

Oracle® Life Sciences Clinical One

Digital Gateway User Guide



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Preface

This preface contains the following sections:

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

Documentation accessibility

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

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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1

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.
- [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](#)

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	<ul style="list-style-type: none">• Google Chrome version 119.0.6045.124 (recommended)• Microsoft Edge version 119.0.2151.58	<p>Make sure the resolution display of your computer is configured using the following values</p> <ul style="list-style-type: none">• 1920x1080 (recommended) for a full High Definition (HD) monitor• 1366x768 px or higher (standard resolution) for most non-HD computers

2

Available integrations

- [Randomization & Trial Supply Management \(RTSM\)](#)
- [Data Collection](#)
- [Oracle Life Sciences InForm to Oracle Argus Safety](#)

Randomization & Trial Supply Management (RTSM)

- [Supply Systems](#)
- [EDC Systems](#)
- [CTMS Systems](#)

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, contact your Oracle Project Manager.

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

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 2-1 Status details

Status details
The status changes automatically to Pending when a new shipment is raised.
The status changes automatically to Confirmed or Invalid when a shipment request is sent to the depot. <ul style="list-style-type: none"> • Confirmed: indicates the depot received the request. • Invalid: indicates an issue occurred with the request.
<div data-bbox="444 1329 492 1369" data-label="Image"> </div> <div data-bbox="488 1327 573 1360" data-label="Section-Header"> <h4>Note:</h4> </div> <div data-bbox="488 1381 1438 1505" data-label="Text"> <p>For an invalid shipment, a clinical supply manager should cancel the request and do one of the following:</p> <ul style="list-style-type: none"> – Allow the resupply process to create a new shipment the next time inventory runs. – Create a new manual shipment. </div>
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.
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, contact your Oracle Project Manager.

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 2-2 Status details

Status details
The status of a shipment changes automatically to Pending when a new shipment is raised.

Table 2-2 (Cont.) Status details

Status details
<p>The status changes automatically to Confirmed or Invalid when a shipment request is sent to the depot.</p> <ul style="list-style-type: none"> • Confirmed: indicates the depot received the request • Invalid: indicates an issue occurred with the request
<p> Note:</p> <p>for an invalid shipment, a clinical supply manager should cancel the request and do one of the following:</p> <ul style="list-style-type: none"> – allow the resupply process to create a new shipment the next time inventory runs – create a new manual shipment
<p>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.</p> <p>Once the site receives the order, one of the following can happen:</p> <ul style="list-style-type: none"> • 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 gets 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, contact your Oracle project manager.

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 2-3 Status details

Status details
The status of a shipment changes automatically to Pending when a new shipment is raised.
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.
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, contact your Oracle Project Manager.

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 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 Health 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 details


- 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 below.

Subject event data

Type of data	Notes
Clear a visit date	<p>By default, the visit date is cleared in Oracle InForm as long as the Oracle Central Designer Date Time Properties for the visit date item are configured correctly.</p> <p>In Oracle Central Designer, ensure the Required option is disabled for all date and time components under the Date Time Component Setting section.</p>
	<p> WARNING:</p> <p>The integration does not verify the setting. If the date and time components are enabled, the integration fails, and the update is not posted to InForm.</p>
	<p>The integration template can be updated if you do not want to integrate clear visit date events.</p>
Screen a subject	You choose the data to send.
Screen fail a subject and undo screen failure	<ul style="list-style-type: none"> • For screen failure, the screen failure user-entered date and reason along with any other relevant information related to the screen failure event are sent to Oracle InForm. You can map these fields to any form you use to collect the screen failure reason. The status for the subject in Oracle InForm isn't changed. • For undo screen failure, the screen failure date is updated to blank in Oracle InForm. The status for the subject in Oracle InForm isn't changed.
Randomize a subject	You choose the data to send.
Update a form for a subject	You choose the data to send.
Complete a subject's visit	You choose the data to send.
Transfer a subject	You choose the data to send.

Type of data	Notes
Withdraw a subject and undo withdrawal	<ul style="list-style-type: none"> For subject withdrawal, the withdrawal form in Oracle InForm is updated with the withdrawal date and reason, as well as any other relevant information. For undo subject withdrawal, the completion date and other details that were sent are cleared out in Oracle InForm. Oracle Clinical One Platform retains the information in the withdrawal form.
<p> Note:</p> <p>Data related to these events can also be sent for subjects who failed screening. This is dependent on the study setting Screen Failed Subjects.</p>	
Complete a study for a subject and undo study completion	<ul style="list-style-type: none"> For a study completion, the completion date and any other relevant information for a subject completion event is sent to Oracle InForm. For undo study complete, the completion date and other details that were sent are cleared out in Oracle InForm. The information in the study completion form in Oracle Clinical One Platform remains.
<p> Note:</p> <p>Data related to these events can also be sent for subjects who failed screening. This is dependent on the study setting Screen Failed Subjects.</p>	
Kit event data	
Type of data	Notes
Replace a kit that was damaged or lost	Data about replaced kits and new kits that are dispensed is sent to Oracle InForm and included in a visit form. The new information includes dispensation date, original kit number and new kit number, amongst others.
Re-dispense a conserved kit	The conserved kit number and any other relevant data can be sent to Oracle InForm and included in a visit form.

Form data

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

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 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](#).

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

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

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

 **Note:**

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

- **Screen a subject**
You choose the data to send.
- **Screen fail a subject, and undo screen failure**
 - For screen failure, the screen failure date and reason along with any other relevant information related to the screen failure event are sent to the third-party EDC system. You can map these fields to any form you use to collect the screen failure reason. The status for the subject in the third-party EDC system isn't changed.
 - For undo screen failure, the screen failure date is updated to blank in the third-party EDC system. The status for the subject in the third-party EDC system isn't changed.
- **Randomize a subject**
You choose the data to send.

Data for these events can be sent for subjects who failed screening, as well.
- **Complete a subject's visit**
You choose the data to send.
- **Withdraw a subject, and undo withdrawal**
 - For subject withdrawal, the withdrawal form in the third-party EDC system is updated with the withdrawal date and reason, as well as any other relevant information.
 - For undo subject withdrawal, the completion date and other details that were sent are cleared out in the third-party EDC system. Oracle Clinical One Platform retains the information in the withdrawal form.
 - Data for these events can be sent for subjects who failed screening, as well.
- **Code break**
If a user performed a code break in Oracle Clinical One Platform, Oracle Clinical One Platform sends the date and time when the code break was performed to the third-party EDC system.
- **Kit replacement**
When a kit is replaced, the dispensed kit information is updated with the replacement kit information on the specified form and item in the third-party EDC system.

CTMS Systems

- [Oracle's Siebel Clinical Trial Management System \(CTMS\)](#)
The CTMS integration offering consists of four separate integrations; they are Study Version Template (SVT) Integration, Site Integration, Subject Visit (SV) Integration, and Source Data Verification (SDV) Integration. You only need to implement what is necessary for your study.
- [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.

- [Veeva Vault CTMS](#)
The integration between Oracle Clinical One Platform and Veeva Vault CTMS allows you to better monitor subject enrollment information.

Oracle's Siebel Clinical Trial Management System (CTMS)

The CTMS integration offering consists of four separate integrations; they are Study Version Template (SVT) Integration, Site Integration, Subject Visit (SV) Integration, and Source Data Verification (SDV) Integration. You only need to implement what is necessary for your study.

In the sections below, you will find details for each of the two-way data integrations between Oracle Clinical One Platform and CTMS. These include study design, site information, subject visit data, and subject verification details.

- [Study Version Template \(SVT\) Integration](#)
This incremental integration configured at the study version level runs on a schedule to identify study versions created and updated (for a configured study mode) since the last run in Oracle Clinical One Platform and creates corresponding templates in CTMS.
- [Site Integration](#)
This cumulative integration runs on a schedule to retrieve a list of sites from CTMS based on their status. The integration then creates the sites in Oracle Clinical One Platform if they do not already exist or applies updates if they do.
- [Subject Visit \(SV\) Integration](#)
This incremental integration based on the subject number runs on a schedule to identify events that occurred in a study since the last run. The integration then sends completed visit, form, and item data, subject status transitions for any subject event, and information for planned visits to CTMS.
- [Source Data Verification \(SDV\) Integration](#)
This integration runs on a schedule to generate a cumulative list of subjects that have been selected for Source Data Verification (SDV) in a study. The integration also sends incremental information on the SDV status changes at the visit level.

Study Version Template (SVT) Integration

This incremental integration configured at the study version level runs on a schedule to identify study versions created and updated (for a configured study mode) since the last run in Oracle Clinical One Platform and creates corresponding templates in CTMS.

This integration runs first if all four (4) CTMS integrations have been implemented.

Table 2-4 Details

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

Overview

- The integration retrieves study design metadata and visit schedule information corresponding to the study version, then sends them to CTMS.
- Each study version is imported as a Subject Visit Template in CTMS and includes visits, forms, items of type date/time and Boolean (Yes/No questions), and the visit schedule for each study version.
- Data is integrated in the order the requests are received.

- Data received for multiple study versions is processed in parallel.
- The integration schedule for all visits is calculated starting from the first visit.

Pre-requisites: the following should be confirmed before running the integration

- The protocol should exist in CTMS, and the name should match the study title in Oracle Clinical One Platform.

Integration user and roles

An integration user needs to be created and assigned to a custom role that includes the following permission.

- View Design

For more information about permissions, see Descriptions of permissions in Clinical One.

Exceptions

- Advanced study versioning is not supported.

Configuration

Working with the customer, the Oracle integration team creates a Configuration Setup Details Document (CSDD), which details the configuration specifications defined for integrations between Oracle Clinical One Platform and CTMS.

Site Integration

This cumulative integration runs on a schedule to retrieve a list of sites from CTMS based on their status. The integration then creates the sites in Oracle Clinical One Platform if they do not already exist or applies updates if they do.

This integration runs second if all four (4) CTMS integrations have been implemented.

Table 2-5 Details

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

Overview

- Each time the integration runs, a job is created for each site retrieved from CTMS.
- Sites created in CTMS have a different status once created in Oracle Clinical One Platform

Table 2-6 Site statuses


Status in CTMS	Status in Oracle Clinical One Platform
Initiated	New
Enrolling	Active
Terminated	Retired

- The Upsert functionality is enabled by default, and uses the unique site IDs in Oracle Clinical One Platform to determine what action to take.

- If the site does not exist, it is created.
- If the site does exist, then information for the site is updated.
- If the Site ID itself is updated, a new site is created in Oracle Clinical One Platform because it is a new site from the perspective of the integration.

CTMS site details

Table 2-7 CTMS site details

CTMS Field	Details
Time Zone	Site Time Zone is specified in the Site Management/Target Site/More Info/Site info section in CTMS.
	 Note: If the source CTMS system did not define a time zone for a site, the Oracle Clinical One Platform defaults the setting to UTC.
Primary Site Address	Primary Site Address is specified in the Site Management/Accounts tab in CTMS. The integration can be configured to define which Address type in CTMS is to be used as the Site address in Oracle Clinical One Platform.
Shipping Site Address	Shipping Site Address is specified in the Site Management/Addresses tab in CTMS. Shipping site address is not required when executing the Site integration. If the Shipping Site Address is not defined, the Site primary address is mapped to Oracle Clinical One Platform shipping address.

Pre-requisites: the following should be confirmed before running the integration

- Country names in CTMS match the template codelist values. If they do not, the job fails with an error: Country not found: <country>.

Integration user and roles

An integration user needs to be created and assigned to a custom role that includes the following permissions.

- Answer Queries
- Create and Manage Sites
- View Sites

For more information about permissions, see Descriptions of permissions in Clinical One

Exceptions

- Site status is not updated in Oracle Clinical One Platform if it is updated in CTMS.

Configuration

Working with the customer, the Oracle integration team creates a Configuration Setup Details Document (CSDD), which details the configuration specifications defined for integrations between Oracle Clinical One Platform and CTMS.

Subject Visit (SV) Integration

This incremental integration based on the subject number runs on a schedule to identify events that occurred in a study since the last run. The integration then sends completed visit, form, and item data, subject status transitions for any subject event, and information for planned visits to CTMS.

This integration runs third if all four (4) CTMS integrations have been implemented.

Table 2-8 Details

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

Overview

- You can find a list of supported Oracle Clinical One Platform events and their actions in the table below.
- Once the integration process completes, the subject data from Oracle Clinical One Platform is present in CTMS under each site, located in Site Management/{Target Site}/Subjects.

Note:

Data corresponding to these events is processed in the order of occurrence. Also, event processing for multiple subjects is done in parallel.

- 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.

Table 2-9 Supported events



Event	Action
Pre-screening	Subject information is sent to CTMS along with the visit completion date. The Encounter Date in CTMS is equivalent to the Visit Complete date in Oracle Clinical One Platform.
<div style="border-left: 2px solid #0070C0; border-right: 2px solid #0070C0; border-bottom: 2px solid #0070C0; padding: 10px;"> <p> Note:</p> <p>The Encounter Date is updated to the screening date once the subject is screened.</p> </div>	
Screening	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.
Enrolling	This event is configured for non-randomization studies. If used, the Enrolled status is sent to CTMS after the subject is screened in Oracle Clinical One Platform.
Subject Number Change	Updates the subject number for the current subject in CTMS with an updated subject number from Oracle Clinical One Platform.
Randomization	Status transition and randomization data, including randomization date, randomization number, and cohort name, are sent to CTMS after a subject is randomized in Oracle Clinical One Platform.
Withdraw	Sends subject status transitions for Subject withdraw and Undo Subject Withdraw.
Screen Fail	Sends subject status transitions for Screen Fail and Undo Screen Fail.
Completion	Sends subject status transitions for Subject Complete and Undo Subject Complete
Subject Transfer	Sends subject status transitions for Subject transfer.
Visit Dump	Sends visit and item completion dates when the visit is completed or items are updated in Oracle Clinical One Platform. This includes visits completed during Screening, Randomization, SubjectComplete, SubjectWithdraw, and SubjectTransfer.

Table 2-9 (Cont.) Supported events

Event	Action
Visit Schedule	<p>A subject's visit schedule can change based on previous visits, their treatment arm, or the completion of a form question by choosing a particular option.</p> <p>The sub-integration retrieves the planned visits for the subject and marks the corresponding visits as planned in CTMS.</p>

 **Note:**

For CTMS SV Visit schedule, sub integration would get the list of future visits from the current state of subject in the study.

Pre-requisites: the following should be confirmed before running the integration

- Sites in CTMS are active and associated with an approved study version.
- Study versions for the site in CTMS and the site in Oracle Clinical One Platform match.

Integration user and roles

An integration user needs to be created and assigned to a custom role that includes the following permissions.

- Answer Queries
- Edit Supply Settings, Blinded Groups, Label Groups and Resupply Strategies (Unblind)
- Integrate Subject Data
- View Form Data for Subjects

For more information about permissions, see Descriptions of permissions in Clinical One

Exceptions

- Subject Visit information for Adverse Events is not sent.

Configuration

Working with the customer, the Oracle integration team creates a Configuration Setup Details Document (CSDD), which details the configuration specifications defined for integrations between Oracle Clinical One Platform and CTMS.

Source Data Verification (SDV) Integration

This integration runs on a schedule to generate a cumulative list of subjects that have been selected for Source Data Verification (SDV) in a study. The integration also sends incremental information on the SDV status changes at the visit level.

This integration runs fourth if all four (4) CTMS integrations have been implemented.

Table 2-10 Details

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

Overview

- The integration sends only the first SDV performed for a visit to CTMS.
- Once the integration process completes.
 - The subject data from Oracle Clinical One Platform is displayed in CTMS under each site in the Site Management/{Target Site}/Subjects/SDV Required column.
 - Subject visit verification data is displayed in CTMS under Site Management/{Target Site}/CRF Tracking tab in the columns marked Source Verified and Source Verified Date.

Pre-requisites: the following should be confirmed before running the integration

- Study versions for sites in CTMS and in Oracle Clinical One Platform match.
- The Source Data Verification setting in Oracle Clinical One Platform is configured to allow for source data verification in a study.

Integration user and roles

An integration user needs to be created and assigned to a custom role that includes the following permissions.

- Answer Queries
- Integrate Subject Data
- Perform Source Data Verification and Reconcile Inventory

For more information on permissions, see Descriptions of permissions in Clinical One

Exceptions

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

Configuration

Working with the customer, the Oracle integration team creates a Configuration Setup Details Document (CSDD), which details the configuration specifications defined for integrations between Oracle Clinical One Platform and CTMS.

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.
- [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.
- [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.
- [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 Gateway web 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.

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](#)
- [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.

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, exposed by the Clinical One Platform Digital Gateway Builder.
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

- The web service validates the data, then triggers the parent integration (a specific integration configuration), which controls the entire integration process.
- 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.

- 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.
- Subject data is transformed per the Oracle Clinical One Platform study design.
- 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*.

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, exposed by the Clinical One Platform Digital Gateway Builder. 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.

- 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.

- 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.
- Subject data is transformed per the Oracle Clinical One Platform study design.
- 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](#).

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

About the Oracle InForm to Oracle Argus Safety integration

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

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

What does it do?

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

With this integration, AE/SAE data is sent directly from Oracle InForm to Oracle Argus Safety, eliminating the need for transcribing data into Oracle Argus Safety, thus enhancing the transparency of such data to sponsor Safety personnel, and reducing the challenges of reconciling multiple databases.

What products do I need for this integration?

The following products are required to achieve this integration:

- Oracle 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 than the one you intend to integrate, you will need the Annotated Study Book for that study, too. The instructions in this guide assume you are using the same study.

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

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

Step 2. Create an SFTP credential key

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

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

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

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

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

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

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

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

3. Click **Create**.

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

Tip:

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

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

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

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

This downloads the integration file template.

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

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

Step 5. Create a test integration

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

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

Step 5.1: Create the test integration file

Tip:

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

Task 1 Add general information

1. Open the integration template in any editor.

We recommend using an editor that is adequate for editing XML, such as Notepad++, to preserve the formatting that makes the file easier to read.

2. Specify a company name as the value for the CompanyName element:

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

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

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

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

4. Replace the constant value placeholders with the details for the study you are integrating.
 - **DTDFILEPATH** (line 315 in template): Replace this string with the full path to the DTD file on the Oracle Argus server (for example, E:\Argus\InterchangeService\DTDFiles\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.inpub.ebm.com.oracle.xmlns.informtosafety.drugsafetyreport.v1.
ReportDrugSafetyReportType</class-a>
  <class-b>oracle.hsgbu.argus.e2b.r2.Safetyreporttext</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.inpub.ebm.com.oracle.xmlns.informtosafety.drugsafetyreport.v1.
ReportDrugSafetyReportType</class-a>
  <class-b>oracle.hsgbu.argus.e2b.r2.Safetyreporttext</class-b>
  <field map-id="IchicsrSafetyReportPrimarySourceMap">
    <a>drugSafetyReportPrimarySource</a>
    <b>primarysource</b>
  <a-
hint>oracle.hsgbu.inpub.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.clinicalone.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.DefaultCodeListMapper" 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.DefaultNVLInitializer">
    <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.DefaultConcatenator" 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
1545     "toLower" decapitalizes all characters -->
1545     <field custom-
1546     converter="oracle.hsgbu.clinicalone.integration.impl.mapper.CaseConverter"
1547     custom-converter-param="toUpper">
1548         <a>this</a>
1549         <b>medicinalproduct.content</b>
1550     </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/>
1726 <!-- 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.

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.
- [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. As an Integration Viewer, follow the steps in this topic to gather information about the status of your 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:

- Title
- Study name

- Number of times to attempt to send data (includes the original attempt)
 - Email addresses that should receive integration failure notifications
 - Download the current integration file or upload a new integration file.
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.

d.

 **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.

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. As an Integration Viewer, follow the steps in this topic to gather information about the status of your integrations.

 **Note:**

With the appropriate role, you may be able to do more than just monitor integrations. For more details about the permissions associated with your roles, see [Request system 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.
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.

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

An enabled integration keeps failing

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

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

Learn more: Frequently asked questions (FAQs)

- [What are the products that I can integrate using Oracle Clinical One Digital Gateway?](#)
You can integrate a variety of applications for clinical supply services, as well as EDC systems using Oracle Clinical One Platform.
- [Do you upload an integration file every time you want to create a new integration?](#)
Yes, you have to do that every time you create a new integration.
- [How do I know when a job failed?](#)
If you add your email address when you configure the integration, you are notified by email whenever an integration failure occurs. The email notification you receive contains the following details to help you identify which job failed.
- [What are the common causes of job failure?](#)
Learn more about the common causes of job failures by reading through the list of possible use cases in this topic.

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

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

For example, you can integrate:

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

Note:

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

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

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

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

How do I know when a job failed?

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

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

What are the common causes of job failure?

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

1. If the status is Blocked, check to see which other jobs in this integration have failed and are blocking this job. Troubleshoot those Failed jobs and come back to the Blocked one to see if it works. (Does not apply to the Oracle InForm to Oracle Argus Safety integration.)
2. If this is the first time this job has failed, check and see if your credential key is still valid. If not valid, update the credential key and save your changes.
3. If this is the first time you run this integration, check that mappings in the integration file are set up correctly. After you fix the issue, re-upload the integration file.
Don't know how to create an integration file? See [Create a test integration](#) or [Create the production integration](#).
4. If this is the first time you run an Oracle InForm to Oracle Argus Safety integration, check that the path to the folder on the SFTP server is correct.
5. If none of the above helped, in the Job Details pane on the right, click Resend for this job. It may have been only a timeout issue.

6

Revision history

Date	Part number	Description
19-June-2024	F91501-03	The Time Zone setting for the Oracle Siebel Clinical Trial Management System (CTMS) - Site integration was updated with a note about the UTC default.
23-May-2024	F91501-02	The following topics were added for this version: <ul style="list-style-type: none">• Medrio Integration• ObvioHealth Integration
May-2024	F91501-01	Original version of the document. Below is a list of updates that were applied to this version. <ul style="list-style-type: none">• Get access was rewritten for accuracy.• Almac Global Depot Network, Catalent Clinical Supply Services, Fisher Clinical Services, SmartSupplies PMD were edited for clarity and readability.