Oracle® Life Sciences InForm

User Guide for Administrators

Release 7.0.1
F56798-01
August 2024

Oracle Life Sciences InForm User Guide for Administrators, Release 7.0.1

F56798-01

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

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

Additional copyright information

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System configuration and settings

In this chapter:

- System settings
- Home page

System settings

In this section:

- Setting system configuration options
- Stopping and restarting an InForm study
- Loading a study logo
- Viewing system information
- Viewing study workarounds
- Changing the Help location
- Resolving system alerts

Setting system configuration options

System configuration options control the behavior of the study for all users. Changing some options requires that you stop and restart the study.

For more information, see Stopping and restarting an InForm study.

1. Click **Admin**.
2. On the left, click **Configuration**.
3. Fill in the fields, and click **Update**. For more information, see System Configuration page.

Stopping and restarting an InForm study

1. Open a Command Prompt window.
2. To stop a study, use the `pfadmin` command: `pfadmin stop trial`*`study name`*
3. To restart a study, use the `pfadmin` command: `pfadmin start trial`*`study name`*

Loading a study logo

The study logo appears in place of a user image in the upper-right corner of the main Oracle InForm user interface window.

The maximum width of the image file is 90 pixels, and the maximum height is 90 pixels. GIF, JPG, and PNG file types are supported.

1. Click **Admin**.
2. On the left, click **Study Logo**.
3. Navigate to, and select the file image, and click **Upload**.

> **Note:**
>
> If you specify a user image, it overrides the study logo.

Viewing system information

1. Click **Admin**.
2. On the left, click **System**.

Viewing study workarounds

1. Click **Admin**.
2. On the left, click **System Changes Log**.

   The page contains a read-only list of workarounds and upgrades applied to your study, and is intended for use by Oracle Global Support and Services.

Changing the Help location

By default, the Oracle InForm documentation set is available on the Oracle Help Center (OHC).

You can use the files from their default location in the OHC, or you can move the files to an internal website that can be located locally, or externally from the Oracle InForm server. Using a pfadmin command you can update the Oracle InForm Help link so that it points to the new location. For more information, see the *Installation Guide*.

1. Open a Command Prompt window.
2. To change the Help location, use the `pfadmin` command:

   ```
   pfadmin config service /HelpUrl <Full URL for the Help site>
   ```

3. To access documentation for this release, run the pfadmin command to update the Help location to https://www.oracle.com/goto/inform-701

Resolving system alerts

1. Click **Admin**.
2. On the left, click **Sites**.
3. In the first column, click the name of the site with the invalid time zone.
4. Update the **TimeZone** field, and click **Submit**.

   If you update the time zone successfully, the alert is immediately closed, and it no longer appears on the Alerts page.

Home page

In this section:

- Setting the Home page for a user
- Updating the Home page with an HTML file
- Setting up key contacts

Setting the Home page for a user

1. Click **Admin**.
2. On the left, click **Users**.
3. Click a user.
4. In the **Home Page** field at the bottom of the page, type the path to the Oracle InForm Portal Home page.

   The default path is ./aspmvc/portal/display/renderpage?home=1.
5. To configure the language for the Oracle InForm Portal pages, select the **Product Locale** and **Preferred Study Locale**.
6. Click **Submit**.

Updating the Home page with an HTML file

1. Create an HTML file for the Home page.
   - The HTML file for the Home page must be plain HTML without JavaScript. The application processes and sanitizes the file, removing script tags and other potentially harmful elements.
   - If the HTML file for the Home page contains images, the src attribute of the image tag must use this syntax: <img src=../../Portal/Document/GetImage?filename=<*image_name*.ext>>
     <*image_name.ext*> is the name of the image file, including its extension.
   - If the HTML file for the Home page includes the company logo, the src attribute of the image tag must use this syntax: <img src="../../Portal/Document/GetCompanyLogo?filename=company_logo.gif">
2. In the upper-left of the Home page, select the **Admin** tab.
3. In the Edit Records section, click **Update Homepage**.
4. Browse to the HTML file, and click **Open**.
5. If the HTML file contains five or fewer image files, upload the files individually using the **Select image file** fields, then click **Submit**.

   or

   If the HTML file contains more than five image files:

   a. Submit the files.
   b. Click **Update Homepage**.
   c. Upload the additional image files.

d. Click **Submit**.

Setting up key contacts

1. Click **Admin**.
2. On the left, click **Users**.
3. Click a user you want to designate as a key contact.
4. Verify that the phone number and email fields contain data.
5. In the **Description** field, type: **Public**.
6. Click **Submit**.

2

Rights, groups, sites, and users

In this section:

- Rights and rights groups
- Groups and item groups
- Display overrides
- Sites
- Users

Rights and rights groups

in this section:

- Creating a rights group and assigning its rights
- Specifying archival rights for CRF Submit users
- Modifying a rights group

Creating a rights group and assigning its rights

1. Click **Admin**.
2. On the left, click **Rights**.
3. At the bottom left of the page, click **Add Rights Group**.
4. In the **Rights Group Name** field, type a name for the rights group.

   > **Note:**
   >
   > A rights group name cannot be the same as an existing group name.

5. Select the rights for the rights group, and click **Submit**.

Specifying archival rights for CRF Submit users

1. Click **Admin**.
2. On the left, click **Rights**.
3. Select a rights group.
4. In the Archival Rights section, select the CRF Submit rights to assign to the group.
   - Generate Archives
   - Administer Archives
   - Delete Archives

- View All Completed Archives
- Manage Templates
- Share Archives with Sites
- Confirm Archives Download
- View Download Confirmation
- Download for eTMF

> **Note:**
>
> If you select **Download for eTMF**, you cannot select any other Archival rights.

5. Click **Submit**.

Modifying a rights group

Adding or removing rights in a rights group:

1. Click **Admin**.
2. On the left, click **Rights**.
3. In the first column, click a rights group.
4. Select or deselect any rights, and click **Submit**.

Adding or removing users in a rights group:

1. Click **Admin**.
2. On the left, click **Rights**.
3. In the List Users column, click Change Users for a rights group.
4. Add or remove users as needed, and click Submit.

Groups and item groups

In this section:

- Creating a group or item group
- Modifying a group or item group

Creating a group or item group

1. Click **Admin**.
2. On the left, click **Groups**.
3. At the bottom left of the page, click **Add Group.**
4. Fill in the fields, and click **Submit.**

> **Note:**
>
> A group name cannot be the same as an existing rights group name.

Modifying a group or item group

Modifying the users or items in a group:

1. Click **Admin**.
2. On the left, click **Groups**.
3. On the right in the Members column, click **Change** for the group or item group.
4. Add or remove users or items, and click **Submit**.

Modify the group details:

1. Click **Admin**.
2. On the left, click **Groups**.
3. In the first column, click a **Group Name**.
4. Fill in the fields, and click **Submit**.

Display overrides

In this section:

- Display overrides
- Assigning a display override to a rights groups

Display overrides

1. Create an item group containing the items whose display properties you want to override. For more information, see Creating a group or item group.
2. Assign the item group to a rights group as Editable, Read-only, or Hidden. For more information, see Assigning a display override to a rights group.

Assigning a display override to a rights groups

1. Click **Admin**.
2. On the left, click **Rights**.
3. In the Display Overrides column, click **Change Overrides** for a rights group.
4. At the bottom left of the page, click **Read-Only**, **Editable**, or **Hidden** to specify the type of display override.
5. Add to, or modify the item groups for the display override, and click **Submit**.

> **Note:**
>
> An item group can be in only one display override per rights group.

Sites

In this section:

- Creating a site
- Viewing or modifying site information
- Viewing or modifying the members in a site
- Viewing the list of subjects at a site

Creating a site

1. Click **Admin**.
2. One the left, click **Sites**.
3. At the bottom left of the page, click **Add Site**.
4. Fill in the fields, and click **Submit**.

The Site Name, Site Mnemonic, and Study Locale fields are required.

In the Study Version field, enter the study version associated with the site. The study version determines which version of the forms, study protocol, and study documents for a study appear to users at the site.

Viewing or modifying site information

1. Click **Admin**.
2. On the left, click **Sites**.
3. In the **Site Name** or **Site Abbrv** column, click a link.
4. Modify the site information, and click **Submit**.

   For more information, see Sites detail page.

Viewing or modifying the members in a site

1. Click **Admin**.
2. On the left, click **Sites**.
3. In the Users column, click **Change** for a site.
4. Add or remove users from the site, and click **Submit**.

Viewing the list of subjects at a site

1. Click **Admin**.
2. On the left, click **Sites**.

3. In the Subjects column, click **List** or **Transfer** for a site.

> **Note:**
>
> The name of the link depends on your rights.

Users

In this section:

- Creating a user
- Assigning a password to a user
- Assigning or modifying a user association to a rights group, site, and other groups
- Activating or deactivating a user
- Terminating or reinstating a user

Creating a user

1. Click **Admin**.
2. On the left, click **Users**.
3. At the bottom left of the page, click **Add User**.
4. Fill in the fields, and click **Submit**.

   The User Name, Product Locale, and Preferred Study Locale fields are required.

Assigning a password to a user

1. Click **Admin**.
2. On the left, click **Users**.
3. Click a user.
4. If necessary, deselect **User Active**, and click **Submit**.
5. At the bottom left of the page, click **Change Password**.
6. Enter and confirm a password, and click **Submit**.

   Passwords should have a minimum of 8 characters. For security reasons, Oracle recommends using a combination of letters, numbers, and non-alphanumeric characters. Passwords are case-sensitive.
7. Select **User Active**, and click **Submit**.

Assigning or modifying a user association to a rights group, site, and other groups

After you create users, you assign them to a rights group and associate them with certain sites.

Before you start, make sure that the groups and a site have been created. For more information, see:

- Creating a rights group and assigning its rights.
- Creating a group or item group.
- Creating a site.

1. Click **Admin**.
2. On the left, click **Users**.
3. Click a user.
4. Click the **Group** tab.
5. Select a rights group for the user.

   A user can be a member of only one rights group.
6. Select the user's sites.

   Users have access only to the data for the sites with which they are associated.
7. If applicable, assign the user to one signature group, one query group, and one or more reporting groups.

   For more information, see Group types.
8. Click **Submit**.

Activating or deactivating a user

1. Click **Admin**.
2. On the left, click **Users**.
3. Select the checkbox next to the users you want to activate or deactivate.
4. At the bottom left of the page, click **Activate** or **Deactivate**.

> **Note:**
>
> Oracle recommends that you keep one user with administration rights active at all times.

Terminating or reinstating a user

1. Click **Admin**.
2. On the left, click **Users**.
3. Select the checkbox next to the users you want to terminate or reinstate.
4. At the bottom left of the page, click **Terminate** or **Reinstate**.

> **Note:**
>
> You can only reinstate terminated users. When you reinstate a terminated user, the user's status is updated to inactive. The user can then be reactivated.

3
Rules and events

In this chapter:

- Modifying rule details
- Running rules in batch mode
- Viewing the status of batch run rules
- Viewing or modifying event details

Modifying rule details

1. Click **Admin**.
2. On the left, click **Rules**.
3. Click the reference name for a rule.
4. Edit the details, and click **Submit**.

Running rules in batch mode

Oracle recommends running calculation rules prior to form rules because calculation rules can alter clinical data values.

1. Click **Admin**.
2. On the left, click **Rules**.
3. At the bottom left of the page, click **Select Rules to Run**.
4. At the bottom left of the page, from the **Rule Type** filter, select the type of rule to run.

   > **Note:**
   >
   > To run workflow rules and global conditions, select **Workflow**.

5. Select the rules to run.

   or

   To select all the rules, select the checkbox to the left of **Reference Name**.
6. At the bottom right of the page, click **Run Calculations** for calculation rules.

   or

   At the bottom right of the page, click **Run Rules** for form rules, workflow rules, and global conditions.
7. Select the sites and subjects to run the rules on.
8. At the bottom left of the page, click **Start Running Rules**.

Running the rules may take a long time. When the rules finish running, you can check the applicable items of subject data to ensure that the rules produced the expected results.

> **Note:**
>
> The audit trail for modified item values records the name of the user who runs the rule; it does not record the name of the user who submitted the original data values.

Viewing the status of batch run rules

1. Click **Admin**.
2. On the left, click **Rules**.
3. At the bottom left of the page, click **Batch Run Status**.

   This button appears only after one or more batch rule selections are created.
4. To view more details, click a rule.

Viewing or modifying event details

1. Click **Admin**.
2. On the left, click **Events**.
3. In the first column, click the reference name for an event.
4. View or edit the information on the page, and click **Submit**.

4

Custom events

In this chapter:

- View a study's custom events
- View the transmission history for a study's custom events
- View the error log for a study's custom events

View a study's custom events

1. Click **Custom Events**.
2. On the left, click **Deployed Custom Events**.

   The page contains a read-only list of custom events for your study, and their settings. This feature is only compatible with Oracle InForm Publisher release 6.2 and higher.

View the transmission history for a study's custom events

1. Click **Custom Events**.
2. On the left, click **Transmission History Logs**.

   The page contains a read-only list of custom event transmissions for your study, and indicates whether the transmission completed successfully. This feature is only compatible with Oracle InForm Publisher release 6.2 and higher.

View the error log for a study's custom events

1. Click **Custom Events**.
2. On the left, click **Failed Transmission Logs**.

   The page contains a read-only list of errors due to communication issues, end point unavailability, or Oracle InForm Publisher exceptions. This feature is only compatible with Oracle InForm Publisher release 6.2 and higher.

5
FAQs

In this chapter:

- System configuration and setting FAQs
- Right and rights group FAQs
- Group FAQs
- Display override FAQs
- Site FAQs
- User FAQs
- Rule and event FAQs

System configuration and setting FAQs

Can I set up all the administrative data and configuration parameters with the Oracle InForm Admin user interface?

No. All study parameters are defined in Oracle Central Designer, and then deployed to Oracle InForm. Some parameters can only be modified in Oracle Central Designer. For more information, see the Oracle Central Designer *User Guide*.

After deployment, you can modify some study parameters through the Oracle InForm Admin user interface, or by editing XML files and installing them using the MedML Installer utility. For more information, see Oracle InForm administration tasks.

- You can use the Oracle InForm Admin user interface to modify study elements such as users, groups, and sites one at a time. This guide provides instructions for configuring administrative features through the Oracle InForm Admin user interface.
- You can use MedML and the MedML Installer utility to modify the definitions of multiple study elements and load them into the database in batch mode. For more information, see the *Utilities Guide*.

The User Management Tool can also be used to set up initial study elements such as users and sites. For more information, see the User Management Tool documentation.

What is the difference between a study logo and a company logo?

A study logo appears in place of a user image in the upper-right corner of the main Oracle InForm user interface window. For more information, see Loading a study logo.

A company logo appears in the Home page for a study that is defined with the Oracle InForm Portal. For more information, see the *User Guide for Sponsor Users*.

Do I have to set up a Home page?

No. The Home page is a web portal that appears in the main user interface window when users log in to Oracle InForm. It provides users access to information about the study, such as a company logo, white papers, links to key contacts, and news items.

You use the Oracle InForm Portal to define a Home page. User rights determine the information that users see. Tabs, and sections within the tabs, organize content.

If you do not define a Home page, the center of the main Oracle InForm window is blank when users log in.

What causes an invalid time zone alert?

An invalid time zone alert can occur if:

- You recently started a study.
  When a study starts, all sites are checked for invalid time zones.
- You added or updated the time zone for a site with the MedML Installer utility.
- There was a Windows update.
  Time zone display names can change as part of standard Windows updates, which can cause time zones associated with existing sites to become invalid. As a result, times may not appear in the local time as expected in the user interface.

Right and rights group FAQs

What is the difference between a right and a rights group?

A right is the permission to perform a specific activity. A rights group is a collection of rights.

How do I give a user rights to perform study activities?

When you create a new user, you assign the user to a rights group.

Can users make changes to the rights group that they belong to?

No.

Group FAQs

What is a group?

A group associates users with others in similar roles for a study. To perform certain activities, users have to be granted certain rights, and be a member of a group associated with that activity.

What is an item group?

An item group is a set of items that you group together so that you can assign a display override to them. Display overrides allow you to specify that, for a particular rights group, the group of items that makes up an item group is Hidden, Editable, or Read-Only. This designation overrides the rights conveyed by membership in the rights group and also overrides the display properties of the items in the group.

What types of groups are there?

- Query
- Signature
- ItemGroup
- Reporting

For more information, see Group types.

Can users belong to more than one group?

Yes. Users can belong to one Query group, one Signature group, and multiple Reporting groups.

How many item groups can one item belong to?

An item can belong to one item group.

Can I assign an item group to more than one rights group?

Yes. Multiple rights groups can use the same item group.

Display override FAQs

What is a display override and when do I use it?

A display override is a property that allows you to give the members of a rights group different access to a group of items that make up an item group as Hidden, Editable, or Read-only. This designation overrides the rights conveyed by membership in the rights group and also overrides the display properties of the items in the group.

How are display overrides created?

Display overrides can be defined for rights groups in Oracle InForm or Oracle Central Designer. For more information, see Defining a display override and the Oracle Central Designer *User Guide*.

Display overrides created in Oracle InForm take precedence over display overrides created in Oracle Central Designer.

Site FAQs

What does it mean to associate a user with a site?

A user must be associated with a site to have access to that site's data. You should associate users with every site that they work in.

User FAQs

Why can't a user access Oracle InForm?

Uses that are marked as inactive or terminated can't access Oracle InForm. You must activate the user to grant access.

Why can't a user access all the system configuration options?

In SSO-enabled studies, some configuration parameters are restricted. For example, user information cannot be updated through the Oracle InForm user interface.

Why can't I change a user's password?

To change a user's password, the user must be inactive.

I reinstated a terminated user but the user still can't access Oracle InForm. Why?

You must activate the reinstated user to grant access. Terminated users are always reinstated as inactive and inactive users can't access Oracle InForm.

Rule and event FAQs

What is a rule?

A rule is a script that a study designer creates in Oracle Central Designer that specifies how data in Oracle InForm is calculated or validated.

- Calculation: Used to determine the value of a data item based on the value of another data item.
- Form rule: Edit check on a form data item.
- Conversion: Rule that converts data from the units in which it is entered to normalized units that other rules can reference.
- Randomization: Rule that randomizes subjects in order to assign drug kits to them.
- Workflow: Rules that control how and when dynamic visits and forms appear in Oracle InForm.
- Global condition: Conditions that control how and when dynamic visits and forms appear in Oracle InForm.
- Subject Rule: Rules used for assigning certain types of subjects to the SV eligible and/or excluded pools based on subject data.

For information about rules and rule design, development, and testing, see the Oracle Central Designer *User Guide* and the Oracle Central Designer *Rules Reference Guide*.

What is an event?

An event specifies what happens in Oracle InForm based on the outcome of a rule. For example:

- The event can generate a new query or close an answered query.
- The event can run one or more execution plans that:
  - Send e-mail.
  - Send an entry to the Windows log file.

Events (known as Rule Actions in Oracle Central Designer) are defined as part of the study design.

I didn't modify the details for a rule in Oracle InForm. Why did they change?

When a new package is deployed from Oracle Central Designer, any rule details you modified in Oracle InForm are overwritten by the rule details specified in Oracle Central Designer. To permanently modify rule details, use Oracle Central Designer.

Why do I see errors when I view the status of batch run rules?

You might see errors if:

- You ran the rule on a case report book that is frozen or locked.
- You ran a calculation rule on a case report book with individually frozen or locked forms.

Make sure that on the System Configuration page, you set **Allow sponsor users to edit frozen forms** to **Yes**.

6 What if...

In this chapter:

- A Table does not exist error appears for my custom events
- The transmission history log for my study's custom events is empty
- N/A appears for my custom event's RefName and Subject Number in the error log

A `Table does not exist` error appears for my custom events

If you are using Oracle InForm Publisher 6.2 or later, and you click Custom Events, and select Transmission History Logs, or Failed Transmission Logs, an error that says, `Table does not exist` appears if the study isn't subscribed to an Oracle InForm Publisher subscriber.

To view the transmission history or error log for your study's custom events, configure the study with Oracle InForm Publisher and try again.

The transmission history log for my study's custom events is empty

If you are using Oracle InForm Publisher 6.2 or later, and you click Custom Events, and select Transmission History Logs, the page is empty if your study is successfully subscribed to an Oracle InForm Publisher subscriber but there is no transmission history to report. When custom events begin firing for the study, the page is populated.

N/A appears for my custom event's RefName and Subject Number in the error log

If you are using Oracle InForm Publisher 6.2 or later, and you click Custom Events, and select Failed Transmission Logs, the RefName and Subject Number columns contain the text N/A if an internal Oracle InForm Publisher exception occurred, and the transmission data could not be populated in Oracle InForm. To fix this issue, resolve the Oracle InForm Publisher error.

7

Reference

In this appendix:

- Oracle InForm administration tasks
- Rights required for typical study activities
- System Configuration page
- Group types
- Sites detail page
- User details page

Oracle InForm administration tasks

The following administrative tasks are required when setting up and administering a study.

- For lists of the rights associated with performing all study tasks, see Rights required for typical study activities.
- For information on the MedML elements, see the *Utilities Guide*.

Task	Supported in the Oracle InForm Admin user interface	Supported in the Oracle InForm MedML Installer utility
Manage system settings	Yes Required right: Modify System Configuration	Yes MedML element: SysConfig
Manage rights and rights group	Yes Required right: Manage Rights Groups	Yes MedML elements: – Right – RightsGroup
Manage groups and item groups	Yes Required right: Manage Other Groups	No
Manage display overrides	Yes Required rights: – Manage Rights Groups – Manage Other Groups	No
Maintain rules	Yes Required right: At least one rule administration right: – Deactivate a Rule – Run a Rule – Modify a Rule	No

Task	Supported in the Oracle InForm Admin user interface	Supported in the Oracle InForm MedML Installer utility
Maintain events	Yes Required right: At least one rule administration right: – Deactivate a Rule – Run a Rule – Modify a Rule	No
Manage sites	Yes Required right: Manage Sites	Yes MedML element: Site
Manage users	Yes Required rights: – Create User – Modify User Information – Activate Site User – Deactivate Site User – Activate Sponsor user – Deactivate Sponsor User – Terminate User – Un-Terminate User	Yes MedML element: User
Transfer subjects	Yes Required right: Subject Transfer	No
Assign rights for custom review states for the Data Viewer	Yes Required rights: To assign and view the custom review states in the Data Viewer: – Access Data Viewer / Data Export Listings – One or more of the following: * Assign Review State 1 * Assign Review State 2 * Assign Review State 3 * Assign Review State 4 * Assign Review State 5 – View Review States	No
Configure partial source verification	Yes Required rights: – Mark and Unmark a CRF as SVed – Change Site SV Settings – View CRF	Yes MedML elements: – SVCriticalForm – SVCriticalItem

Rights required for typical study activities

In this section:

- System administration rights
- CRF rights
- Case report book rights

- Oracle InForm Portal rights
- Query rights
- Rule rights
- User rights for display overrides
- Navigation rights
- Miscellaneous user rights
- Data Viewer rights
- Study deployment rights

System administration rights

To perform this activity	A user must have these rights (Category: Right)
Change system configuration settings	User Admin: Modify System Configuration
View system configuration settings	User Admin: View System Configuration
Create a user	User Admin: Create User
View user information	User Admin: View User Information
Change user passwords	User Admin: Modify User Information
Change user name, address, and contact information	User Admin: Modify User Information
Assign a user to rights, query, and signature groups and to one or more sites	User Admin: Modify User Information
Activate an Inactive user designated as a Site user	User Admin: Activate Site User
Deactivate an Active user designated as a Site user	User Admin: Deactivate Site User
Activate an Inactive user designated as a Sponsor user	User Admin: Activate Sponsor User
Deactivate an Active user designated as a Sponsor user	User Admin: Deactivate Sponsor User
Terminate a user	User Admin: Terminate User
Change the status of a Terminated user to Inactive	User Admin: Un-Terminate User (change to Inactive Status)
Create, modify the definition, and manage the membership of rights groups	User Admin: Manage Rights Groups
Create, modify the definition, and manage the membership of query groups and signature groups	User Admin: Manage Other Groups
Create, modify the definition, and manage the authorization of users to sites	User Admin: Manage Sites
Update study logo	User Misc: Update Study Logo
Configure partial source verification	• CRF Rights: Mark and Unmark a CRF as SVed • CRF Rights: Change Site SV Settings • User Misc: View CRF
View the definition and membership of rights groups.	User Misc: View Rights Groups
View the definition and membership of query groups and signature groups.	User Misc: View Other Groups
View the definition and authorization of users to sites.	User Misc: View Sites

CRF rights

To perform this activity	A user must have these rights (Category: Right)
Enter CRF data	• CRF Rights: Enter Data into a CRF • User Misc: View CRF
Edit CRF data	• CRF Rights: Edit Data on a CRF • User Misc: View CRF
Enter comments on a CRF item or on a whole CRF	• CRF Rights: Enter Comments into a CRF • User Misc: View CRF
Freeze a CRF	• CRF Rights: Freeze a CRF • User Misc: View CRF
Unfreeze a CRF	• CRF Rights: Unfreeze a CRF • User Misc: View CRF
Lock a CRF	• CRF Rights: Lock a CRF • User Misc: View CRF
Unlock a CRF	• CRF Rights: Unlock a CRF • User Misc: View CRF
Indicate a CRF is ready for source verification, or indicate that a CRF that was ready for source verification is no longer ready	• CRF Rights: Mark a CRF as Ready for SV • User Misc: View CRF
Perform source verification on CRF data	• CRF Rights: Mark and Unmark a CRF as SVed • User Misc: View CRF To view the Source Verification Listing, the Monitor right is also required.
Sign a CRF	• CRF Rights: Sign a CRF • User Misc: View CRF The user also must be in the same signature group as the CRF to sign.
Configure Partial SV	• CRF Rights: Mark and Unmark a CRF as SVed • CRF Rights: Change Site SV Settings • User Misc: View CRF

Case report book rights

To perform this activity	A user must have these rights (Category: Right)
Sign a case report book	• Case Book Rights: Sign a Case Book • User Misc: View CRF The user also must be in the same signature group as the CRF designated as the signing CRF for the Case Book.
Indicate a case report book is ready for source verification, or indicate that a case report book that was ready for source verification is no longer ready	• Case Book Rights: Mark and Unmark a Case Book as Ready for SV • User Misc: View CRF
Freeze a case report book	• Case Book Rights: Freeze a Case Book • User Misc: View CRF

To perform this activity	A user must have these rights (Category: Right)
Unfreeze a case report book	• Case Book Rights: Unfreeze a Case Book • User Misc: View CRF
Lock a case report book	• Case Book Rights: Lock a Case Book • User Misc: View CRF
Unlock a case report book	• Case Book Rights: Unlock a Case Book • User Misc: View CRF

Oracle InForm Portal rights

To perform this activity	A user must have these rights (Category: Right)
Update company logo	Portal: Update Company Logo
Manage the InForm Portal application as the Home page	Portal: Update Homepage
Work with tabs and sections in the InForm Portal application	• Portal: Add/Edit Tabs • Portal: Add/Edit Sections
Manage documents in the InForm Portal application	Portal: Upload/Update Documents
Set up key contacts	Portal: Add/Edit Tabs

Query rights

To perform this activity	A user must have these rights (Category: Right)
Open a Candidate query so that it becomes visible to the site	• Query Rights: Change Query State from Candidate to Open • User Misc: View CRF The user also must be defined as a Sponsor user.
Delete a Candidate query	• Query Rights: Change Query State from Candidate to Deleted • User Misc: View CRF The user also must be defined as a Sponsor user and must be a member of the same query group as the user who created the Candidate query.
Close an answered query	• Query Rights: Change Query State from Answered to Closed • User Misc: View CRF The user also must be a member of a query group.
Close a query in the Opened state	• Query Rights: Change Query State from Open to Closed • User Misc: View CRF The user also must be defined as a Sponsor user and be a member of the same query group as the user who opened the query.

To perform this activity	A user must have these rights (Category: Right)
Close a query that has been reissued in the Candidate state	• Query Rights: Change Query State from Reissued Candidate to Closed • User Misc: View CRF The user also must be defined as a Sponsor user and be a member of the same query group as the user who reissued the query.
Answer a query	• Query Rights: Answer Query • User Misc: View CRF
Enter a query in the Candidate state so that it is not visible to the site	• Query Rights: Enter Query in Candidate State • User Misc: View CRF The user also must be defined as a Sponsor user.
Enter a query in the Opened state so that it is visible to the site	• Query Rights: Enter Query in Open State • User Misc: View CRF
Reissue an answered query in the Candidate state so that it is not visible to the site	• Query Rights: Re-issue Query in Candidate State • Query Rights: Enter Query in Candidate State • User Misc: View CRF The user also must be defined as a Sponsor user and must be a member of the same query group as the user who created the query.
Reissue an answered query in the Opened state so that it is visible to the site	• Query Rights: Re-issue Query in Open State • Query Rights: Enter Query in Open State • User Misc: View CRF The user also must be a member of the same query group as the user who originally created the query.
Resolve a query that is in a conflict state because multiple users using different copies of a study acted on it before synchronizing	• Query Rights: Resolve Query in Conflict • User Misc: View CRF To resolve a Site Conflict, a user must be defined as a Site user. To resolve a Sponsor Conflict, a user must be defined as a Sponsor user.

Rule rights

To perform this activity	A user must have these rights (Category: Right)
Cancel an active rule	Rule Rights: Deactivate a Rule
Run an existing rule	Rule Rights: Run a Rule
View the list of batch rule jobs	Rule Rights: Run a Rule
Edit an existing rule	Rule Rights: Modify a Rule
View or modify an event	One of the following: • Rule Rights: Deactivate a rule • Rule Rights: Run a Rule • Rule Rights: Modify a rule

User rights for display overrides

Each of the rights applies to all data items on all forms.

To perform this activity	A user must have these rights (Category: Right)
View all items in all forms.	User Misc: View CRF
Add data to items that have not had data entered previously.	• CRF Rights: Enter Data into a CRF • User Misc: View CRF **Note:** These rights are commonly assigned to users in a CRC role. Both the **Enter Data into a CRF** right and the **View CRF** right must be assigned to enable this access.
Update data in items in which data has been entered previously.	• CRF Rights: Edit Data on a CRF • User Misc: View CRF **Note:** These rights are commonly assigned to users in a CRC role. Both the **Edit Data on a CRF** right and the **View CRF** right must be assigned to enable this access.

Navigation rights

To perform this activity	A user must have these rights (Category: Right)
Place subjects (at a site) in a particular order for more efficient data entry.	• Navigation: Reordering Of Subjects • User Misc: View CRF

Miscellaneous user rights

To perform this activity	A user must have these rights (Category: Right)
Print a CRF	User Misc: Print
Create Visit Reports	User Misc: Monitor
Create records of regulatory document reviews	User Misc: Monitor

To perform this activity	A user must have these rights (Category: Right)
Run reports with the InForm Reporting and Analysis module	User Misc: Reports
Screen and enroll study candidates	• User Misc: Enroll Subjects • CRF Rights: Enter Data into a CRF • User Misc: View CRF
View Screening Log (read-only)	• User Misc: Enroll Subjects or • User Misc: Monitor, with no CRF rights
Display Required Signatures page and see CRF signing status for all signature groups (read-only)	User Misc: View CRF Signature Information
Display Required Signatures page and see case report book signing status for all signature groups (read-only)	User Misc: View Case Book Signature Information
Export listings of CRF data to an external data source	Data Viewer Rights: Access Data Viewer / Data Export Listing
Transfer subject records from one site to another	User Admin: Subject Transfer
View Custom Events	User Misc: View Custom Events

Data Viewer rights

To access the data displayed in the Data Viewer, users must have one or more of the Data Viewer rights, as well as the Oracle InForm rights required for that data.

To perform this activity	A user must have these rights (Category: Right)
Access the Data Viewer	Data Viewer Rights: Access Data Viewer / Data Export Listing right
View custom review states assigned to records	Data Viewer Rights: View Review States
Assign custom review states in the Data Viewer	One or more of the following: • Data Viewer Rights: Assign Review State 1 • Data Viewer Rights: Assign Review State 2 • Data Viewer Rights: Assign Review State 3 • Data Viewer Rights: Assign Review State 4 • Data Viewer Rights: Assign Review State 5 **Note:** Custom review states are defined in Oracle Central Designer, not Oracle InForm. For more information, see the Oracle Central Designer *User Guide*.

Study deployment rights

To perform this activity	A user must have these rights (Category: Right)
Schedule or run an Oracle InForm study deployment	Automated Deployment: Study Deployment
Cancel a scheduled deployment	Automated Deployment: Study Deployment
View, save, or delete the deployment log	Automated Deployment: Study Deployment
View deployment information and deployment log files	Automated Deployment: View Study Deployment

System Configuration page

In this section:

- Fields—Optional System Configuration
- Fields—Workflow Options
- Fields—SV Settings
- Fields—System Security Configuration

Fields—Optional System Configuration

Field	Description
Enroll subject with incomplete form	Yes or No (default). Indicates whether the Oracle InForm application permits a subject to be enrolled with incomplete screening or enrollment information, after override authorization.
Require a comment when entering N/A, Unknown, or Not Done	Yes or No (default). Indicates whether the Oracle InForm application requires a user to enter a comment when selecting Not Applicable, Unknown, or Not Done on the Comment page instead of filling in a question on a form.
Display Comment Text Boxes	Yes (default) or No. Indicates whether to enable a text box where users can enter a comment for a form or item. If you select Yes for **Require a comment when entering N/A, Unknown, or Not Done**, you can't select No for FreeCommentTextBox. If you select No, existing comments appear as read-only text, and the option to select Not Applicable, Unknown, or Not Done in the Reason incomplete field is available only for items without data.
Show Unscheduled	Yes (default) or No. Indicates whether to show the word Unscheduled in the visit title of unscheduled visits.
Post a query for conflict resolution	Yes or No (default). Indicates whether to create a query when, during communication with the Central Coding application, data is found to be entered into a data item by the two different servers.

Field	Description
Number of execution plan listener threads	Number of threads running in the background to process pending execution plans. The default is 4; at least 1 is required for any execution plans to run.
Number of Workflow Update threads	Number of threads running in the background to process the workflow update. This value is set during study setup, and typically only needs to be set one time per study. The default value is 2. **Caution:** You should not adjust this setting without input from Oracle Global Support. If the performance of your study deployment or study migration is too slow (for example, timeouts happen), contact Oracle Global Support for assistance.
Number of execution plan re-submits	Maximum number of times to retry submission of a failed execution plan before it is logged as an error in the event log and removed from the queue of execution plans to be run. The default is 2.
Enable SSL	On or Off (default). Indicates whether Secure Sockets Layer should be enabled to provide encryption of data. Secure Sockets Layer is an encryption protocol that is provided with the browser software used to run the Oracle InForm application. **Note:** Before this option can take effect, you must stop and restart the study.

Field	Description
Automatically answer manual queries	On (default) or Off. Indicates whether the Oracle InForm application automatically changes a manual query state to Answered when a data item is updated. **Note:** Regardless of this setting, the query workflow always performs an auto-answer when the Update Data and Answer option is used.
Maximum length of query text	Maximum number of characters of query text displayed below an item on a CRF. The default is 350 characters.

Field	Description
Require unique subject initials and date of birth	Study, Site, or None (default). Indicates whether the Oracle InForm application requires a unique combination of subject initials and date of birth for a study, a site, or not at all. **Note:** If you specify that unique initials and date of birth are not required, and subjects with duplicate initials and date of birth are entered, and later you specify that unique IDs are required, the duplicate information that was entered previously will not be reported. Subject record transfer consideration: If you plan to allow the transfer of subjects from one site to another, set the UniqueIntIDOBSwitch attribute to require unique initials and DOB across the study. This prevents the following situation: • If a study does not require unique initials and date of birth, or only requires site uniqueness, and a user transfers a subject to a site where another subject exists who has the same initials and date of birth, the subject transfer fails. • To transfer the subject, the user must change the subject initials to make the combination unique.

Field	Description
Require unique subject ID	Study (default), Site, or None. Indicates whether the Oracle InForm application requires a unique subject number for a study, a site, or not at all. **Note:** If you specify that a unique subject number is not required and subjects with identical numbers are entered, and later you specify that unique subject numbers are required, the duplicate information that was previously entered will not be reported. **Subject record transfer consideration:** If you plan to allow the transfer of a subject from one site to another, set this option to require subject numbers to be unique across the entire study. The Oracle InForm application does not allow a subject to be transferred to another site in which a subject exists with the same subject number. If a conflict arises, the Oracle InForm application rejects the transfer, and you must manually change the subject number of the transferring subject to a value that is not duplicated at the target site. **Partial SV consideration:** If you plan to use partial source verification, set this option to Study or Site.
Allow sponsor users to edit frozen forms	Yes or No (default). Indicates whether sponsors will be able to edit a CRF after it has been marked as frozen. **Batch run calculation rule consideration:** If you plan to run calculation batch rules on case report books that are unfrozen and unlocked, but that have individually frozen forms, set this option to Yes to prevent errors.
Order of UserName in Signature	Order of the names in the signature. • FirstName,LastName (default) • LastName,FirstName
Visit Calculator	Enabled or Disabled (default). Indicates whether you want the Visit Calculator to appear after a successful enrollment.
Execution plan server	Name of the server(s) on which execution plans run.
MedML installation server/reporting administration server	Name of the server that is defined as the server on which all MedML, including changes to a study, is installed.

Field	Description
Reporting service full url	URL for the Cognos Analytics 11 Web service.
Reporting Internal URI	Cognos parameter that is set when running the CRNConfig installer. It is an internal URI that the Oracle InForm server uses to communicate to the Cognos server. The information can be found in cogstartup.xml. Example: http://appsru02.north.pf.com:9300/p2pd/servlet/dispatch.
Reporting authentication namespace ID	LDAP namespace that is used to authenticate Oracle InForm users on the reporting server.
Reporting user root	The top-level reporting folder for the company. Use this field only if you are hosting several companies on one reporting server and have set up reporting folders for each company. Leave this field blank if you are not hosting studies for different companies, or if you have not set up separate reporting folders for each company.
Date format	The format in which you want the date to appear in the study.
Allow subject ordering	Enabled or Disabled (default). Indicates whether to allow use of the subject ordering feature.
Server friendly name	User-friendly server name to display on the Queries details and Signature Status Details pages. **Note:** You can set this option only through the Admin user interface; there is no equivalent MedML tag.
Trial Center Url	Not supported.
Allowed Rule Objects	The object names that are in the allowed rule objects list. READ-ONLY
Set itemset to Not Verified	When to set a Verified itemset to Not Verified in Oracle InForm. • **When any SV Required item is changed**—A Verified itemset is set to Not Verified any time an item in the itemset that is marked SV Required is modified. • **When any item is changed (Default)**—A Verified itemset is set to Not Verified any time an item in the itemset is modified.

Fields—Workflow Options

Field	Description
Form submit notification style	The location and format of the Form submitted successfully message. • **Inline** (default)—Message displays in the header of the form. • **Pop-up**—Message displays as a pop-up. User must click OK in order to proceed. Default. This setting is global to all users.
Inline notification visible duration	Used when Form submit notification style is Inline. Specifies the number of seconds that the `Form submitted successfully` message remains visible in the header of the form before it fades. Specify a value from 0 to 9 seconds. The default is 3 seconds. A value of 0 (zero) causes the message to remain visible until the user performs an action on the form, such as changing a value or entering focus to a control.
QuerySelection	Specifies whether queries are created in the Opened or Candidate state.

Fields—SV Settings

Field	Description
First N Subjects	The number of subjects to source verify in order, based on the time when the subject is assigned the status Enrolled. For example, to indicate that you must source verify the first seven subjects enrolled in a study, specify SVFIRSTNSUBJECTS=7. The default value is defined in Oracle Central Designer. This can't be less than zero (0). If the system does not contain a SVFIRSTNSUBJECTS setting, the default value will be one hundred (100). **Note:** This is also a Site property. A user with the **Change Site SV Settings** right can change the value at Site level. When a new system level First N is applied through deployment, Oracle InForm compares the value of each site with the current system value. If the site value equals the system value, the new system value will be applied to the site. Otherwise, the site value will not be changed.

Field	Description
Auto Select Rate	The auto select percentage of the subjects to be included in Partial SV. The default value is defined in Oracle Central Designer. The value must be in the range of 0 to 100. If the system does not contain a SVAUTOSELECTRATE setting, the default value will be one hundred (100). **Note:** The auto select percentage is also a Site property. A user with the **Change Site SV Settings** right can change the value at the Site level. When a new system level percentage is applied through deployment, Oracle InForm compares the value of each site with the current system value. If the site value equals the system value, the new system value will be applied to the site. Otherwise, the site value will not be changed.

Field	Description
Default to include	Indicates whether the default is eligible or excluded from the SV Pool—eligible (1) or exclusion (0). The default value is defined in Oracle Central Designer. If the system does not contain a SVDEFAULTINCLUDE setting, the default value will be eligible (1). **Note:** The default of whether to include or exclude subjects from the SV Pool is also a Site property. A user with the **Change Site SV Settings** right can change the value at the Site level. When a new system level percentage is applied through deployment, Oracle InForm compares the value of each site with the current system value. If the site value equals the system value, the new system value will be applied to the site. Otherwise, the site value will not be changed.

Fields—System Security Configuration

Field	Description
Re-authentication inactivity period	Number of minutes of inactivity that can pass before the Oracle InForm application requires a user to log in again.
Password expiration period	Number of days that can pass before the Oracle InForm application requires users to change their passwords. Recommended setting is 90 days.
Re-identification period	Number of minutes that a session can be active before the Oracle InForm application requires a user to log in again.
Minimum password length	Number of characters that must be in the password. Recommended setting is 8 characters.

Field	Description
Inactivate account after number of failed log-on attempts	Number of times a user can attempt to log in with an incorrect user name and password combination before the account is inactivated. If an account is inactivated, an administrator must reactivate the account. Recommended setting is 3. If an account is inactivated, an administrator must reactivate the account.
Require at least one numerical character in password	Yes (recommended) or No. Indicates whether users are required to use at least one numerical character in their passwords.
Require at least one uppercase character in password	Yes (recommended) or No. Indicates whether users are required to use at least one uppercase character in their passwords.
Require at least one non-alpha-numeric character in password	Yes (recommended) or No. Indicates whether users are required to use at least one non-alphanumeric character in their passwords.
Allow password reuse	Yes or No (recommended). Indicates whether to allow users to reuse previous passwords.
Enable password recovery	Yes (recommended) or No. Indicates whether to allow users to request a password reset if they have forgotten their password.
Email address for password recovery notification	The email address of an administrator who receives notification when a user requests a password reset.
Email address for new site and user notification	The email address of an administrator who receives notification when a new site or new user is added.
Trial Company/Short Org ID	For SSO configurations only. The sponsor's Short Org ID (the short name for your organization, assigned by Oracle Health Sciences). Update this field after any TrialCopy process to ensure proper SSO authentication.

Group types

Type	Description
Query	Allows any user who is in the same query group as the user who opened a query to change its status (for example, to close it). A user can be a member of only one query group.
Signature	Allows any member of the same signature group to sign forms, if the user has the Sign form right, or to sign case report books if the user has the Sign a Case Book right. To be considered signed, a form has to be signed by at least one member of each signature group that it is associated with. A user can be a member of only one signature group. A form that requires a signature can be associated with zero, one, or more signature groups.
ManagerUser	Not supported.

Type	Description
ItemGroup	Identifies a set of items that can be assigned a display override. Display overrides allow you to specify that, for a particular rights group, the group of items that makes up an item group is Hidden, Editable, or Read-Only. This designation overrides the rights conveyed by membership in the rights group and also overrides the display properties of the items in the group.
Reporting	Defines the reporting functionality and type of access available to users with reporting rights. Some Reporting groups allow members to access only standard reports; others allow members access Query Studio. Users can belong to more than one reporting group.

Sites detail page

Field	Description
Site Name	Required.
Site Mnemonic	Required. Short name for the site. It appears in the list of sites, under Site Abbrv.
Time Zone	Time zone where the site is located. This value is used to make conversions between internal system time and the time that displays for transactions that occur at the site.
Study Version	Title of the study version associated with the site. The study version determines which version of the forms, study protocol, and study documents for a study appear to users at the site.
Site Server	Name of the designated site sever. The site server is dedicated for doing specific activities, such as randomization, screening and enrollment, and generating subject numbers.
Study Locale	Required. The language(s) in which study metadata are designed using the Oracle Central Designer application. This includes CRFs and related study design labels, such as visit names, CRF (form) names, section labels, CRF questions, item control labels, auto-query text, and so on.

User details page

Field	Description
User Name	Usually the first initial and last name of the user. REQUIRED.

> **Note:**
>
> The User Name can contain alphabetic characters, numeric characters, and underscores; it cannot contain spaces.

Field	Description
User Type	• Site User—User who performs site functions. • Sponsor User—User who performs sponsor functions such as monitoring and data management. Certain features are available only to sponsor users. • Integration User—User for integrations with external applications, such as the Clinical Data API. Integration users cannot access clinical data or be assigned to sites. • Support User—This user type is reserved only for Oracle Support personnel.
Title	The job title for a user. For example, you might enter PI for a site user.
Description	A description of the user's job title. For a PI, you might enter Principal Investigator.
Country	The country where the user is located. Make sure that you always enter the country in the same way so that the field is used correctly in the Oracle InForm reports. For example, US and United States are recognized as two different countries in the reports.
Display Name	The user's name as it appears under the picture in the upper-right corner of the main window.
Home Page	The URL for the page the user sees after they log in to Oracle InForm. You must enter the full URL, beginning with `http://`. This can be any valid URL that points to an internal or external site that is identified by an IP address or host name.
Product Locale	The language—English or Japanese—of the product user interface. REQUIRED. Menus, controls, commands, system screen labels, error messages, and so on are written in the selected language. Oracle creates product locales.
Preferred Study Locale	The preferred language for CRFs. REQUIRED. The available options are based on the languages specified during the study design. This setting: • Is used for pages that can span multiple sites. • Controls some study locale information presented outside of the CRFs, such as headings on the Time and Events Schedule page or choices in the Source Verification page filter control.