

General features



HALOPV 3.X USER GUIDE

This is an end-user guide for the general features of the drug safety solution HALOPV.

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1. HALOPV

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2. Preface

The latest product information including release notes for HALOPV is available at

<https://www.halopv.com/>

Insife Support

Insife Support team can be reached out at Support@insife.com

3. Introduction

3.1. Purpose

This User Manual describes General features of HALOPV.

You will find a manual for each module separately, on <https://www.halopv.com/user-guides-tutorials>. At the time of writing of this manual, the modules comprise of:

Aggregate reporting module, HALOPV 3.x
Clinical studies module, HALOPV 3.x
Complaints module, HALOPV 3.x
Data collection programs module, HALOPV 3.x
Entities and Agreements module, HALOPV 3.x
ICSRs module, HALOPV 3.x
Literature module, HALOPV 3.x
Medical information and communications module, HALOPV 3.x
Products module, HALOPV 3.x
Quality module, HALOPV 3.x
Requirements intelligence module, HALOPV 3.x
Risks module, HALOPV 3.x
Signals module, HALOPV 3.x
Submissions module, HALOPV 3.x

3.2. About HALOPV

HALOPV is a cloud-based system. Internet connectivity is required, but you can use your computer, tablet or smartphone to access the system. Your organization should have provided you with the correct link to allow you to access your instance of HALOPV.

4. The login screen

As a user, you will have been provided a URL to access HALOPV. Opening the URL, you will be presented with a login screen. Here, you have the possibility to either use a Microsoft Azure Office 365 account for single sign-on. In case this is setup for your enterprise, you can simply click the Azure login button. Or, In case you have a username and password for HALOPV, please enter that now and click the log in button.

4.1. First login

If it is the first time you login to HALOPV, you may be prompted to change your password. Please note that password complexity policies apply. If your organization has set specific standards, these will apply. Otherwise, HALOPV defaults to the following rules: Minimum: 10 characters, 1 upper case character, 1 lower case character, 1 special character

5. The Home screen

After login, you will be presented with the Home screen. This screen may contain very different things, depending on the roles you have been assigned in your business and also if you are working in an organizational entity that have a specific remit.

Title (identifier)	Task	Organization	Created by	Task due by
General form updates (ICSR-PROC-989)	Register ICSR information	Root organization	JOYDEEP.CHAKRABORTY@INSIFE.COM	03-FEB-2021
test (TRAIN-GR-11)	Perform Access Granting Training	Root organization	JOYDEEP.CHAKRABORTY@INSIFE.COM	10-FEB-2021
Ibuprofen PSUR (AGG_RPT-15)	Review document	Egypt affiliate	MARTIN.HOLM-PETERSEN@INSIFE.COM	28-FEB-2021
Eudravigilance (EVHUMAN) (ORG-EXT-18)	Create/Update Entity	Root organization	MARTIN.HOLM-PETERSEN@INSIFE.COM	28-FEB-2021
Sick from taking SuperDrug (CC-33)	Conclusion and inform customer	Root organization	ADMIN	28-FEB-2021

The Home screen includes the following components:

At the top section of the screen, there is an indication of which username you have logged in as, and also which organizational entity you are working in.

To the left of the screen, there is a list of available **modules**. These processes will include only the items you have been granted access to. It includes “My Tasks” and “Active Tasks” that allow you to get a full list of tasks that have been or are about to be processed by you - or someone with a similar role as you.

In the center left of the screen, you may find the Quick links feature (not enabled in the screenshot above). These are links that can provide a convenient way for you to access various parts of the application – or even outside the application. You may have a different set of quick links on your screen, depending on how it has been setup in your enterprise. You probably have a “Support” link here.

Below the Quick links, you will find your top 5 task list. These tasks are to be handled by you – or someone with a similar role as you. There are indicated due dates for each of the tasks on the list. It is per default sorted to have the closest approaching task in the top of the list, but the list can be sorted by clicking on the column headers. You can also add a search string to easily filter the task list – or click the “Actions” button for more advanced features, such as Excel download, graphing etc.

In the far bottom of the screen, there are two compliance indicators. To the left, the compliance chart displays the compliance of the entire enterprise. To the right, the compliance chart displays the compliance of your role, understood as your roles intersected with the Organizational entity you work in.

Finally, at the very top of the screen, you will find a menu bar which will allow you to log out after you end your work session with HALOPV. It also includes links to “Profile”, “My Organization”, “My tasks” and “Help Center”. These are all features that will make it easier to get an overview of your use of HALOPV.

“**Profile**” allows you to view or change some of the data about you – and you can enable or disable notification emails. If you enable it, you will get an email notifying you when a task matches your role and remit. If you need to change other things such as your roles, you may be able to subscribe to the role here, if not, please contact the application support.

“**My organization**” allows you to see what remits have been assigned to the entity you work in. It may be limited by Products, Territories, Studies or access to other entities than your own.

“**My tasks**” allows you to review all your tasks – it links to the same page as in the left menu

“**Help Center**” allows you to quickly access our support portal on <https://www.halopv.com/support>

“**Log out**” ends the session and takes you back to the login screen.

6. The Module overview

On the left menu, you will find a list of modules available for your user profile. Please select any module.

In this example, we have clicked the ICSRs module.

Once clicking **ICSRs**, you will find the **Available workflows** of the ICSRs module (may vary based on configuration) to the left of the screen, as well as the **Functionality menu** to the right.

Below, the latest updated Records will be listed, for easy access to ongoing work (Clicking on the title will take you directly to the Record view/edit screen, see section 4.4).

ICSRs

ICSR(s) Module is a comprehensive toolbox for managing the ICSR life cycle. Capture ICSRs / other safety information from local or centralized sources – and manage linked follow-ups in an easy and structured way.

Available workflows

- ICSR Processing
- ICSR Intake
- ICSR follow-up
- Refuted ICSRs

Functionality menu

- Simple web form ICSR data entry
- ICSR Submission compliance dashboard
- ICSR listing
- ICSR submissions (automated via gateway)
- ICSR submissions (manual)

Last Updated Records

Title (Identifier)	Type	Countries	Active task	Task due by	Last changed	Master Title
Case TEST 123 (ICSR-PROC-25711)	Spontaneous Report	-	Register ICSR information	29-DEC-2021	28-DEC-2021	Case TEST 123
test123 (ICSR-PROC-22280)	Spontaneous Report	-	Register ICSR information	17-DEC-2021	16-DEC-2021	test123
EMA report (ICSR-PROC-25721)	-	-	Register ICSR information	29-DEC-2021	28-DEC-2021	EMA report
Argus Case Number: Case ID: (ICSR-PROC-22284)	-	-	Register ICSR information	22-DEC-2021	21-DEC-2021	Argus Case Number: Case ID:
Argus Case Number: Case ID: (ICSR-PROC-22282)	-	-	Register ICSR information	22-DEC-2021	21-DEC-2021	Argus Case Number: Case ID:

7. The Records list

Click on any of the workflows, you will see the **Records** that are either in progress or have been completed within this workflow. Some workflows will let the record stay as “Completed” in this view, while other workflows will automatically move out records to a new workflow (the latter is normally the case for the ICSR “intake” workflow)

ICSRs / ICSR Intake Records

Process description
Intake safety information for potential ICSR processing

Display **All** Active Include nullified records Include records assigned to others

You have read-only access to the current workflow

Records

Go 1. Primary Report Rows: 50 Actions

Obs	Record ID	Parent record	Intake record	Type	Active task	Countries	Organization	Created by	Assigned to	Dueby	Overall Due Date	Last updated	Next Scheduled Event
	ICSR-IN-1669	-	Testing keyword detection	-	Duplicate search	-	Root organization	ADMIN	-	03-JUL-2021	03-JUL-2021	29-NOV-2021 09:16AM	-
	ICSR-IN-1507	-	My report	-	Duplicate search	-	Insife Germany	MARTIN	-	21-JUN-2021	21-JUN-2021	26-NOV-2021 01:55PM	-
	ICSR-IN-1563	-	test	-	Duplicate search	-	Root organization	ADMIN	-	23-JUN-2021	23-JUN-2021	10-NOV-2021 10:27AM	-
▲	ICSR-IN-	-	-	-	Intake	-	Root	-	-	-	-	16-SEP-2021	-

The Records list view may have different columns available, depending on which module and workflow you have selected, however the principle is the same for all workflows. You will have a Record ID, Title of the record, the type, active task etc. on this list, as well as Dueby (the date that the task is due to comply with set timelines). The Records list is an **Interactive Report**. As with all Interactive Reports, there are a number of actions that can be performed, please see section 10).

8. Creating a new Record from the Records list

You may have been assigned a role (user roles are generally assigned by the User Admin) that allows you to also create a new Record. You can see the button on the top right (in the screenshot above, the role hasn't been assigned to the user, hence does not have the possibility to create new records, only click on the ones already there).

Create from Wizard

N.B. Is you are a User Admin and want to read more about setting up roles and permissions, please consult the separate User Guide - User Administration overview

Setting up the new record with title and key attributes

The Create screen contains **Record Title** is the identifier of the ICSR you are about to create. It will not be visible in the actual report, so it is for your internal reference.

You can in this screen also set the due date (**Master Duedate**) - If you do not set a date, the system will set a default value based on the configuration. If configured on the workflow, you will also be able to select the **Type** of the record.

9. The view/edit record screen

No matter if you are creating a new record or clicking on an existing record from the records list, you will get to the same screen called **View/edit record**.

The **Record and task information** section of the view/edit record screen will indicate what is expected of the user, e.g. activities to be performed in the workflow task. The **Top workflow navigation bar** will indicate where in the workflow (which task step) your record is currently. If there is no workflow in the top of the screen, it is because the record has been completed.

9.1. Understanding the workflow

The workflow is shown in the top of the record, e.g. in the example below, the ICSR Processing workflow:



This also means that records in this example will start in the **Register ICSR Information** task step and the last step is **Submission**.

N.B. It should be noted that the configuration of the workflow may vary, as the tasks are configurable using the Application.

9.2. The More menu

The **More** menu is marked with ... in the top right of the screen. Here you can perform additional actions that are general for any type of record. This menu has a lot of important features that you can access by selecting the item:

9.2.1. Record Info

Takes you to the same screen as when creating the record, allowing to view/modify the Title, Type, Master Dueby etc.

9.2.2. Record Scope

The scope is important to set if the record is to be specifically accessible under certain circumstances. You can set the:

Product (select a Product, from the Products module – N.B. only products that are available to you can be configured here)

Study (select a Clinical study, from the Clinical Studies module – N.B. only studies that are available to you can be configured here)

Organizational entity (select an Organizational Entity, from the Entities and Agreements module – N.B. only entities that are available to you can be configured here)

Assigned to (select a username that you would like to assign the record to, only users in the selected entity will be selectable here)

Countries (select one or more countries – N.B. only countries configured in your organizational entity will be selectable here).

The information under scope will be used on all lists etc. in HALOPV to determine if a user has access to the record or not.

N.B. Any user is placed within an organizational entity. This entity may have a configured list of Products, Studies, Countries as well as potentially other organizational entities that is controls. HALOPV uses this configuration to match if you have a matching scope to see or access records.

9.2.3. Workflow History

The workflow history allows you to see a list of workflow steps the record has travelled through as well as the task created and completed, including a number of attributes:

Notes (some workflow task steps allow for notes to be entered, these are shown here)

User (the name of the user completing the task)

Routed back (If a task has been pushed back for a second pass, to do the task again, by the subsequent user, this is set to Yes)

Compliance Impact (in case of breach of timeliness, this field is mandatory to fill in, allowing user to indicate if the breach has any potential impact on compliance)

CAPA Required (in case of breach of timeliness, this field is mandatory to fill in, allowing user to indicate if the breach has any potential CAPA to be created)

Breach Reason (in case of breach of timeliness, this field is mandatory to fill in, allowing user to indicate why the breach occurred)

Electronic Signature (ES) (if an electronic signature task action has been completed, this field will be populated with a key icon)

9.2.4. Record Revisions

The list of revisions for the record will be shown here. For each time a record is completed and re-initiated, another revision is created and timestamped. Revisions cannot be modified, but it is possible to enter a previous revision by clicking on the revision number. Here, the record will be shown in read-only mode as it looked like when the revision was completed.

9.2.5. Notifications

The feature allows for creating a new notification, by typing in the **New Notification** field. Then, either a **Role** (select list) or a list of **Individual recipients** can be selected. If role is selected, the notification will go out to everyone who has been configured as member of that role group. Finally, the **Send notification** button actually sends the notification. It is now listed to the left of the screen as historic notifications for the record.

9.2.6. View Audit log

This feature allows for viewing a complete list of changes that were applied on a record, including old value, new values, user, date etc. The audit log is an interactive report, so the view can be customized, see section 10

The second tab on the audit log screen is the record access log. This allows for viewing the complete list of accesses on the record, including when the record was accessed, released and by whom. This is also an interactive report.

9.2.7. Nullify or De-activate Record

This feature allows for nullifying the record, which will render it de-active. The nullification is not a deletion, since a nullified record can be un-nullified later.

Please note the menu item "Nullification" requires the role **Nullification**, the item will be hidden if the role is not assigned to you.

Nullification of a record will open a screen for providing a reason for nullification. This reason is stored with the nullified record.

9.2.8. Clone Record

This feature simply allows for clicking a button to produce a clone of the record. The cloned record will have a new identifier number, but it will be identical to the original.

9.2.9. Keywords

This feature allows for reviewing previously set keywords and tags on the record. The system may set both keywords and tags, e.g. **Duplicate** when it performs certain automations. It is also in the screen possible to set tags manually, by selecting the tag in the **Add predefined Tag dropdown**.

9.2.10. Print

This feature allows for selecting a pre-defined template via the **Template** dropdown, selecting the format in the **Format** dropdown (where you can choose between MS Word and PDF), and finally an optional selection of interactive report.

The printed output is downloaded directly to the desktop, i.e. not saved in the attachments section of HALOPV.

N.B. Some modules, like Aggregate reporting or PSMF, have template actions that allow you to add documents to the attachments section directly

9.3. Task Activities

The configured actions for the task are listed to the right of the screen in the **Task Activities** section. The Task activities include both **Link** actions (links to functionality) and **Form** actions (opens forms for capturing of information). For ICSR Intake, the default list of actions is described in the following section

9.3.1. Task status

The Task status is a “traffic light” style indicator that displays how many warnings there are for a task action. No warnings is indicated by the coloured circle as green with a 0 inside. If a validation rule is flagging an issue in a form, the task status will indicate this by marking the coloured circle red and adding a 1, for the one rule flagged. If multiple validation rules are flagging, the number indicated will increase accordingly. Once the data is corrected, the validation rule no longer flags any warning, and the count will decrease again, and eventually marking the indicator green. If configured, all red flags must be cleared before allowing the user to complete the task. Please see section 9.4

9.4. Completing a Task and Sending it Forward

Once you have finished reviewing/entering the data and completed the assigned tasks, click on **Complete task** to send the report forward. When clicking on Complete task, the task proceeds to the next step in the workflow. If you are in the last workflow task step, the record will now be in “Complete” state.

Please note that you may be prevented from completing the task if there are warnings on any task actions. Please see section 9.3.1 for details.

9.5. Re-initiating a Completed record

Next time editing is needed of a completed record, click the **Initiate Workflow** button. The record will now be lifted to a new revision number, and it will travel through the workflow again.

10. Interactive Reports

10.1. Searching and sorting

At the top of each interactive report page is a search region. This region (or Search bar) provides the following features:

Select columns icon enables you to identify which column to search (or all).

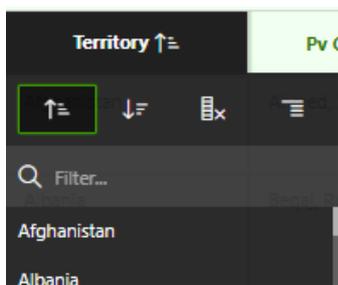
Text area enables you to enter case insensitive search criteria (wild card characters are implied).

Go button executes the search. Hitting the enter key will also execute the search when the cursor is in the search text area.

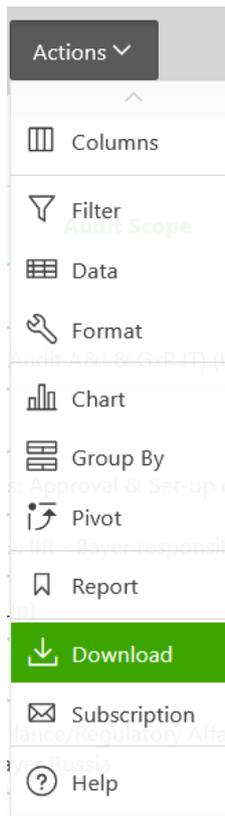
Reports displays alternate default and saved private or public reports.

Actions Menu enables you to customize a report. See the sections that follow.

To sort your data alphabetically, click on the column title and select the ascending or descending arrow.



10.2. The actions menu



The Actions menu appears to the right of the Go button on the Search bar. Use this menu to customize an Interactive report.

The individual features are described in the sections below. They are accessed by clicking the Actions button, and clicking on the desired functionality

10.2.1. Columns

Used to modify the columns displayed. The columns on the right display. The columns on the left are hidden. You can reorder the displayed columns using the arrows on the far right. Computed columns are prefixed with **.

Toggle columns to be displayed (shift the column to the right) or not displayed (shift the column to the left) in the interactive report.

Change the order to the columns in the interactive report by moving them up or down with the arrows.

10.2.2. Filter

Focuses the report by adding or modifying the WHERE clause on the query. You can filter on a column or by row.

There are two filter types available in the section:

Column: If you filter by column, select a column (it does not need to be one that displays), select a standard Oracle operator (=, !=, not in, between), and enter an expression to compare against. Expressions are case sensitive. Use % as a wild card (for example, STATE_NAME like A%).

Row: If you filter by row, you can create complex WHERE clauses using column aliases and any Oracle functions or operators (for example, G = 'VA' or G = 'CT', where G is the alias for CUSTOMER_STATE). Many functions and operators can be combined. The list of functions and operator can be found in the bottom left of the filter screen.

10.2.3. Data

The Data menu items has four different sub items:

Sort: Used to change the columns to sort on and determines whether to sort in ascending or descending order. You can also specify how to handle NULLs. The default setting always displays NULLs last or always display them first. The resulting sorting displays to the right of column headings in the report.

Aggregation: Aggregates are mathematical computations performed against a column. Aggregates display after each control break and at the end of the report within the column they are defined. Options include:

Aggregation enables you to select a previously defined aggregation to edit.

Function is the function to be performed (for example, SUM, MIN).

Column is used to select the column to apply the mathematical function to. Only numeric columns display

Compute: Enables you to add computed columns to your report. These can be mathematical computations (for example, `NBR_HOURS/24`) or standard Oracle functions applied to existing columns. Some display as examples and others (such as `TO_DATE`) can also be used). Options include:

Computation enables you to select a previously defined computation to edit.

Column Heading is the column heading for the new column.

Format Mask is an Oracle format mask to be applied against the column (for example, `S9999`).

Computation is the computation to be performed. Within the computation, columns are referenced using the aliases displayed.

Below computation, the columns in your query display with their associated alias. Clicking on the column name or alias includes them in the Computation. Next to Columns is a keypad. This keypad functions as a shortcut to commonly used keys. On the far right are Functions.

The following example computation demonstrates how to display total compensation:

```
CASE WHEN A = 'SALES' THEN B + C ELSE B END
```

(where A is ORGANIZATION, B is SALARY and C is COMMISSION)

Flashback: A flashback query enables you to view the data as it existed at a previous point in time. The default amount of time that you can flashback is 3 hours (or 180 minutes) but the actual amount will differ for each database

10.2.4. Format

Control Break: Used to create a break group on one or several columns. This pulls the columns out of the interactive report and displays them as a master grouping

Rows Per Page: Sets the number of records to display per page.

Highlight: Enables you to define a filter. The rows that meet the filter criteria display as highlighted using the characteristics associated with the filter. Options include:

Name is used only for display.

Sequence identifies the sequence in which the rules are evaluated.

Enabled identifies if a rule is enabled or disabled.

Highlight Type identifies whether the row or cell should be highlighted. If Cell is selected, the column referenced in the Highlight Condition is highlighted.

Background Color is the new color for the background of the highlighted area.

Text Color is the new color for the text in the highlighted area.

Highlight Condition defines your filter condition.

10.2.5. Chart

You can define one chart per saved report. Once defined, you can switch between the chart and report views using view icons the Search bar. Options include:

Chart Type identifies the chart type to include. Select from horizontal bar, vertical bar, pie, or line.

Label enables you to select the column to be used as the label.

Axis Title for Label is the title that displays on the axis associated with the column selected for Label. This is not available for pie chart.

Value enables you to select the column to be used as the value. If your function is a COUNT, a Value does not need to be selected.

Axis Title for Value is the title that displays on the axis associated with the column selected for Value. This is not available for pie chart.

Function is an optional function to be performed on the column selected for Value.

Sort allows you to sort your result set.

10.2.6. Group By

You can define one Group By view per saved report. Once defined, you can switch between the group by and report views using view icons on the Search bar. To create a Group By view, you select:

the columns on which to group

the columns to aggregate along with the function to be performed (average, sum, count, etc.)

10.2.7. Pivot

You can define one Pivot view per saved report. Once defined, you can switch between the pivot and report views using view icons on the Search bar. To create a Pivot view, you select:

the columns on which to pivot

the columns to display as rows

the columns to aggregate along with the function to be performed (average, sum, count, etc.)

10.2.8. Report

Save report: Saves the customized report for future use. You provide a name and optional description and can make the report accessible to the public (that is, all users who can access the primary default report). You can save four types of interactive reports:

Primary Default (Developer Only). The Primary Default is the report that initially displays. Primary Default reports cannot be renamed or deleted.

Alternative Report (Developer Only). Enables developers to create multiple report layouts. Only developers can save, rename, or delete an Alternative Report.

Public Report (End user). Can be saved, renamed, or deleted by the end user who created it. Other users can view and save the layout as another report.

Private Report (End user). Only the end user that created the report can view, save, rename or delete the report.

If you save customized reports, a Reports selector displays in the Search bar to the left of the Rows selector (if this feature is enabled).

Reset: Resets the report back to the default settings, removing any customizations that you have made.

10.2.9. Download

Enables the current result set to be downloaded. The download formats differ depending upon your installation and report definition but may include CSV, HTML, Email, XLS, PDF, or RTF.

10.2.10. Subscription

When you add a subscription, you provide an email address (or multiple email addresses, separated by commas), email subject, frequency, and start and end dates. The resulting emails include an HTML version of the interactive report containing the current data using the report setting that were present when the subscription was added.

10.2.11. Help

Opens a help section on screen similar to the explanations above