Oracle® Life Sciences InForm User guide for Lab Normals Management Tool





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About this guide

This guide provides instructions to use the Lab Normals Management Tool for Oracle InForm to add, update, or remove lab vendors and lab normal ranges (LNRs), as well as source-verify data for lab vendors and lab test range data.



LNMT module overview

The Lab Normal Management Tool (LNMT) allows Oracle InForm to collect lab data entered for individual lab tests from different sites and ensures it aligns with predefined lab normal ranges (LNRs).

LNMT enhances data quality, reduces manual errors, and ensures regulatory compliance in clinical studies.



Lab vendors

In this chapter:

- Direct operations
- CSV file operations

Direct operations

In this section:

- Add a new lab vendor
- Edit a lab vendor
- Delete a lab vendor
- Audit a lab vendor

Add a new lab vendor

- 1. Log in to Oracle InForm.
- Select the LNMT tab.

The Lab List page appears.

- 3. In the Add New Lab Vendor section (bottom section) enter values for the following fields:
 - Lab ID



The Lab ID must be unique and can be an alpha numeric string up to 50 characters long.

- Lab vendor name
- Phone number
- Address
- City
- State
- Country
- 4. OPTIONAL—In the **Select Site(s) to associate with this Lab Vendor** section, select a site or sites from the **Available Sites** box and click **Add**.
- 5. Click Add Lab.

Edit a lab vendor

- 1. Log in to Oracle InForm.
- 2. Select the LNMT tab.

The Lab List page appears.

3. Select a lab from the list and click on **Edit Lab**.

The **Update Labs** section appears.

- 4. Edit the fields as needed.
- 5. Select a valid Reason For Change.
- 6. Click the **Update Labs** button.

Delete a lab vendor

- 1. Log in to Oracle InForm.
- Select the LNMT tab.

The Lab List page appears.

- 3. Select a lab and click **Delete**.
- 4. Click OK.



Lab Vendors can only be deleted if its corresponding Lab ID has not been used with any studies to send LNRs.

Audit a lab vendor

- 1. Log in to Oracle InForm.
- 2. Select the **LNMT** tab.

The Lab List page appears.

- 3. Do one of the following:
 - To get audit history for all lab vendors, click Lab Vendor Audit Report.
 - Select a specific lab from the list and click the audit () icon

A new browser window opens, displaying the audit history of the selected lab vendors.

CSV file operations

Lab vendors can be added, updated, or deleted using a CSV file. To add a lab vendor you must create this CSV file from scratch. For existing lab vendors, you can download the CSV file from the **Lab Vendor List** to make edits or remove entries.

The CSV file a lab vendor contains the following 15 columns:



Column	Description
Lab Vendor ID	Must be unique and can be an alpha numeric string up to 50 characters long.
Lab Vendor Name	Name of the lab vendor.
Address 1	First line for lab vendor's address.
Address 2	Second line for lab vendor's address.
City	Lab vendor's city.
State/Province	Lab vendor's state.
Postal Code	Lab vendor's postal code.
Country	Lab vendor's country.
Phone Number	Lab vendor's phone number.
Fax Number	Lab vendor's fax number.
Comments	Comments regarding the lab vendor.
Labdbid	Internal database identifier for the lab vendor. This is only required for updates or deletion of existing vendors. This is populated automatically in the CSV file when the CSV file is downloaded from the Lab List page.
TransactionType(I/U/D)	Only accepted values are:
	 I – Used for "Insert" commands. U – Used for "update" commands. D – Used for "delete" commands. Any other value will raise an error for that row. If no value is provided, application defaults to "I" (insert).
ReasonForChange	Used during updates or deletion of existing vendors. If not provided, application defaults to "changed information".
Associated Sites	Used if lab vendor is to be associated with sites. Lists the site mnemonics that lab vendor should be associated with.

- CSV file requirements for adding a new lab vendor
- CSV file requirements for updating an existing lab vendor
- CSV file requirements for deleting an existing lab vendor

CSV file requirements for adding a new lab vendor

To add a lab vendor, provide values for the following columns:

- Lab Vendor ID: Lab ID to be updated. This is the only true required field.
- Associated Sites: This value is only required if the lab vendor is to be associated with any sites.

You can leave **TransactionType(I/U/D)** empty, as it defaults to "I" (insert). The rest of the fields can also be empty.

If there are less than 11 columns in a row, the application will not process that row. It will give an error and process the next row.



CSV file requirements for updating an existing lab vendor

To update existing lab vendors, provide values for the following columns:

- Lab Vendor ID: Lab ID to be updated. Required.
- Labdbid: Internal Lab database identifier for the lab vendor. Required.
- TransactionType(I/U/D): Value must be "U" (update). Required.
- **ReasonForChange:** Used for auditing. If not provided, the application defaults to "changed information".
- Associated Sites: Used only if the lab vendor is associated with sites.

Any other values provided for the rest of the columns will also get updated.

CSV file requirements for deleting an existing lab vendor

To delete existing lab vendors, provide values for the following columns:

- Labdbid: Internal Lab database identifier for the lab vendor.
- TransactionType(I/U/D): Value must be "D" (delete).
- ReasonForChange: Used for auditing. If not provided, the application defaults to "changed information".

Lab vendors cannot be deleted if their corresponding Lab Vendor ID is associated with one or more studies.



Lab normal ranges (LNRs)

In this chapter:

- Direct operations
- · CSV file operations

Direct operations

In this section:

- Add a new LNR for a lab test
- · Edit LNRs for existing lab tests
- Delete an LNR
- Audit an LNR

Add a new LNR for a lab test

- 1. Log in to Oracle InForm.
- Select the LNMT tab.

The Lab List page appears.

3. Click on a Lab Vendor ID.

The **Lab Normals** page appears.

4. On the **Add New Normals** section, select or enter values for the following fields:



All fields are required except **Comments**.

- Lab Test
- Effective dates
- Specimen Type
- Gender
- Age Range

Note:

Age Range can be entered either by selecting operators and entering age with unit (for example, > 5 Years or <= 10 Months), by entering **Lower Age/Unit** and **Upper Age/Unit**, or by selecting **Not Applicable** if LNRs are note age-dependent.

- Comments
- Range Type
- Lab Normal Limits
- Unit

Note:

The combination of Lab test, Date Valid From/To, Lab Specimen Type, Lower/ Upper Limits, Unit, Gender, and Age must be unique.

5. 5. Click Add Normals button.

Edit LNRs for existing lab tests

- 1. Log in to Oracle InForm.
- 2. Select the **LNMT** tab.

The **Lab List** page appears.

3. Click on a Lab Vendor ID.

The Lab Normals page appears.

- 4. Select a Lab Test and click Edit Normals.
- 5. In the bottom section, edit fields as needed.

All fields can be updated except **Lab Test**.

- 6. Select Reason For Change. This field is required.
- Click the Update Normals button.

Delete an LNR

- 1. Log in to Oracle InForm.
- 2. Select the **LNMT** tab.

The Lab List page appears.

3. Click on a Lab Vendor ID.

The **Lab Normals** page appears.

- 4. Select a Lab Test and click Delete.
- 5. Click OK.





LNRs can only be deleted if they are not associated with any studies using LNMT.

Audit an LNR

- 1. Log in to Oracle InForm.
- 2. Select the **LNMT** tab.

The Lab List page appears.

3. Click on a Lab Vendor ID.

The **Lab Normals** page appears.

- 4. Do one of the following:
 - To get an audit report for all LNRs, click LNR Audit Report
 - Select a specific **Lab Test** from the list and click the audit () icor

A new browser window opens, displaying the audit history of the selected lab tests.

CSV file operations

LNRs can be added, updated, or deleted using a CSV file. To add a LNR you must create this CSV file from scratch. For existing LNRs, you can download the CSV file from the **Lab Normals** page to make edits or remove entries.

The CSV file a lab vendor contains the following 25 columns:

Column	Description
Lab Vendor ID	This is the ID of the lab vendor for which LNRs are being uploaded. Lab vendor ID should already exist in a system.
Lab Vendor Name	Name of the lab vendor.
Lab Test	Name of the lab test for which LNR is being added.
Result Unit	LNR Unit.
Date Valid From (dd/MMM/yyyy)	LNR Effective Start Date.
Date Valid To (dd/MMM/yyyy)	LNR Effective End Date.
Specimen Type	Lab test specimen type (enter "N/A" if not applicable).
Range Type	LNR range type (character or numeric).
Numeric Oprtr	The operator value if the numeric range is without defined lower or upper ranges.
Lower Limit	Lower numeric range.
Upper Limit	Upper numeric range.
Acceptable Character Values	If Range Type is character-based, then the valid in-range character values must be separated by ";".
Unacceptable Character Values	If Range Type is character-based, then the invalid range character values must be separated by ";".
Gender	Gender value (Male/Female) if LNR is gender- dependent; otherwise, "Both".



Column	Description
Lower Age	Lower age value if the LNR is age-dependent.
Upper Age	Upper age value if the LNR is age-dependent.
Lower Age Unit	Age unit (Days/Weeks/Months/Years).
Upper Age Unit	Age unit (Days/Weeks/Months/Years).
Valid Age Oprtr	The operator value if age is without a defined lower or upper age.
Valid Age	Age value the LNR is valid for.
Valid Age Unit	Age unit (Days/Weeks/Months/Years).
Comments	Any LNR-related comments.
LNRdbid	This is an internal database identifier for the LNR and is required for updates or deletions for existing LNRs. This is automatically populated in the CSV file when the CSV file is downloaded from the Lab Normals page.
TransactionType	Only accepted values are:
	 I – Used for "Insert" commands.
	 U – Used for "update" commands.
	 D – Used for "delete" commands.
	Any other value will raise an error for that row. If no value is provided, application defaults to "I" (insert).
ReasonForChange	This is used during updates or deletions of existing vendors. If not provided, the application defaults to "changed information".

- CSV file requirements for adding LNRs
- CSV file requirements for updating LNRs
- · CSV file requirements for deleting LNRs

CSV file requirements for adding LNRs

To add an LNR, enter placeholders for all 25 columns.

You can also leave TransactionType empty, as it defaults to I (insert).

If there are less than 25 columns in a row, the application will not process that row. It will give an error and move to the next row.

CSV file requirements for updating LNRs

To update an LNR, provide values for the following columns:

- LNRdbid: This is an internal database identifier for the LNR.
- TransactionType: ∪
- **ReasonForChange:** This is required for auditing. If not provided, application defaults to "changed information".

Any other values provided for the rest of the columns will get updated.



CSV file requirements for deleting LNRs

To delete an LNR, provide values for the following columns:

- LNRdbid: This is an internal database identifier for the LNR.
- TransactionType: D
- **ReasonForChange:** This is required for auditing. If not provided, application defaults to "changed information".



Source data verification (SDV)

LNMT allows CRA or sponsor users with the *SDV* Access right to source-verify both lab vendors and lab test range data defined in LNMT.



Users and right groups with the *SDV Access* right can only modify the SDV attribute for data entries. All other lab vendor and LNR data items appear as read-only.

SDV status can be:

- Not started No data is source-verified.
- Partially SDVd Some items are source-verified.
- SDVd All items are source-verified.

To source-verify data for either lab vendors or LNRs:

- Log in to Oracle InForm as a user with SDV access.
- 2. Select the **LNMT** tab.

The **Lab List** page appears.

3. Click on a Lab Vendor ID.

The **Update SDV** page appears.

- 4. Do one of the following:
 - Check the Verify checkbox for each individual data entry.
 - Check Select All to source-verify all data entries.
- 5. Select a valid Reason For Change.
- 6. Click the **Update Lab Vendor** button.



Source data verification does not affect LNMT integration with Oracle InForm. All functionality remains unchanged, regardless of SDV status on any LNMT data item.

LNMT Import Log Viewer

In this chapter:

Access the LNMT Import Log Viewer

Access the LNMT Import Log Viewer

The **LNMT Import Log Viewer** will display error and informative messages for each transaction.

To access the LNMT import log viewer:

- Log in to Oracle InForm.
- Go to LNMT.
- 3. Go to LNMT Import Log Viewer.

A detailed list of import transactions appears.

You can filter transactions by:

- Data Submission Status—Represents the current status of the data submission.
- Processed Date From—Starting date for filtering records based on the processed date.
- Processed Date To—Ending date for filtering records based on the processed date.
- Site—Site mnemonic.
- Visit—Visit refname.
- Form—Form refname.
- Patient Number—Unique identifier for the patient.
- Lab Vendor ID—Identifier for the lab vendor.
- Lab Test—Lab test identification value.
- LNMT Import Log Viewer display fields

LNMT Import Log Viewer display fields

This table describes the fields displayed in the LNMT Import Log Viewer.

Fields	Description
Site	Site mnemonic.
Visit	Reference name for the visit.
Form	Reference name for the form.
Patient Number	Unique identifier for the patient.
Lab Vendor ID	Identifier for the lab vendor.
Lab Test	Name of the lab test.
Collection Date	Date when the sample was collected.

Fields	Description
Lab Specimen Type	Type of specimen collected.
Lab Test Result	Outcome or result of the lab test.
Result Unit	Unit of measurement for the result.
Range Display Text Unit	Text showing the range for the lab test.
Import Error	Details errors for submissions queued for processing.
Processed Date	Most recent processing date logged by LNMT.

