platform, if a user manually updates question fields in the resurfaced study completion visit, this updated value will integrate into third-party EDC system without any jobs failing.
Withdraw a subject, undo a subject's withdrawal, or update a subject's withdrawal date and reason	• Data for these events can be sent for subjects who failed screening, as well. • For a subject's 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 the undo subject withdrawal event, 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. • In the Oracle Clinical One Platform, if a user manually clears question fields in the resurfaced withdrawal visit, no job failures occur for this action. Jobs associated with the clear event should succeed inOracle Clinical One Digital Gateway. • In the Oracle Clinical One Platform, if a user manually updates question fields in the resurfaced withdrawal visit, this updated value will integrate into third-party EDC system without any jobs failing.
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.

Type of data	Details
Kit replacement	**Note:** If your study uses non-serialized kits and you would like data about non-serialized inventory sent to the third-party EDC system, reach out to your Oracle point of contact. 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.

3

Monitor and manage integrations

Manage an integration and its jobs

The configuration of an integration or the jobs associated with it might require your attention and assistance if there are any errors that prevent the integration from running properly.

As an integration manager, you create an integration using a configuration file. Once an integration is enabled, it will have jobs associated with it. You need to disable the integration to make changes to its configuration. 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. You can also make changes to the statuses of integrations. Follow the steps in this topic to manage your integration.

1. On the Home page, filter the list of integrations or integration groups as needed, based on one or more of the following criteria:
   - **Last modified date** filters by date range.
   - **Integration name** filters by the name of the integration.
2. Click an integration group row to expand it and to see a list of integrations associated with it.
3. Click the integration you wish to manage. 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:

   

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

   You can edit the following details for an integration:

Table 3-1 List of integration settings

Field	Details
Title	Add or change the title of the integration.
Job Start Date	Add or change the date on which the integration starts running.
Days When to Send Data	Select the days of the week when the integration will run, Monday through Sunday. You can also choose one of the following, which allow you to configure the intervals at which the data is sent: • **At** • **Every**
Send Data	Add the time when the data is sent. Only available when **At** is selected as part of the **Days When to Send Data** setting.
Send Data Every	Define the interval at which data is sent. Only available when **Every** is selected as part of the **Days When to Send Data** setting.
Data Transfer Options	Configure how much of the data is transferred. Select one of the following: • **Transfer all data**: transfer all the data associated with a study • **Only transfer data from specific date**: select a date from which the data will be transferred.
Reattempt to Send Data	The number of times the integration will re-attempt to send data, should the data transfer fail.
Send Notifications to	Add the email addresses to which notifications are sent.
Integration File	Add or replace integration files.

6. To manage the jobs associated with an integration, do the following:
   a. Click the row of the integration that failed.
   b.
   > **Tip:**
   >
   > You can search for the job using the filters along the top. For example, you can filter for **Status** or a date range.

   Find the job that you want to resend or cancel.
   c. Select the checkbox for that job.

   > **WARNING:**
   >
   > Never cancel an Oracle InForm or Argus Safety job. Canceled jobs are never resent and the data would be lost.

> **Note:**
>
> To see the history of a job, select the job and look into **Job Details**, on the right.

d. On the right, below **Job details**, click **Resend** if the job isn't working or click **Cancel Job** if you want to stop the job.

7. 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.

> **Note:**
>
> With the appropriate role, you may be able to do more than just monitor integrations. For information about access, see Get access. For guidance on how to troubleshoot any issues with your integrations, see Manage an integration and its jobs.

Search for a job or safety report that is failing

> **WARNING:**
>
> Error messages for failed jobs may contain integrated data that could be unblinding. Users who can review error messages should not be blinded study users.

1. On the Home page, filter the list of integrations as needed, based on one or more of the following criteria:

Filter	Description
Last Modified Date (UTC)	Filters by date range.
Integration Name	Filters by the name of the integration.

> **Tip:**
>
> We recommend sorting by date range as the easiest way to find an integration.

2. Click an integration to see a list of its jobs.
3. Filter the list of jobs based on one or more of the following criteria:

Filter	Description
Last Modified Date (UTC)	Filters by date range.
Job ID	Filters based on the ID of the integration.

Filter	Description
Status	Filters based on job status.

Here's what the status of each job means:

Status	Description
All	This means you can see all jobs no matter their status.
Successful	Only the successful jobs are shown.
Processing	Only the in-progress 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.
Blocked	Only the blocked jobs are shown.
Canceled	Only the jobs you canceled are shown.
Fail No Retry	This status is only applicable for the Siebel CTMS integration and indicates the job failed and no retry attempt is made.

4. Click one of the shipment IDs to see a list of associated jobs.
5. Click one of the jobs from the list below the shipment ID.

> **Tip:**
>
> To see the history of a job, select the job and look into **Job Details**, on the right.

6. Once you have finished viewing the list of jobs, you can select **Back to Integrations** on the left to return to the Integrations home page.

4

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.

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, visit the Oracle Health Sciences Support Cloud 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 Life 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 Life 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 Life 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.

5 Revision history

Date	Part number	Description
02-April-2025	G22972-03	We separated the Clinical Trial Management Systems (CTMS) section from the RTSM section and gave it its own space.
18-March-2025	G22972-02	• The following topics were updated. – Oracle Clinical One Platform to Oracle InForm – Outbound subject data integration • New content was added under Oracle Siebel CTMS making it easier for customers to configure their own Oracle Siebel CTMS integrations.
17-January-2025	G22972-01	Original version of the document.