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

Release 7.0.1.1

G25129-02

May 2025

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About this guide

This guide provides administrator-level setup tasks for Lab Normals Management Tool for Oracle InForm.

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Configure access

You can assign the following LNMT rights to users and rights groups created for the core Oracle InForm application.

> **✎ Note:**
>
> After the initial installation, only the solAdmin rights group is given full access to all LNMT rights.

Right	Description
LabVendorDataEntryGroups	Provides permission to update lab vendors.
LNRDataEntryGroups	Provides permission to update lab ranges for a lab.
ReadOnlyGroups	Provides read-only access to LNMT and ranges.
AdminGroups	Provides access to admin tabs and Inbound Settings for LNMT.
ViewReportsGroups	Provides permission to view the Import Log Viewer, as well as Lab and LNMT audit reports.
SDV	Provides permission to source-verify lab and range data in LNMT.
Lock/UnlockLabVendors	Provides permission to lock or unlock lab vendors.
LNMTAccess	Provides permission to give other users and rights groups access to LNMT.

- Provide access to LNMT to rights group
- Provide access to LNMT to users

Provide access to LNMT to rights group

During the initial Oracle InForm installation, only the solAdmin rights group has full access to the LNMT application.

To further modify access to rights groups:

1. Log in to Oracle InForm as a user with the *LNMTAccess* right.

2. Select the **LNMT** tab.

3. Go to **LNMT Access**.

4. Select the **Rights Group Access** tab.

   A list of users and available rights appears.

5. Select or deselect rights for each group as needed.

Provide access to LNMT to users

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1. Log in to Oracle InForm as a user with the *LNMTAccess* right.

2. Select the **LNMT** tab.

3. Go to **LNMT Access**.

4. Select the **User Access** tab.

   A list of users and available rights appears.

5. Select or deselect rights for each user as needed.

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Configure studies

In this chapter:

Associate a lab vendor with a site

When lab vendors are associated with sites, only the users belonging to those sites can see those lab vendors. This setting is required before any lab vendors can be entered in LNMT.

> **Note:**
>
> Oracle does not recommend changing this attribute once a study has been started.

To associate a lab vendor with a site:

1. Log in to Oracle InForm.
2. Select the **LNMT** tab.
3. Select **Admin (Configuration)**.
4. On **Associate Lab Vendor with Site**, select **Yes**.
5. Click **Submit**.

Lock or unlock LNMT during study lock

You can lock the LNMT application during study lock periods.

> **Note:**
>
> Locking LNMT turns the application into read-only mode, stopping all LNMT back end processing jobs.

1. Log in to Oracle InForm.
2. Select the **LNMT** tab.
3. Select **Admin (Configuration)**.

4. On **Lock LNMT for this Trial**, click **Lock**.

Configure lab vendor and LNR fields for source data verification (SDV)

Only configured fields for source data verification (SDV) include an SDV checkbox on the **Lab Vendor List** page or lab normal ranges (**LNR**) page.

1. Log in to Oracle InForm.

2. Select the **LNMT** tab.

3. Select **Admin (Configuration)**.

4. Under **Configure Lab Vendor Fields for SDV**, either **Add** or **Remove** available items to the **Fields to SDV** box and click **Save**.

5. Under **Configure Lab Normal Ranges (LNR) Fields for SDV**, either **Add** or **Remove** available items to the **Fields to SDV** box and click **Save**.

Update the LabTests.config file

To configure LNMT to display Lab Tests/with Units in the dropdown on the Admin (Lab eCRF) page or LNR page, you must download and modify the base LabTests.config file.

This file will have just the outer tags for <Tests>

```
<Tests>
    <Test name="">
        <Units>n/a</Units>
        <SpecimenTypes>n/a</SpecimenTypes>
    </Test>
</Tests>
```

For example, when adding sodium and potassium with units (separated by comma), the file looks like this:

```
<Tests>
  <Test name="Sodium">
    <Units>mEq/L, mmol/L, mEq/dL, mg/dL, mm/L</Units>
        <SpecimenTypes>Blood, Plasma, Urine</SpecimenTypes>
  </Test>
  <Test name="Potassium">
    <Units>mEq/L, mmol/L, mm/L</Units>
        <SpecimenTypes>N/A</SpecimenTypes>
  </Test>
</Tests>
```

To update the LabTest.config file:

1. Log in to Oracle InForm.

2. Select the **LNMT** tab.

3. Select **Admin (Configuration)**.

4. Click the **LabTest.config** link to download the base file.

5. Modify the LabTest.config file as needed.

6. Under **Upload Lab Tests/Units configuration (LabTests.config) to server**, click **Browse**.

7. Select the updated LabTests.config file from your computer and click **Upload**.

The base LabTest.config file will be then replaced by the new version.

Update the LabNormalsData.config file

To configure LNMT back end to process lab data for importing LNRs into Oracle InForm, you must download and modify the base LabNormalsData.config file.

This file will have just the outer tags for Labs, Visits, and TestRefs.

```
<LabForms>
  <LabForm name="">
    <RefPath></RefPath>
<RptForm>True</RptForm>
  </LabForm>
</LabForms>
<Visits>
  <Visit name="">
    <RefPath></RefPath>
<RptVisit>True</RptVisit>
  </Visit>
</Visits>
<TestRefs>
  <TestRef name="" type="C">
     <DisplayString></DisplayString>
    <InRangeFlag></InRangeFlag>
  </TestRef>
</TestRefs>
```

> ✎ **Note:**
>
> The item path reference for lab tests in the TestRefs section should reference the complete path. Do not use any 0s (zero) as placeholders for any reference in this path.

For example, when configuring Repeating Lab Form HEM, Repeating Visit Screening, the file looks like this:

```
<LabForms>
  <LabForm name="LBHEM_LBHEM_1">
   <RefPath>LBHEM_1</RefPath>
   <RptForm>True</RptForm>
  </LabForm>
</LabForms>
<Visits>
  <Visit name="ScrVisit">
    <RptVisit>True</RptVisit>
    <RefPath>ScrVst</RefPath>
```

```
    </Visit>
</Visits>
```

To update the LabNormalsData.config file:

1. Log in to Oracle InForm.

2. Select the **LNMT** tab.

3. Select **Admin (Configuration)**.

4. Click the **LabNormalsData.config** link to download the base file.

5. Modify the LabNormalsData.config file as needed.

6. Under **Upload Labs/Visits/TestRefs configuration (LabNormalsData.config) to server**, click **Browse**.

7. Select the updated LabTests.config file from your computer and click **Upload**.

The base LabNormalsData.config file will be then replaced by the new version.

Reset LNMT

LNMT allows you to reset LNMT tables if the study gets refreshed or redeployed in Oracle InForm. This functionality will back up and clean the existing LNMT processing tables so the existing LNMT instance can be used without any reference to data from old Oracle InForm instance.

To reset LNMT for a study:

1. Log in to Oracle InForm.

2. Select the **LNMT** tab.

3. Select **Admin (Configuration)**.

4. Under **Reset LNMT Database for this Trial**, click **Reset**.

5. Click **OK** on the confirmation window.

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Configure eCRF options

In this chapter:

Map lab test item controls on a lab eCRF

You can map eCRF item controls for LNMT to retrieve lab data from the Oracle InForm transactional database.

To map patient eCRF item controls for LNMT:

1. Log in to Oracle InForm.

2. Select the **LNMT** tab.

3. Select **Admin (Lab eCRF)**.

   The browser updates with two sections. **Configure Lab Controls with LNMT** (top) and **Add New lab Test with control data** (bottom).

4. Under **Add New lab Test with control data** configure all items as necessary.

   > ✏️ **Note:**
   >
   > If there are no units for the lab test on the eCRF, select **N/A** on both **Unit Radio Control** and **Unit Dropdown Control**.

5. Click **Add Lab Test**.

   The mappings are added to the LNMT database and are displayed in the **Configure Lab Controls with LNMT** section.

You can download a lab eCRF configuration CSV file for import in the **Configure Lab Controls with LNMT** section. Once the lab test configurations are QA-tested, they can be downloaded from the tested environment (for example, UAT) and uploaded into another environment for the same study (for example, Live).

Map Patient Demographic Item controls

You can map the demographics item controls for LNMT to retrieve demographic data from the Oracle InForm transactional database. There is only one entry on this form as the demographic page is common for all subjects.

To map patient demographic item controls for LNMT:

1. Log in to Oracle InForm.

2. Select the **LNMT** tab.

3. Select **Admin (Demographics)**.

The browser updates with two sections. **Configure Demographic Controls with LNMT** (top) and **Select Gender and DOB control data (select only once)** (bottom).

4. Under **Select Gender and DOB control data (select only once)**, configure all items as necessary.

> **Note:**
>
> If DOB is captured, select **N/A** for **Age Reference Date Form**.

5. Click **Add Demog**.

The mappings are added to the LNMT database and are displayed in the **Configure Demographic Controls with LNMT**.

You can download a lab demographics configuration CSV file for import in the **Configure Demographic Controls with LNMT** section. Once the demographic configurations are QA-tested, they can be downloaded from the tested environment (for example, UAT) and uploaded into another environment for the same study (for example, Live).

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Configure queries

In this chapter:

- Manage queries

Manage queries

You can configure different LNMT error conditions for creating queries in Oracle InForm. The default selection is **No**, meaning no queries will be created for any error conditions.

To configure queries:

1. Log in to Oracle InForm.

2. Select the **LNMT** tab.

3. Select **Admin (Manage Queries)**.

4. In **Enable sending Queries for this study**, select **Yes**.

5. 9. Click **Submit**.

   A table of LNMT error conditions appears.

6. Select **Yes** or **No** in **Enable Query** for each error condition.

7. Select **Open** or **Candidate** in **Query Type** for each error condition.

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Configure inbound settings

In this chapter:

- Synchronize the password for the import user
- Configure pre-processors
- Configure email preferences

Synchronize the password for the import user

You must perform the **Reset Password** operation after the initial Oracle InForm installation to synchronize the password for the import user. This is required for both native and SSO authentication modes.

In native authentication mode, the LNMT module will reset the password automatically after clicking on the **Reset Password** link.

In SSO authentication mode, the LNMT module will attempt to reset the password automatically when clicking the **Reset Password** link. If it fails, the tenant administrator credentials are required to continue.

To reset the password:

1. Log in to Oracle InForm.
2. Go to **LNMT**.
3. Go to **LNMT Inbound Settings**.
4. Under **Inbound Settings**, go to **Import User Password** and click **Reset Password**.

Configure pre-processors

1. Log in to Oracle InForm.
2. Go to **LNMT**.
3. Go to **LNMT Inbound Settings**.
4. Under Inbound Settings, click on the **Configure PreProcessors** link.

   A window with all available pre-processors opens.
5. Select or deselect pre-processors as needed.

   - **FormFrozen**—Allows data import to frozen forms.
   - **FormLocked**—Allows data import to locked forms.
   - **FormComment**—Removes any current pre-defined comments and allows data import.
6. Click **Submit**.

Configure email preferences

Email recipients, subject and content can be configured for each email type.

To configure email preferences:

1. Log in to Oracle InForm.

2. Go to **LNMT**.

3. Go to **LNMT Inbound Settings**.

4. Under **E-mail Settings**, select **Enable Sending Emails**.

5. In **SMTP Server**, enter a valid SMTP server name.

6. In the main **LNMT Inbound Settings**, configure the specific email preferences:

   • Failure Email Settings

   • Success Email Settings

   • Configuration Email Settings

Failure Email Settings

Category "Failure" emails are sent when data file fail to be imported.

Failure email settings	Description
Send Mail for Messages	Enables or disables the sending of Failure emails.
Mail From	Determines the sender email address.
Mail To	Determines the recipient email address.
Mail CC	Determines additional email recipients. Must be separated by comma.
Mail Subject (Solution name and Trial Name will be appended to the configured value)	Determines the email subject line for the emails.
Message Body for Inbound Error(s)	Determines the main body for the emails.

Success Email Settings

Category "Success" emails are sent when data file is imported successfully.

Success email settings	Description
Send Mail for Messages	Enables or disables the sending of Success emails.
Mail From	Determines the sender email address.
Mail To	Determines the recipient email address.
Mail CC	Determines additional email recipients. Must be separated by comma.
Mail Subject (Solution name and Trial Name will be appended to the configured value)	Determines the email subject line for the emails.
Message Body for Inbound Success	Determines the main body for the emails.

Configuration Email Settings

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Category "Configuration" emails are sent when an error occurs due to password reset or inbound validations.

Success email settings	Description
Send Mail for Messages	Enables or disables the sending of Configuration emails.
Mail From	Determines the sender email address.
Mail To	Determines the recipient email address.
Mail CC	Determines additional email recipients. Must be separated by comma.
Mail Subject (Solution name and Trial Name will be appended to the configured value)	Determines the email subject line for the emails.
Message Body for Configuration Error(s)	Determines the main body for the emails.