



Introduction to



Guiding Slides on **HALOPV**
General Overview and Main Features



Introduction to



HALOPV

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Accessing HALOPV using credentials or SSO

The image shows a login interface for 'HALO DEV'. At the top, the text 'HALO DEV' is displayed in a grey header. Below this is a large orange and blue abstract graphic. Underneath the graphic are two input fields: the first is labeled 'username' with a magnifying glass icon, and the second is labeled 'password' with a magnifying glass icon. At the bottom of the form are two green buttons: 'Single-sign-on with Azure AD' with a circular arrow icon, and 'Log In'.



Use login details below to access HALO.





<https://halo.clientname.insife.cloud:8080/ords/halo/>

- As a HALO user, please access the application by enter your password or by clicking the **Single sign-on with Azure AD** button.
- If you have access but not a HALO account, enter your username and password and click the **Log In** button.

Access record(s) via email

EU PSMF - Annex H.1 List of Medicinal Products

 support@insife.com
To  Michelle Romero Nørregaard



Annex H.1- List of Medicinal Products

Annex H.1 is ready for review and adjustments in case needed. Thank you in advance!

[Open record in HALO](#)

Task due date: 07-APR-2022

This email was sent automatically from HALO PV. To disable automatic emails, please modify your user configuration settings in HALO: [User Settings](#) (Edit my Information > Email notifications)

Record's title

Workflow and task

Link directly to application

General Overview - Front Page

The screenshot shows the HALO front page. On the left is a dark sidebar menu with the HALO logo and version 4.0. The main content area includes a top navigation bar with a search bar, system time, and user profile. Below this is a 'Welcome back' message and a 'Record search' button. The central part of the page features a 'ribbons' section with various task-related widgets, including a 'Task ribbon provides' widget with a 'Yes' status, and several task count widgets for different time periods. At the bottom, there is a 'Quick Links' section and a 'My top 5 open tasks' table.

Record search

User's menu

Widgets on home screen

The left Menu contains the Modules, Dashboards & Reports, and User/Application Management.

My top 5 open tasks

Priority	Title (identifier)	Task	Task due by	Assigned to	Organization	Territories
1	Yellowcard Medicines incident 1683104860 (ICSR-Proce-6)	Data Entry	23-JUN-2021	MARTIN	Root organization	United Kingdom of Great Britain (the)
1	Industry case intake 567890 (ICSR_IN-2)	Duplicate search	23-JUN-2021	-	Root organization	-

General Overview - Front Page

The screenshot displays the HALOPV front page interface. On the left is a dark sidebar with the HALOPV logo and version 4.0.2, and a menu with items: Processes, Dashboards and reports, My settings, Application management, and User administration. The main content area includes a system time box (23-AUG-2022 13:34:20 GMT), a search bar, a user profile box (MICHELLE.NOERREGAARD@INSIFE.COM), a welcome message, a 'My organization' box (Root organization), and an 'Individual task ribbon' showing task counts: 'Allow assigning of tasks to me' (Yes), 'My open assigned tasks' (51), 'My handled tasks last 24h' (4), 'My handled tasks last 7 days' (5), and 'My handled tasks last 30 days' (31). Annotations with arrows point to these elements: 'HALOPV version' points to the sidebar; 'Indicates the organizational entity the user belongs to e.g., partners, affiliates, etc.' points to the 'My organization' box; 'Processing compliance widget' points to the task ribbon; 'Your username' points to the user profile box; and 'Quick search' points to the search bar.

HALOPV version

Indicates the organizational entity the user belongs to e.g., partners, affiliates, etc.

Processing compliance widget

Your username

Quick search

General Overview – Front Page

Processes

Dashboards and reports

My settings

Application management

User administration

My top 5 open tasks

Q

Go

Actions

Priority	Title (identifier)	Task	Task due by	Assigned to	Organization	Territories	Workflow due by
1	ICSR-PROC14 (ICSR-Proce-14)	Medical Review	17-AUG-2021	ADMIN	Root organization	-	17-AUG-2021
1	Intake module: (ICSR-Proce-92738)	Medical Review	19-OCT-2021	ADMIN	Root organization	-	19-OCT-2021
1	Sample file - FULL [DO NOT TOUCH] (ICSR-Proce-92780)	Register ICSR information	21-OCT-2021	-	Root organization	-	21-OCT-2021
1	Intake module: CA-POHLBOSKAM-AM-2021-00079 (ICSR-Proce-92852)	Register ICSR information	26-OCT-2021	MARTIN.HOLM-PETERSEN@INSIFE.COM	Root organization	-	27-OCT-2021
1	Intake module: (ICSR-Proce-92822)	Register ICSR information	26-OCT-2021	MARTIN.HOLM-PETERSEN@INSIFE.COM	Root organization	-	26-OCT-2021

Processing Compliance

Completed late

Completed after route back

Completed as expected

Completed late

Completed after route back

Completed as expected

Refresh the list of your top 5 open tasks

You can remove or add available widgets as a personal preference. To remove a widget, click on the 3 dots and click on 'Remove this widget'

My top 5 open tasks lists the 5 due by records that require your attention.

Processing Compliance charts display the number of records completed as expected or late across all Processes. Compliance is set up in the workflow configuration, e.g., KPI, and days assigned to the workflow.

General Overview – Task due by

The screenshot displays the HALOPV system interface. On the left is a dark sidebar with a menu including 'Processes', 'My tasks', 'Active Tasks', 'Agreements', 'Entities (organizations)', 'Product Management', 'Labeling', 'Environment Overview', 'Device Incident Processing', 'ICSRs (Medicines incidents)', 'PSMF Management', 'Requirements Intelligence', 'Records Management', 'Signal Management', 'Defective Medicines', 'Risk Management', 'Data Collection Programs', 'Interactions', 'Time management', 'Quality Management', 'Customer Support', 'Literature Monitoring', 'Customer complaints', and 'Submissions'. The main content area at the top shows the system time as '30-AUG-2022 10:28:31 GMT (Europe/Copenhagen)' and the user as 'MICHELLE.NOERREGAARD@INSIFE.COM'. Below this is a 'Welcome back' message and 'My organization' information. The 'Individual task ribbon' section contains several cards: 'Allow assigning of tasks to me' (Yes), 'My open assigned tasks' (51), 'My handled tasks last 24h' (3), 'My handled tasks last 7 days' (25), and 'My handled tasks last 30 days' (45). A 'Quick Links' section is also present. The 'My top 5 open tasks' section features a table with columns: Priority, Title (identifier), Task, Task due by, Assigned to, Organization, Territories, and Workflow due by. Two tasks are listed, both with 'Task due by' dates highlighted in red: '17-AUG-2021' and '19-OCT-2021'. A yellow box highlights the 'Task due by' column header and the two red dates. A yellow arrow points from this box to a separate callout box on the right.

Priority	Title (identifier)	Task	Task due by	Assigned to	Organization	Territories	Workflow due by
1	ICSR-PROC14 (ICSR-Proce-14)	Medical Review	17-AUG-2021	ADMIN	Root organization	-	17-AUG-2021
1	Intake module: (ICSR-Proce-92738)	Medical Review	19-OCT-2021	ADMIN	Root organization	-	19-OCT-2021

Tasks are highlighted in red for past due tasks and yellow for tasks close to the deadline.

Days are allocated per step in the Application Management section.

A vertical callout box with a yellow border containing three dates: '29-AUG-2022' in a red box, '30-AUG-2022' in a yellow box, and '12-SEP-2022' in a white box. A yellow arrow points from the 'Task due by' column of the table in the screenshot to this callout box.

General Overview – ‘Search’ functionality

The screenshot shows the HALO Search interface. At the top left is the HALO logo with 'Release version 4.0'. To its right is a system time display: 'System time 25-APR-2022 12:24:48 +00:00'. Below this is a 'Search' section with a 'Workflow filter' area. This area contains three input fields: 'Search term (general search)' with the value '8220930', 'Search in module' with the value 'Entities', and 'Search in workflow' with the value 'Entities (Internal)'. A green 'Search' button is to the right of these fields. Below the 'Search' button is a 'Custom search' dropdown menu. Below the 'Custom search' dropdown is a 'Saved Searches' dropdown menu. Below the 'Saved Searches' dropdown is a 'Search configuration name' input field with the placeholder text 'Add a name to create a new stored Query' and a green '+' button. A yellow callout box points to the 'Search' button and the 'Search' section, containing the text: 'Use the **Search** button to find records in HALO. In the **Search term (general search)** write the record number (excluding prefix e.g., 8220930) or a term. Remember to click the **Search** button to run the query. Use semicolon to separate multiple search strings. To narrow the search use **Search in module** and **Search in workflow**. You can also create custom queries for your search. **Custom search** which allows the user to build stored queries and search in the content of custom case keywords. Custom search queries are stored as personal queries for each user.'

A yellow callout box points to the 'Custom search' dropdown menu, containing the text: 'Custom Search is used to store queries. To create a new query, add a new name in the Search configuration name and click on +'

A green callout box points to the 'Custom search' dropdown menu, containing the text: 'Custom search queries are stored as personal queries for each user.'

The 'Custom search' dropdown menu is expanded, showing a 'Saved Searches' dropdown menu with the value 'Entities (2022-AUG-23)'. Below this is a 'Search configuration name' input field with the placeholder text 'Add a name to create a new stored Query' and a green '+' button. Below the input field are 'Edit' and 'Save' buttons. Below the buttons is a table with columns: 'Pre op.', 'Keyword', 'Operator', 'Value', and 'Post op.'. The table has one row with a checkbox and a menu icon in the 'Pre op.' column, and a redacted row in the 'Keyword' column. Below the table is a '1 - 1' indicator and an 'Add criteria' button.

General Overview – Custom search: Saved Searches

Duplicate search

Workflow filter

Search term (general search) Search in module Search in workflow **Search**

Separate multiple search strings with semicolon

Custom search

Saved Searches **Male (2022-MAY-02)** Search configuration name **Add a name to create a new stored Query** **+**

Edit **Save**

	Pre op.	Keyword	Operator	Value	Post op.	Logical Op.	Sorting ↑↓
<input type="checkbox"/>	(Patient sex	=	MALE)		1
		patient					1-1
		Patient age	!=				
		Patient age group	<				
		Patient initials	=				
		Patient sex	>				
			CONTAINS				
			LIKE				
			NOT CONTAINS				
			NOT LIKE				

Show detailed

Q

Record ID	Master Title	Type	Patient sex	Keywords	Attachment (mouse-over to see all)
3729515	US-VC-000384	Industry/Manufacturer XML	Male	Original filename: icsre2bstore/US-VC-000384/US-VC-000384_1_360ad097-f34c-48e0-9f57-da329137af22.xml, Sender identifier: 100006053TEST, Transmission date: 20220419165735-0400, Report type: Spontaneous Report, Patient initials: pname, Patient sex: Male, Medicine Incident Title: GB-MHRA-ICSR3729515	
3729514	KR-Merck Healthcare KGaA-9303303	Industry/Manufacturer XML	Male	Original filename: icsre2bstore/KR-Merck Healthcare KGaA-9303303/KR-Merck Healthcare KGaA-9303303_1_be411d45-405b-4900-bfa0-a3543e8a50f6.xml, Identifier: EMERCKTEST, Transmission date: 02-MAY-2022 15:19:52, Report type: Report from study, DUP-SEARCH-ID: VAL000000004832468 - KR-Merck Healthcare KGaA-9303303, Patient initials: PAT01, Patient age: 1, Patient age group: Infant, Patient sex: Male, Reporter family name: Kiran, Report creation date: 02-MAY-2022, KR-Merck Healthcare KGaA-9303303, Safety report ID: KR-Merck Healthcare KGaA-9303303, Medicine Incident Title: GB-MHRA-ICSR3729514	
3729513	KR-Merck Healthcare KGaA-9303300	Industry/Manufacturer XML	Male	Original filename: icsre2bstore/KR-Merck Healthcare KGaA-9303300/KR-Merck Healthcare KGaA-9303300_1_dab0db76-b4f6-457c-a351-48a8c8a628ed.xml, Sender identifier: EMERCKTEST, Transmission date: 02-MAY-2022 15:04:19, Report type: Report from study, DUP-SEARCH-ID: VAL000000004832452 - KR-Merck Healthcare KGaA-9303300, Patient initials: PAT01, Patient age: 1, Patient age group: Infant, Patient sex: Male, Reporter family name: Kiran, Report creation date: 02-MAY-2022, KR-Merck Healthcare KGaA-9303300, Safety report ID: KR-Merck Healthcare KGaA-9303300, Medicine Incident Title: GB-MHRA-ICSR3729513	

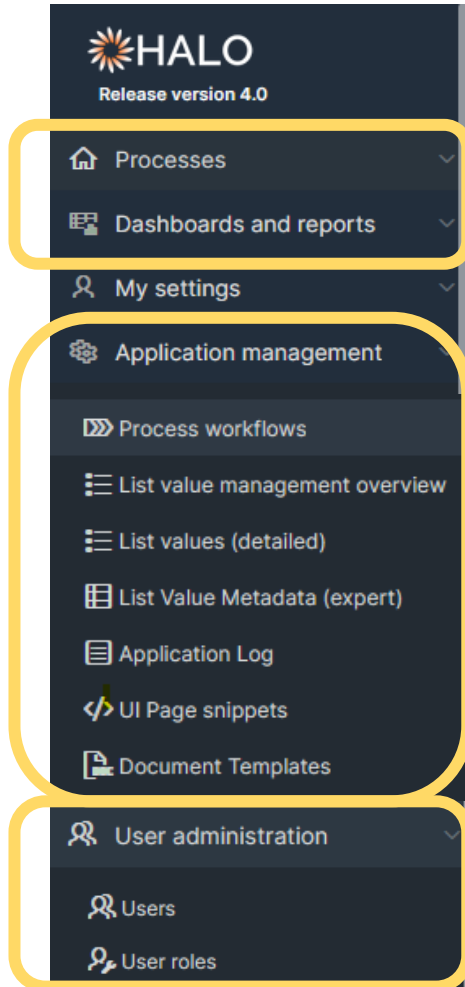
In this form you can either review a previous **Saved Search** or create a new one, by using the **Search configuration name** field, and clicking on **+**

Create the query based on the available values and click on **Add criteria**. Remember to save the query using the **Save** button.

Click on **Search** to run the query.

A list of records will display below your search.

General Overview – Main Menu



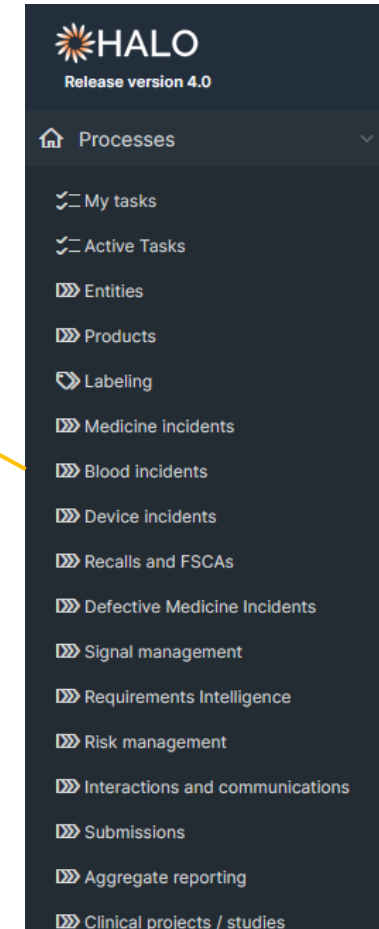
In the left pane, you will find the sections **Processes** (This section list all **Modules** available to your HALO user) and **Dashboards and Reports**.

Modules and workflows are configurable using **Application Management**.

Note: depending on your role, other links may be available




The **Application management** role gives access to the **Application management process**. In this section the user can update workflows configuration, list of values, document templates – including access to the general application log.

The **User Admin** role gives access to the **User administration process**. In this section users can be created/updated, and roles updated.



General Overview: List of HALOPV Modules

Base (always included)

-  Products
-  Clinical studies
-  Entities






Case processing

-  ICSRs (Medicines incidents)
-  Complaints
-  Device reporting
-  Literature

Regulatory and Science

-  Signals
-  Risks
-  Labelling
-  Aggregate Reporting

Oversight and Quality

-  PSMF
-  Requirements Intelligence
-  Data Collection Programs
-  Quality
-  Agreements

Data exchange

-  Submissions
-  Medical Information and Communication

General Overview – Processes and workflows

HALO
Release version 4.0

System time
02-MAY-2022 14:35:42 +00:00

Processes

- My tasks
- Active Tasks
- Products**
- Labeling

Products

Available workflows

- Product families**
- Product (medicinal) management

Products / Product families Records

Process description

The product families are a common denominator for a grouping of medicinal products.

Records updated after: 02-APR-2021

Completed records? ☐

Nullified records? ☐

Assigned to others? ☐

Records (Products families)

Obs	Record ID	Parent record	Title / Identifier	Type	Active task	Countries	Organization
	PRODFAM-32	-	SuperDrug Family	-	Create/Update Product Family	-	Root organization
	PRODFAM-37	-	Paracetamol	-	Create/Update Product Family	-	Root organization

View/edit record

Create/Update Product Family

Complete task

Paracetamol (PRODFAM-37) (Revision 1)

Task instructions

Create a new / Update an existing Product family record.
Product Families are the top level of the product hierarchy

Task activities (red status means mandatory)

Data forms

Product Family details

About

Workflow description. Wording is configurable.

When selecting a **Process**, a list of **Workflows** will display.
Each workflow has a set of workflow steps configured.
E.g., **Module Products > Product Families**.
In the current example **Product Families** workflow has only one step configured.
Click on a **Workflow** to review the list of records listed under the workflow.

List of records (Record Worklist) in the current process workflow

General Overview – List of Workflows

The screenshot displays the HALOPV system interface. On the left is a dark sidebar with the HALOPV logo and release version 4.0.2, along with a list of navigation items including Processes, My tasks, Active Tasks, Agreements, Entities (organizations), Product Management, Labeling, Environment Overview, Device Incident Processing, ICSRs (Medicines incidents), PSMF Management, Requirements Intelligence, Records Management, Signal Management, Defective Medicines, Risk Management, Data Collection Programs, Interactions, Time management, and Quality Management. The main content area is titled 'Products' and includes a system time display (25-AUG-2022 13:42:15 GMT (Europe/Copenhagen)), a search bar, and a user profile (MICHELLE.NOERREGAARD@INSIFE.COM). Below this is a description of the product repository management. A yellow rounded rectangle highlights the 'Available workflows' section, which lists: Product Families, Medicinal Products, Device Products (and constituents), Product Licenses (Authorizations), External Products, Substance Groups, and Scientific Ingredient groups. To the right of this is a 'Functionality menu' listing various tools like Product tree overview, Product index browser, Product faceted search, Product index faceted search, ATC code browser, GMDN Browser, Manage Admin Routes, Manage Pharm Forms, Manage Master File Locations, Manage Substances, and Term based coding of products.

The Module front page contains workflows and functionalities. The list of workflows are configurable. The same applies for Module's description and the list in the Functionality Menu.

To know more on how to update the wording, please review **Admin Manual: Application Management and User Admin**.

Record Worklist

System time
03-AUG-2022 12:49:16 GMT (Europe/Copenhagen)

Q Search

MICHELLE.NOERREGAARD@INSIFE.COM

ICSRs (Medicines Incidents) / ICSR Processing Records

☒ Completed records?

☒ In workflow records?

☐ Nullified records?

☐ Assigned to others?

Create from Wizard

Batch

Auto-assign

Records (ICSRs)

Q

Go

1. Primary Report

Rows 50

Actions

The maximum row count for this report is 500 rows. Please apply a filter to reduce the number of records in your query.

1 - 50 of more than 500

Record ID	Title / Identifier	Type	Fatal/life Threatening Events	Serious Events	Non-serious Events	Suspect Products	Non-suspect Products	Priority	Current Task	Keywords
ICSR- Proce- 6436769	Migrated Case: TW- 009507513- 16111WN000170	Spontaneous Report			Drug-induced encephalopathy	PEMBROLIZUMAB; CISPLATIN; FLUOROURACIL; CISPLATIN; 5- FLUOROURACIL; 5-FLUOROURACIL	HYDROCORTISONE; NOT CLASSIFIED; NOT CLASSIFIED; RANITIDINE; METOCLOPRAMIDE; COMBIVENT; XYZAL; NOT CLASSIFIED; MAGNESIUM SULFATE; SENNOSIDES; MANNITOL; CHLORPHENIRAMINE MALEATE; NOT CLASSIFIED; LASIX; ESOMEPRAZOLE; NOT CLASSIFIED; NOT CLASSIFIED; HYDROCORTISONE; CHLORPHENIRAMINE MALEATE; XANAX; ELTROXIN; LEVOCETIRIZINE; NOT CLASSIFIED; ZOPICLONE; NOT CLASSIFIED; NOT CLASSIFIED; METOCLOPRAMIDE; METOCLOPRAMIDE; GRANISETRON; METOCLOPRAMIDE;	4	COMPLETED	-

Records (Products)

Q

Go

1. Primary Report

Rows 50

Actions

The maximum row count for this report is 1,000 rows. Please apply a filter to reduce the number of records in your query.

1 - 50 of more than 1,000

Current Revision	Record ID	Title / Identifier	Product Type	Active Ingredients	Current Task	Last updated	Overall due date	Withdrawn Date	Effective Date
1	PRODUCTS- 6404326	Advil	Medicinal Product / Drug	IBUPROFEN	Create/Update product	03-AUG-2022 12:59	25-APR-2023	-	01-JAN-2022
1	PRODUCTS- 6404676	Aminomix 1.9	Vaccine	Maleic acid; Amino acids nos; Chloride; Proline; Glycine; Alanine; Lysine; Glycerophosphoric acid; Lysine hydrochloride; Sodium glycerophosphate; Leucine; Methionine; Phenylalanine; Glucose monohydrate; Malic acid; Magnesium; Potassium; Sodium; Zinc; Calcium; Potassium chloride; Zinc chloride; Sodium chloride; Magnesium chloride hexahydrate; Histidine; Calcium chloride dihydrate; Valine; Threonine; Tyrosine; L- Asparagine; Arginine;	-	07-JUN-2022 13:36	26-MAY-2022	-	-

You can access a record worklist by clicking on a workflow. E.g., ICSRs (Medicine Incidents) > ICSR Processing

The view will display the **Records** that are either in progress or have been completed within this workflow.

The Records worklist 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**, **Current task**, **Overall Due date** (the date that the task is due to comply with set timelines).



Record Worklist

System time
03-AUG-2022 12:49:16 GMT (Europe/Copenhagen)

Search MICHELLE.NOERREGAARD@INSIFE.COM

ICSRs (Medicines Incidents) / ICSR Processing Records

☒ Completed records? ☒ In workflow records? ☐ Nullified records? ☐ Assigned to others?

Create from Wizard Refresh Batch Auto-assign

Records (ICSRs)

Go 1. Primary Report Rows 50 Actions

The maximum row count for this report is 500 rows. Please apply a filter to reduce the number of records in your query.

1 - 50 of more than 500

Record ID	Title / Identifier	Type	Fatal/life Threatening Events	Serious Events	Non-serious Events	Suspect Products	Non-suspect Products	Priority	Current Task	Keywords
ICSR- Proce- 6436769	Migrated Case: TW- 009507513- 1611TWN000170	Spontaneous Report			Drug-induced encephalopathy	PEMBROLIZUMAB; CISPLATIN; PEMBROLIZUMAB; 5- FLUOROURACIL; CISPLATIN; 5- FLUOROURACIL; 5-FLUOROURACIL	HYDROCORTISONE; NOT CLASSIFIED; NOT CLASSIFIED; RANITIDINE; METOCLOPRAMIDE; COMBIVENT; XYZAL; NOT CLASSIFIED; MAGNESIUM SULFATE; SENNOSIDES; MANNITOL; CHLORPHENIRAMINE MALEATE; NOT CLASSIFIED; LASIX; ESOMEPRAZOLE; NOT CLASSIFIED; NOT CLASSIFIED; NOT CLASSIFIED; HYDROCORTISONE; CHLORPHENIRAMINE MALEATE; XANAX; ELTROXIN; LEVOCETIRIZINE; NOT CLASSIFIED; ZOPICLONE; NOT CLASSIFIED; NOT CLASSIFIED; METOCLOPRAMIDE; METOCLOPRAMIDE; GRANISETRON; METOCLOPRAMIDE; DEXAMETHASONE; NOT CLASSIFIED; HYDROCORTISONE; NOT CLASSIFIED; CHLORPHENIRAMINE MALEATE; NOT CLASSIFIED; LASIX; SODIUM CHLORIDE; METOCLOPRAMIDE; LASIX	4	COMPLETED	-
ICSR- Proce- 6436759	Migrated Case: JP- 009507513- 1611JPN010796	Spontaneous Report			Bullous pemphigoid	GLACTIV	METFORMIN HYDROCHLORIDE	4	COMPLETED	-
ICSR- Proce- 6436722	Migrated Case: US- 009507513- 1611USA009870	Spontaneous Report			Thrombocytopenia; Hyponatraemia; Hypomagnesaemia	CARBOPLATIN; PEMBROLIZUMAB; 5-FLUOROURACIL; 5- FLUOROURACIL; PEMBROLIZUMAB; CARBOPLATIN; 5-FLUOROURACIL; CARBOPLATIN; 5-FLUOROURACIL;	ZOFRAN; SYNTHROID; LIPITOR; ANTABUSE; CYMBALTA; XANAX; ZOFRAN; PRILOSEC; NORVASC	-	COMPLETED	-

Actions available in all
Interactive Reports

The Records list is an **Interactive Report**.
As with all Interactive Reports, several
actions can be performed.

For more detailed information on how to
use additional functionalities on your
reports. Please check the **User Guide -
Public Reports**.

Record Worklist

Batch allows the user to batch update multiple records. It is possible to perform Batch actions, including re-assignment of the cases, changing case priority, changing workflow status (routing), and addition/ removal of Tags from cases.

Tick the **In workflow records** box to include existing open records

Tick the **Completed records** box to include existing completed records



By ticking this box, previous nullified (soft deleted) records will display in the list of records.

Records which are assigned to others are included if this switch is enabled.




Process description

Manage partners, clients accounts or entities within the organization e.g. other geographic location.

☒ Completed records? ☒ In workflow records? ☐ Nullified records? ☐ Assigned to others?

Create from Wizard   **Batch** **Auto-assign**

Records (Org. Entities)

Q  Go Rows 50  Actions 

1 - 9 of 9

Record ID	Entity name	Priority	Orgentities Address	Orgentities Postal	Orgentities City					
ORG-INT-8221060	Insife	-	Gladsaxevej 384A, st., Søborg	2860	Gladsaxe					
ORG-INT-1	Root organization	-	Gladsaxevej 384A, st. Søborg	2860	Gladsaxe	Denmark	Yes	HALODEV	COMPLETED	-

Auto-assign can be triggered either on case level (assigning individual cases) or on a workflow level (running on all records in the workflow) – this requires the Workflow manager role. If no limit is provided, the system limits to 50 cases per user.

Interactive Report - Hide and Sort columns

Click on the column label to enable the sorting and hide options

Hide the column from the list

Records

Q Go Rows 50 Actions

Obs	Record ID	Parent record	Intake record	Type	Active task	Countries	Organization	Assigned to	Due by	Overall Due Date	Last updated
	ICSR-IN-717	-	ICSR-100	-	Intake	-	-			SEP-2021	23-SEP-2021 11:4

Sort the data ascending or descending

Control break allows to sort data after the list of values, e.g., record type

Note : To save the new changes, please refer to the slide **Save your new public report.**

Interactive Report - Enable columns

Records

Search Go Rows 50 Actions ▾

Columns

Obs	Record ID	Parent record
⚠	ICSR-IN-717	-
⚠	ICSR-IN-147	-
	ICSR-IN-668	-
	ICSR-IN-656	-
	ICSR-IN-586	-
	ICSR-IN-580	-

Filter
Data
Format
Chart
Group By
Pivot
Report
Download
Help

Select the number of records to show in your window

Use the **Actions** button to access the list of actions. Here you can add additional filters to your data, remove or add columns, create a chart or download your data as a report.

Click **Columns** to select the columns you want to display in your report. On the right list, you can organize the columns' order using the available arrows. Click on Apply when you are done.

Note: To save the new changes, please refer to the slide **Save your new public report.**

Select Columns

Do Not Display		Display in Report
Created by	⊞	Obs
Destination	>>	Record ID
Master Description	>	Parent record
Master Notes	<	Intake record
Master Url	<<	Type
Prefix		Active task
Revision		Countries
Wf Task Instance Id		Organization
Wfcompletedflag		Assigned to

Cancel Apply

Interactive Report - Filter Data in Columns

There are different options to filter your data. For example:

1. Clicking on the header and selecting a value from the list. The list will display the data based on the filters applied. The green **Filter** icon indicates that a filter is active. Pressing **X** will remove the filter.
2. Using the option **Actions > Filter** allows you to create simple or advanced filters, such as creating your own query, as in the example below.

The screenshot displays the InSight Interactive Report interface. At the top, there are checkboxes for 'Completed records?', 'In workflow records?' (checked), 'Nullified records?', and 'Assigned to others?'. A green 'Create from Wizard' button and icons for refresh, print, batch, and auto-assign are also present.

The main section is titled 'Records (ICSRs)'. It includes a search bar, a 'Go' button, a dropdown for '1. Primary Report', a 'Rows' dropdown set to '50', and an 'Actions' dropdown. A filter is applied: 'Type = Spontaneous Report', indicated by a green filter icon and an 'X' to remove it. Below this, a message states: 'The maximum row count for this report is 500 rows. Please apply a filter to reduce the number of records in your query.' The table shows '1 - 50 of more than 500' records.

The table has columns: 'Record ID', 'Title / Identifier', 'Type', 'Fatal/life Threatening Events', 'Serious Events', 'Non-serious Events', and 'Suspect Products'. The 'Type' column is highlighted, and a dropdown menu is open, showing options: 'Not available to sender (unknown)', 'Other', 'Report from study', and 'Spontaneous Report' (selected).

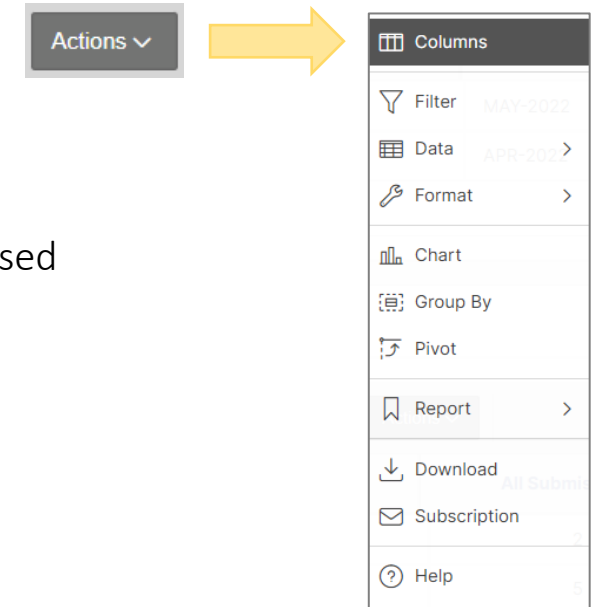
Two 'Filter' dialog boxes are shown. The first dialog has tabs for 'Column' and 'Row'. The 'Column' tab is active, showing a filter for 'Organization' with the operator '=' and the expression 'Affiliate (Denmark)'. The second dialog has tabs for 'Column' and 'Row'. The 'Row' tab is active, showing a filter for 'Name' with the expression 'WITHIN LAST 2 YEARS' and a 'Filter Expression' field containing 'D> SYSDATE - 730 OR D IS NULL'. Below these fields are sections for 'Columns' and 'Functions / Operators' with various options like 'A. Last updated', 'C. Prefix', 'D. Overall due date', 'H. Workflow status', 'J. Assigned to', 'K. Organization', 'L. Master Url', and 'ABS'. At the bottom of the second dialog are 'Cancel', 'Delete', and 'Apply' buttons.

Interactive Report – Additional functionalities

Several Actions are available for Interactive Reports.

Press the drop-down arrow of the **Actions** button to display the list of functions:

- **Columns:** select the columns to display in the report
- **Filter:** apply additional filter criteria
- **Data:** sort columns, sum columns, create a new column (e.g., aggregate data) or view data based on previous timepoint (aka Flashback)
- **Format:** add control breaks (e.g., by type) or highlight columns in the table
- **Chart:** create charts based on available columns
- **Group By:** group data based on available columns
- **Pivot:** create a pivot table
- **Report:** save the current report settings as a **Public Report** or **Personal Report**
- **Download:** download the records in CSV, HTML, XLS or PDF formats
- **Subscription:** subscribe to the report via email, e. g. to receive the report results on a weekly basis
- **Help:** review in details what each functionality can perform



Save your new Public Report

Records

Organization = 'ABC Company Ltd.'

Obs	Record ID	Parent record
	ICSR-IN-72	-
	ICSR-IN-57	-
	ICSR-IN-539	American journal of respiratory cell and molecu
	ICSR-IN-580	-
	ICSR-IN-147	-

Actions > Report > Save Report

The **Default** section **Primary Report** includes all entries stored in that specific process.

To save your new report:

1. Click on **Action > Report > Save Report**. A new window will open.
2. Give a name to your new report and select **Public** if you want to share the new report publicly. To proceed, click on **Apply**. *If you do not click on **Public**, it will save the report as **Private**.*
3. Click on the drop-down list of reports. The new Public Report is available in the section **Public**.
4. To reset your view to **Default** settings, click **Actions > Report > Reset**. Please note that this will not affect your saved **Public Reports**.

Save Report

Name: ABC Company Ltda.

Description:

☒ Public

Cancel Apply

1. Primary Report

Default

1. Primary Report

Public

1. ABC Company Ltda.

ID	Parent record	In take	Active task	Countries	Organization	
-	-	My new case from email	-	Duplicate search	-	ABC Company Ltd.
-	-	Third test	-	Duplicate search	-	ABC Company Ltd.
-	American journal of	American journal of	Duplicate	-	ABC	

Note: Only the user who created the **Public Report** can update or delete it. If you are the data owner of a Public Report, you can always go back and make changes. But remember to save it again under the same name once you are done.

Creating a new Record

The screenshot displays the insafe application interface. On the left, a dark sidebar contains a menu with items: Processes, My tasks, Active Tasks, Agreements, Entities (organizations), Product Management, Labeling, Environment Overview, Device Incident Processing, ICSRs (Medicines incidents), PSMF Management, and Requirements Intelligence. The 'Entities (organizations)' item is highlighted with a yellow box, and an arrow points from it to the 'Entities' section in the main content area. The 'Entities' section has a header 'Entities' and a sub-header 'Manage the global organization'. Below this, there is a section 'Available workflows' with a list of items: Entities (Internal), Entities (External), Imported Companies, and PV Country contacts. The 'Entities (External)' item is highlighted with a yellow box, and an arrow points from it to the 'Entities / Entities (External) Records' breadcrumb at the top of the main content area. The breadcrumb is also highlighted with a yellow box. Below the breadcrumb, there is a 'Process description' section with a text area containing the text 'Regulators, Sub-contractors, Committees, and Customers.' To the right of the text area, there is a row of buttons: 'Create from Wizard', a refresh icon, a print icon, 'Batch', and 'Auto-assign'. The 'Create from Wizard' button is highlighted with a yellow box. Below the buttons, there is a text box with instructions on how to create a new record.

Entities / Entities (External) Records

Process description

Regulators, Sub-contractors, Committees, and Customers.

Entities

Manage the global organization

Available workflows

- Entities (Internal)
- Entities (External)
- Imported Companies
- PV Country contacts

Create from Wizard

Nullified records?

Assigned to others?

Batch

Auto-assign

To create a new record, click on a **Module** and choose a **workflow**, e.g., *Entities > Entities (External)*

If your user has the role to create records, a green button, **Create from Wizard**, will show on the top of the record worklist.

When clicking on **Create from Wizard**, a new window will pop up for you to enter the record information.

Note: User needs to have the role to perform this task (user roles are generally assigned by the User Admin.)

Creating a new Record: Record Title

The image displays two side-by-side screenshots of the 'Create record Wizard' form. Both windows have a title bar 'Create record Wizard' and a close button. The main heading is 'New record' with a subtext: 'You are about to create a new record. Please fill in the fields in this form to get started!'. The form is divided into two main sections: 'Enter basic information' and 'Static information'. In the left screenshot, the 'Enter basic information' section has a red mark next to 'Record Title' (value: 'Pharma ABC') and 'Record Type' (value: 'Entities'). The 'Static information' section has 'Process' (value: 'Entities') and 'Workflow' (value: 'Entities (External)'). In the right screenshot, the 'Enter basic information' section has a red mark next to 'Record Title' (value: '[The title will be auto-populated ...]') and 'Record Type' (value: 'Entities (External)'). The 'Static information' section has 'Process' (value: 'ICSRs (Medicines Incidents)') and 'Workflow' (value: 'ICSR Processing'). Both screenshots have a yellow box around the 'Enter basic information' section and a green box around the 'Create' button. The 'Create' button is green with white text, and the 'Cancel' button is grey with black text.

The **Record Title** can be added manually or auto-populated, as shown on the right image. It might be that some additional fields are available, e.g., **Record type**, **Reporting to**, etc. The red mark indicates a mandatory field; a value must be entered to proceed. If you do not set a **Master Due date**, the system will set a default value based on the workflow configuration. Fill in accordingly and click on **Create** to open the record view.

View/edit record: Main features

Example of an active step. The record is currently on the first step.

Record's title.

Prefix accompanied by a unique HALO record ID.

Task instruction describes the task to perform in the step.

Tags can be manually or automatically added. This function helps overview records, e.g., Serious ICSRs.

About

- **Priority:** it is used to sort records in the worklist.
- **Role to process task:** role requires to perform the tasks in the step.
- **Assigned user:** you can assign the record to your user or another user or auto-assign it to someone with the group role.
- **Task due:** days assigned to complete the step (*Days are set up in the configuration. For more information on how to set up days, check Admin Manual: Application Management and User Admin.*)
- **Workflow due:** it is the total days to complete the workflow. If you click on the record's title, you will find both 'task due' and 'Workflow to be completed by.'

The screenshot shows the 'View/edit record' interface for a record titled 'Pharma ABC ORG-EXT-6404206 Partner (Revision 1) Entities (External)'. The interface includes a top navigation bar with 'Create/Update Entity' and 'Review and Approve' buttons. A user profile for 'MICHELLE.NOERREGAARD@INSIFE.COM' is visible. The main content area is divided into several sections: 'Task instructions' (Populate the details of the organizational entity in the form and complete workflow step.), 'About' (Priority: Set priority, Role to process task: Entities processor, Assigned user: Assign user | Assign to me | Auto-assign, Task due: 11-JUN-2022, Workflow due: 11-JUN-2022), 'Tags' (Privacy, Valid), 'Records owned by entity' (ICSR Processing 1, Data collection programs 1), 'Task activities' (red status means mandatory), 'Data forms' (External Partner form), 'Status' (0), 'Links / other activities' (Create PV Agreement, Create Data Collection Program), 'Description' (Description), 'Notes and linking' (Notes, URL), and 'Basic information' (Entity name: Pharma ABC, Type: Partner, Task due by: 11-JUN-2022, Workflow to be completed by: 11-JUN-2022, Priority, Source (External) ID). Annotations point to various elements: 'Record's type' points to 'Entities (External)'; 'Record's title' points to 'Pharma ABC ORG-EXT-6404206 Partner (Revision 1)'; 'Prefix accompanied by a unique HALO record ID' points to 'ORG-EXT-6404206'; 'Task instruction describes the task to perform in the step' points to 'Populate the details of the organizational entity in the form and complete workflow step.'; 'Tags can be manually or automatically added. This function helps overview records, e.g., Serious ICSRs' points to the 'Tags' section; 'About' points to the 'About' section; 'Priority: it is used to sort records in the worklist' points to 'Priority: Set priority'; 'Role to process task: role requires to perform the tasks in the step' points to 'Role to process task: Entities processor'; 'Assigned user: you can assign the record to your user or another user or auto-assign it to someone with the group role' points to 'Assigned user: Assign user | Assign to me | Auto-assign'; 'Task due: days assigned to complete the step (Days are set up in the configuration. For more information on how to set up days, check Admin Manual: Application Management and User Admin.)' points to 'Task due: 11-JUN-2022'; 'Workflow due: it is the total days to complete the workflow. If you click on the record's title, you will find both 'task due' and 'Workflow to be completed by.'' points to 'Workflow due: 11-JUN-2022'; 'Indicates in which workflow the record is stored in HALO' points to 'Entities (External)'; 'Record's revision' points to '(Revision 1)'; 'Description and Notes and linking can be enable/disable in Process Configuration' points to the 'Notes and linking' section.

View/edit record: Main features

Task activities shows the tasks needed to perform your task in the current workflow step. Each task will open a new window. Additional tasks might be configured and are available on the right section **Link/other activities**.

Status indicates if any action is still pending in the step. If the status is marked red, a validation rule **Pending actions** will display on the top of the window.

- **Add related record:** add a child/related record to the current record.
- **Associated records:** include any related record to the current main record (Parent/ Child/ Linked record.) Also listed on the '*Records created by*' area.

View/edit record

Navigation: Create/Update Entity → Review and Approve

User: MICHELLE.NOERREGAARD@INSIFE.COM

Buttons: Complete task, Save, Close X

Pharma ABC (ORG-EXT-6404206) - Partner (Revision 1) Entities (External)

Task instructions
Populate the details of the organizational entity in the form and complete workflow step.

About
Priority: Set priority
Role to process task: Entities processor
Assigned user: Assign user | Assign to me | Auto-assign
Task due: 11-JUN-2022
Workflow due: 11-JUN-2022
Tags: Priority, Valid

Task activities (red status means mandatory)

Data forms
External Partner form

Status
Green circle with plus sign

Links / other activities
Create PV Agreement
Create Data Collection Program

Description
Description

Notes and linking
Notes
URL

Records owned by entity
ICSR Processing 1
Open 0

Records owned by entity
Data collection programs 1

Associated records
Agreements 2
Open 2

Associated records
ICSR reporting requirements 1
Open 1

Add Related record

Related Records

Title	Type	Workflow	Organization	Status	Territory	Reporting destination	Link Type	Reason
Pharma ABC (6404207)	Post-marketing - Device	ICSR reporting requirements	Root organization	Register / update ICSR reporting requirements		Pharma ABC	Child record	
Data collection programs - Pharma ABC DCP (6404233)	Market research program	Data collection programs	Root organization	COMPLETED			Child record	
Agreements management - Pharma ABC - IT Provider (822262)	Technical Provider	Agreements	Root organization	Create/update agreement	China (CN), Denmark (DK), Italy (IT), Japan (JP), EUROPEAN UNION (EU)		Child record	
Agreements management - Pharma ABC (6404208)	Commercial arrangement partner	Agreements	Root organization	Agreement to Company link	Albania (AL), Angola (AO), Germany (DE)		Child record	
Data collection programs - Pharma ABC PSP (8223499)	Patient support program	Data collection programs	Root organization	Review			Linked record	

View/edit record: Main features

Example of an active step.

Allows user to move the record to a different step or workflow

Assign a parent/related record to the current record

To proceed to the next step, click on **Complete task**

If an action/document is missing, you can **send back task** to the previous data owner. If notifications are configured, the group role will receive a message

Summary auto-calculates the summary of the case. The summary is configurable via Workflow configuration (Advanced > Summary to display). The summary uses HALO document templates (HTML) to allow configuration of the summary.



- A Workflow shows a graphical representation of an active and inactive step, your role, the tasks assigned to that role, and the due date.

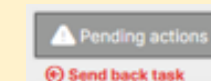
- Some sections are configurable and might not be available in all workflows, e.g., Summary, Description, Notes, and linking.

IMPORTANT: The user who opens the record is the only one who can edit the record - meaning the record gets locked by the user. And the read-only mode is activated for other users.

After completing your task, please remember to close the record. To close a record, click on **Close X**. If you forgot to close it properly, the record will be locked by your user for 30 mins.

Attach document(s) to the record

Emails alert for workflow with correspondence content



If the **Complete task** button is not available: A task(s) is mandatory, and the step cannot be completed before it is done. Click on **Pending actions** to review pending tasks in the step.

Print allows the user to generate ad-hoc documents from the Document template repository.

View/edit record: Workflow steps

View/edit record

→ Register ICSR information → **Medical Review** → Quality control → Submission → Send positive acknowledgment

Pending actions

Send back task

ICSR-PROC82

Task instructions

About

Priority: 1

Role to process task: Automations

Assigned user: MICHELLE.NOERREGAARD@INSIFE.COM

Task due: 20-JUN-2022

Workflow due: 20-JUN-2022

Tags

Non-UK Privacy Missing UDI Valid Serious ICSR +

Patient / Parent

Reporter(s)

Drug(s) information

Event(s)

Drug(s)-reaction(s) / Event(s) Matrix

Narrative / Summary

Event listedness and datasheets

→ ⌚ Create/Update Entity → ⏹ Approve

- Completed steps are marked with an 'approval' icon.
- Pending step will show a clock icon.
- Active step is highlighted in yellow.
- Automatic steps are characterized by the 'play' icon.

There are two types of steps; manual, which require user intervention to be completed, and automatic steps, which are run and completed by an **Automator**.

View/edit record: Pending task

Workflow: Create/Update Entity → Review and Approve

Complete task

ABC-DK (ORG-EXT-6404370) - Clinical site (Revision 1) Ent

Task instructions
Populate the details of the organizational entity in the form and complete workflow step.

Task activities (red status means mandatory)

Data forms	Status
External Partner form	0

- When tasks are completed, or no validation rule is set up, the **Status** will show a **green** icon with '0.'
- When tasks are **not** completed, validation rules will trigger. The **Status** will show a **red** icon with the number of validation errors. When validation errors are present, a warning is shown, and it is not possible to route the case to the next workflow step. Detailed errors can be seen if clicking **Pending actions**. On the tab **Quality issues**, you will find details of the validation errors in the data forms. Once you have completed the pending tasks, the **Pending actions** button will be replaced by the **Complete task** button.

N.B. Remember to click on **Complete task** button after completing the task(s).

Workflow: Register ICSR information → **Medical Review** → Quality control → Submission → Send positive acknowledgment

Pending actions

ICSR-PROC8219600 - Spontaneous Report (Revision 1) ICSR Processing

Task instructions

Task activities (red status means mandatory)

Data forms	Status
Sender(s) and Case info	5
Patient / Parent	1
Reporter(s)	2

Field extensions and AI scores | **Quality issues** | Quality issues - Closed

Quality issues

Q Go Actions

Error	Value	Element	Page
At least one patient attribute must be populated (Initials, Age + unit, Age group, Date of birth or Gender)	(Validation Issue)	P684_D_1	PAGE 684 - Patient
Date of Most Recent Information for This Report must be filled	(Validation Issue)	P600_C_1_5	PAGE 600 - Sender and Reporter information
Medicinal Product Name as Reported by the Primary Source must be filled	(Validation Issue)	P640_DRUG_NAME_VERBATIM	PAGE 640 - Product(s) information

View/edit record: Attachment area

Documents

Folders

REV1/

Add new folder

+

Upload file(s)

Drop files here (click to browse)

Upload

Documents > General/8219600/REV1/

Actions Edit Save

File	Title	Description / type	Author	Comment	Related Narr.
Download	Hello World.pdf	Record attachment			

1 rows selected Total 1

Working files (Sharepoint/Onedrive)

Q Go Actions

No files found. To see working folder files, you need to be signed in.

It may take a minute or two for updates to be reflected in the list

Print 0 3 Save Close

The **Attachment area** has the following sections:


- **Folders:** It is possible to create folders per revision. Users can have access to the documentation previously uploaded.
- **Upload file(s):** Click to browse or drop files in the grey area. Click on Upload. Once uploaded, the documents will show in the Documents section.
- **Documents:** Section where uploaded documents are stored.
- **Working files (SharePoint/OneDrive):** If your environment is linked to our SharePoint service, documents can be uploaded and shared with others. If you want to upload your document to the GxP area, click on Load to HALO. The document will be listed in the **Documents** area.

Working files (Sharepoint/Onedrive)


Object	Last Modified	Action
Hello World.pdf	19-AUG-2022 08:28:18	Load to HALO
Hello World.docx	19-AUG-2022 08:31:37	Load to HALO

View/edit record: Attachment area

Files uploaded using the section **Upload file(s)** will show in the **Documents** section. Users can download documents to their local computers using the **Download** link.

Documents stored in the GXP section cannot be altered. If you need to upload a newer version, click on  and select **Delete Row** and upload the new document.

The record view will display '1' file in the paper click icon (as shown in the picture.) Please note that only documents in the GxP area will count, as documents in the SharePoint area are not considered GxP.


File	Title	Description / type	Author	Comments
 Download	Annex A.1 - QPPV Delegated tasks.pdf	Record attachment		

View/edit record

PSMF-MAIN-5633570 → Upload Document → Review final PDF

Complete task

MICHELLE.NOERREGAARD@INSIFE.COM

1  Save Close X

Annex A.1 (PSMF-A.1-8220485) (Revision 2) >>> Annex A.1 - QPPV Delegated Tasks

View/edit record: Additional features

View/edit record

→ Create/Update product → Update Product Index

Complete task

Advil (PRODUCTS-6404326) - Medicinal product (Revision 1)

Task instructions
Enter relevant information pertaining to the product attributes

About

Priority: Set priority

Role to process task: Generic product management

Task due: 23-MAR-2023

Workflow due: 25-APR-

Task activities (red status means mandatory)

Data forms	Status
Medicinal Product Details	0

Description

- Record info
- Record scope
- Workflow history
- Record revisions
- View audit log
- Nullify or deactivate record
- Clone record
- Help
- Keywords
- Print
- Metadata
- Generate regulatory report

To access additional functionalities on a record, click on the 3 dots. A drop-down will display a list of options:

- Record info: Record scope
- Workflow history
- Record revisions
- View audit log
- Nullify or deactivate record
- Clone record
- Help
- Keywords
- Print:
- Metadata
- Generate regulatory report

View/edit record: Additional features

Record details

Record scope

Organizational entity
Root organization

Assigned to
Michelle Norregaard

Countries

Add country
Belgium (BE)

Country	Remove
Belgium	
Denmark	

Audit Log

Audit Log Record access log

Audit no.	Updated	Master title	Field	Old value	New value	User	Record link
3	14-JUL-2022 09:27AM (GMT Europe/Copenhagen)	Annex C.1 -	Master Record Org. Entity	-	Root organization	MICHELLE.NOERREGAARD@INSIFE.COM	8220790
3	14-JUL-2022 09:27AM (GMT Europe/Copenhagen)	Annex C.1 -	Master Record Due Date	-	28-jul-2022	MICHELLE.NOERREGAARD@INSIFE.COM	8220790
2	14-JUL-2022 09:27AM (GMT Europe/Copenhagen)	Annex C.1 -	Master Revision Current (Revision 1)	-	[Current]	MICHELLE.NOERREGAARD@INSIFE.COM	8220790

Workflow history

Worklog Active routing rules for this workflow

Revision	Workflow > Task	Task Created	Task Completed	Task notes	User	Late	Routed back
3	ICSR follow-up > Completed Follow up	30-MAR-2022 09:33AM	13-APR-2022 10:13AM	→ Auto-complete (Completed Follow up)		Yes	
2	ICSR follow-up > Completed Follow up	30-MAR-2022 09:30AM	30-MAR-2022 09:31AM	-	SLOBODAN.VUCINIC@INSIFE.COM	No	

Q

Go

Actions

Audit no.	Updated	Master title	Field	Old value	New value	User	Record link
3	14-JUL-2022 09:27AM (GMT Europe/Copenhagen)	Annex C.1 -	Master Record Org. Entity	-	Root organization	MICHELLE.NOERREGAARD@INSIFE.COM	8220790
3	14-JUL-2022 09:27AM (GMT Europe/Copenhagen)	Annex C.1 -	Master Record Due Date	-	28-jul-2022	MICHELLE.NOERREGAARD@INSIFE.COM	8220790
2	14-JUL-2022 09:27AM (GMT Europe/Copenhagen)	Annex C.1 -	Master Revision Current (Revision 1)	-	[Current]	MICHELLE.NOERREGAARD@INSIFE.COM	8220790

Record info

Record scope

Workflow history

Record revisions

View audit log

Nullify or deactivate record

Clone record

Help

Print

Metadata

Generate regulatory report

To access additional functionalities on your record, click on the 3 dots. A drop-down will display a list of options:

- **Record info:** will show basic record information. You can achieve the same by clicking on the record title.
- **Record scope:** displays your organizational entity. Additional fields could be enabled, e.g., Assigned to, Countries.
- **Workflow history:** shows revisions, completed steps, and the users who completed the steps.
- **Record revisions:** displays record ID, the last time record was updated, and the number of revisions.
- **View audit log:** include changes made to the record and user responsible.
- **Nullify or deactivate record:** use this option to nullify a record. To see this option the user requires the 'nullification' role.
- **Clone record:** records can be cloned using this functionality.

Additional features: Keywords and tags

The screenshot displays the 'View/edit record' interface for an ICSR. Key features highlighted include:

- Keywords Section:** A table listing predefined keywords with columns for Keyword, Context, Score, and Modified By. The keywords listed are QC Check, Non-E2B, Invalid, Manual/Paper, and Non-Serious ICSR.
- Tags Section:** A section for adding predefined tags, with a 'Save' button and a list of tags: QC Check, Non-E2B, Invalid, Manual/Paper, and Non-Serious ICSR.
- Record Info Panel:** A panel on the right showing record details and a dropdown menu with options: Record scope, Workflow history, Record revisions, View audit log, Nullify or deactivate record, Clone record, Help, Keywords, Print, Metadata, and Generate regulatory report.
- Records (ICSRs) Table:** A table showing a list of records with columns for Record ID, Title / Identifier, Type, Fatal/life Threatening Events, and Serious Events. The first record is ICSR-Proc-8223503, identified as ICSR-PROC8223503, with a Type of Other.

Annotations on the screenshot include:

- A yellow box around the record ID 'ICSR-PROC8223503' in the top left.
- A yellow box around the 'Keywords' dropdown menu in the right panel.
- A yellow box around the 'Keywords' section header.
- A yellow box around the 'Tags' section header.
- A yellow box around the 'Delete Keywords' button.

To access additional functionalities on your record, click on the 3 dots. A drop-down will display a list of options:

- **Keywords:** Allows the user to add keywords including tags in records. Keywords are created in the List of values, available on the left pane, **Application Management**. These data elements are created as SQL statements and can be limited to workflows, steps, or roles.

Keywords are used as **TAGS** in records (see image) and **KEYWORDS**. For instance, if an ICSR case is duplicated, a tag can auto-route the duplicated record to a different workflow e.g., Refuted ICSRs.

Additionally, keywords can be sorted in the Record Worklist, e.g., *ICSRs workflows*. (For further details on the duplicate search automation, please refer to the Automation specification)

Keywords are weighed (0 to 1), and the higher the weight, the higher the score of each keyword. If an existing record matches all possible keywords, and all keywords are configured with the weight 1, the score will be 100% - fewer matching keywords or lower scores on some of the keywords result in a lower score.

Keywords are configurable per client. If you require specific keywords, contact Insife.

View/edit record: Additional features

Print document

Template Parameters to include

Template
CIOMS v1.1

Format
WORD

WORD
PDF

Generate Return

☒ Download locally?
Leave blank to upload the generated document

Regulatory report print

Master Id
8222270

Sender Destination

Sender Identifier Receiver Identifier

For automatic submission handling please create a submission child record (this page is intended for ad-hoc generation of reports only)
The generated report is attached to the case

Report Type *

☐ E2B XML (R2)
☐ E2B XML (R2) PSUR
☐ E2B XML (R2-CP)
☐ E2B XML (R3 CHINA)
☐ E2B XML (R3 KOREA)
☐ E2B XML (R3)
☐ MIR

Generate Blinded *

☐ Yes ☐ No ☒ NA

Generate without Personal identifiable information

☒ Yes ☐ No

Generate Return

Record info

Record scope

Workflow history

Record revisions

View audit log

Nullify or deactivate record

Clone record

Help

Keywords

Print

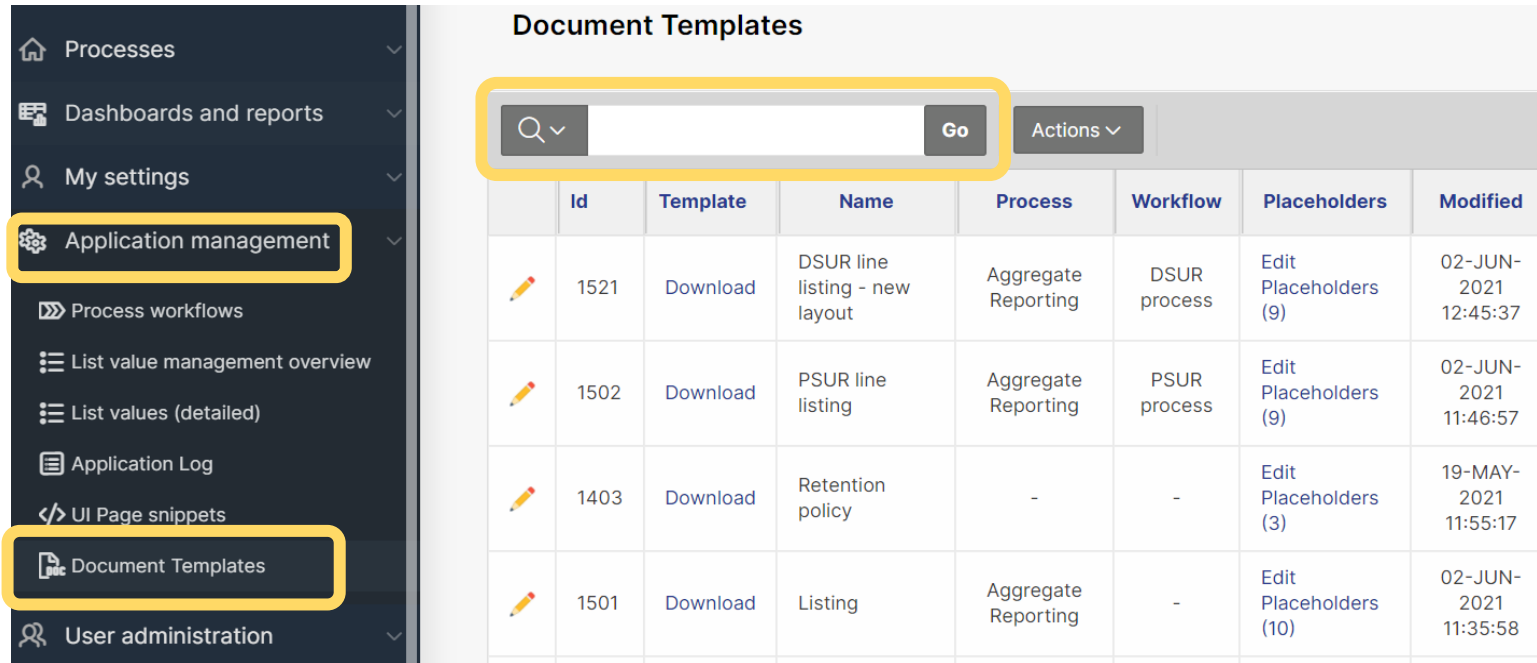
Metadata

Generate regulatory report

To access additional functionalities on a record, click on the 3 dots. A drop-down will display a list of options:

- **Print** allows the user to generate ad-hoc documents from the Document template repository. If a template is configured in the workflow, users can generate reports in the attachment or '**Download locally**' to save a copy to your local computer. This functionality can be used instead of the task action 'Generated documents from reports.' To understand how data is generated in templates, review section 'HALOPV Templates'
- **Metadata** allows the user to see and modify metadata. Metadata is also used to store validation- or quality issues and Field extensions (i.e., AI generated data values). End users cannot add data directly in the metadata tables but can see existing data using the Metadata link in the main form
- **Generate regulatory report**, this option allows the user to print a regulatory report (XML-type reports) for drafting purposes. Unlike the automated report generation which must run on a child submission record, this feature works directly on incident records (i.e., ICSRs or Device cases)

HALOPV Templates



Document Templates

Search: Go Actions ▾

	Id	Template	Name	Process	Workflow	Placeholders	Modified
	1521	Download	DSUR line listing - new layout	Aggregate Reporting	DSUR process	Edit Placeholders (9)	02-JUN-2021 12:45:37
	1502	Download	PSUR line listing	Aggregate Reporting	PSUR process	Edit Placeholders (9)	02-JUN-2021 11:46:57
	1403	Download	Retention policy	-	-	Edit Placeholders (3)	19-MAY-2021 11:55:17
	1501	Download	Listing	Aggregate Reporting	-	Edit Placeholders (10)	02-JUN-2021 11:35:58

The user can find all available templates in the system in the **Application management > Document Templates**.

Use the search box to find a predefined template.

Available features in the section are:

- Modify existing document templates
- Create new document templates
- Modify placeholders in templates
- Download template file

HALOPV Templates: Modify existing document templates

2



The pencil icon allows you to edit the name or upload a new template

1

Download template file

The **Download** option is available in the list of templates or when clicking the pencil icon.

Before updating a template, please ensure to download two copies to avoid losing the current version.

Document Templates								
<input type="text" value="Q"/>		Go		Actions ▾		Create		
	Id	Template	Name	Process	Workflow	Placeholders	Modified	Modified by
	1521	Download	DSUR line listing - new layout	Aggregate Reporting	DSUR process	Edit Placeholders (9)	02-JUN-2021 12:45:37	MARTIN.HOLM-PETERSEN@INSIFE.COM
	1502	Download	PSUR line listing	Aggregate Reporting	PSUR process	Edit Placeholders (9)	02-JUN-2021 11:46:57	MICHELLE.NOERREGAARD@INSIFE.COM

HALOPV Templates: Modify existing document templates

3

Open a copy of the document template on your local computer by right-clicking and selecting **Open with > Word**. Edit header, footer, and placeholder position, e.g. {TITLE}, {COL1}, but avoid changing the order and name of the placeholders in brackets **{#DATA}{/DATA}**. **Placeholder name** should always be the same in the HALO application and the Word document template.

SUSPECT ADVERSE REACTION REPORT					{CASEIDENTIFIER}				
I. REACTION INFORMATION									
1. PATIENT INITIALS (first, last) {PATIENTINITIALS} {PATIENTWEIGHT} {PATIENTHEIGHT}	1a. COUNTRY {COUNTRY}	2. DATE OF BIRTH Day {DD DOB} Month {MMD OB} Year {YY DOB}			2a. AGE {AGE}	3. SEX {SEX}	4-6. REACTION ONSET Day {DD ONS ET} Month {MMO NSET} Year {YY ONS ET}		
7-13 DESCRIBE REACTION(S) (including relevant tests/lab data) {#NARRATIVE1} {@NARRATIVE1} {/NARRATIVE1}									

Example of a validated template.

Note: Validated templates should not be changed.



Annex G.1 - Planned and Ongoing Aud

Data Lock Point {DATE}, Revision {REVISION}

Single values placeholders

Table (Interactive Report) placeholders

(Planned) Audit Start Date	Audit Scope	Ref. No. (ID of Audit Plan)
{#DATA}{/DATA} {COL1}	{COL2}	{COL3}{/DATA}

Template Placeholders

Placeholders

View/edit template

Template

1884

	Template Id	Id	Placeholder Type	Placeholder Name	IR Page ID	Region (Report) ID	Saved Report
	1884	3603	Single value (parameter)	DATE	-	-	-
	1884	3604	Single value (parameter)	REVISION	-	-	-
	1884	3605	Single value (parameter)	TITLE	-	-	-
	1884	3606	Table (Interactive Report)	DATA	86	PSMF Annex C - Contact info	-

{#DATA} {/DATA}
This type of placeholders are used to create tables to list your data, e.g., list of Audit records

RESTRICTED

HALOPV Templates: What are Placeholders

Placeholders are a select statement which returns a distinct value. The query must contain one bind variable which is set to the master id of the record triggering the notification – i.e.:

```
SELECT T.TYPE FROM GOM_PROCESS_MASTER M JOIN VIEW_MASTER_TYPES T ON T.TYPE_ID = M.MASTER_TYPE WHERE M.MASTER_ID = :MASTER_ID AND CURRENT_REVISION = 1
```

Edit Placeholders is mainly restricted to **Insife**. Please do not change/delete the information in the existing placeholders.

Document Templates / Template Placeholders

Placeholders

Template
1521

Template name
DSUR line listing


	Template Id	Id	Placeholder Type	Placeholder Name	IR Page ID	Region (Report) ID	Saved Report	Report parameters	Placeholder SQL (Custom)
	1521	2501	Single value (parameter)	PERIODEND	-	-	-	-	select TO_CHAR(CHILD_DATE_2, 'DD-MON-YYYY') from gom_process_child where child_revision = v('P119_REVISION') AND CHILD_ID = v('P119_MASTER_ID') AND PAGE = 143

Document Templates

	Id	Template	Name	Process	Workflow	Placeholders	Modified
	1521	Download	DSUR line listing - new layout	Aggregate Reporting	DSUR process	Edit Placeholders (9)	02-JUN-2021 12:45:37

HALOPV Templates: Modify existing document templates

Upload a new document template

Document Templates					
<div><input type="text" value="Q"/> <input type="button" value="Go"/> <input type="button" value="Actions"/></div>					
	Id	Template	Name	Process	Workflow
	1521	Download	DSUR line listing - new layout	Aggregate Reporting	DSUR process

4

After modifying a template, click on the pencil to upload the new version of your template

5

Upload your new Word Document template by clicking on **Choose file**

6

Save your new template

Modify Template

Template

View/edit placeholders

Template

Choose File

Download

Template name

CIOMS v1.4

Filename

CIOMS

Process mapping

Submission

Workflow mapping

Type Mapping

Modified

17-JUN-2022 07:40:53

Modified by

ANTE.PENAVA@INSIFE.COM

Save

Save a Copy

Delete

Close

HALOPV Templates: How to generate a report

View/edit record

Upload Data Annex C.1 → Verify and Generate PDF document

Complete task
Send back task

Annex C.1 (PSMF-C.1-8220790) (Revision 1) Annex C.1 - PV Country Contact List

Task instructions
Fill in the PSMF details form available in the Task Activities section. Generate the annex document using the **Generate document from template** button. Upon checking the PDF document, please click on Complete Task.

Task activities (red status means mandatory)

Data forms	Status
PSMF details form (populates I.2)	0
Generate document from template	0

Document link

Action: Assign Document Template

Record Title: Annex C.1

Document Template: **PSMF Template Annex C.1**

Interactive report (Optional)

Template file (Optional)
Select a WORD file as template instead of the default document template

Template file from working area (Optional)
Select a WORD file as template instead of the default document template

Output format: **WORD**

Upload to working folder
☐

Print document

Template: Parameters to include

Template: **PSMF Template Annex C.1**

Format: **PDF**

Interactive report (Optional)

Generate Return

Download locally?
☒ Leave blank to upload the generated document to the record

There are three ways to generate your HALOPV Templates:


- **Generate document from Template** allows users to create a report directly in the attachment area.
- **Print button / More options > Print** allows users to download the report to the local computer or the record.

Formats available: Word and PDF

HALOPV Templates: Duplicate a template

1

Document Templates

	Id	Template	Name	Process	Workflow
	1402	Download	PRR Signal Detection	Aggregate Reporting	Aggregate reporting process

To duplicate a template, select an existing template and click on the pencil icon.

2

Template name
PRR Signal Detection

Filename
PRR Signal Detection

Process mapping
Aggregate Reporting

Workflow mapping
Aggregate reporting process

Type Mapping

Modified
07-JUN-2021 08:49:51

Modified by
ADMIN

Save Save a Copy Delete Close

To duplicate the template, e.g., *testing purpose, version2*, etc. click on **Save a copy**.
Open the new template from the list of templates and rename it.

Note: All templates require placeholders, it's better to create a copy of the template instead of creating a new one, as no placeholders will be assigned. Please contact Insife in case you require assistance creating placeholders.

HALOPV Templates: Create a new document template

1

At the top of the list of templates, you will find the **Create** button. Click to proceed.

2

A new window will pop up. Fill in the form using the available fields:

- **Template name:** Template name in HALOPV list of templates.
- **Filename:** Name will be displayed when downloading/generating the document from the template.
- **Process Mapping:** Map the template to a specific Module, *e.g.*, *PSMF Module*.
- **Workflow Mapping:** After selecting the module, you can further map it to a Workflow, *e.g.*, *Annex B.2*.
- **Type Mapping:** Map the template to a record 'Type,' *e.g.*, *CIOMS*. The template will be available for records with that type.

3

Click on **Create**

The screenshot displays the 'Document Templates' interface. At the top, there is a search bar with a magnifying glass icon, a 'Go' button, and an 'Actions' dropdown menu. A green 'Create' button is highlighted with a yellow box. Below this is a table with columns: Id, Template, Name, Process, Workflow, Placeholders, Modified, and Modified by. The 'Modify Template' form is open, showing fields for Template name (PSMF - Annex B.2), Filename (Annex B.2.docx), Process mapping (PSMF Management), Workflow mapping (Annex B.2 - Contact Details of Data Entry Sites), Type Mapping, Modified, and Modified by. A 'View/edit placeholders' link is also present. On the right, a 'View/edit record' sidebar shows a 'Complete task' button, a 'Send back task' button, and record information including 'ICSR Submission (Automated via gateway Argus Submission - 101488 (ICSR-SUBM-121673) - CIOMS)' and 'Basic information' with 'Title / Identifier' (Argus Submission - 101488) and 'Type' (CIOMS). A green 'Create' button is also visible at the bottom right of the form, highlighted with a yellow box. Yellow arrows point from the text instructions to the 'Create' buttons and the 'Type Mapping' field.

Id	Template	Name	Process	Workflow	Placeholders	Modified	Modified by
	PSMF - Annex B.2	Annex B.2.docx	PSMF Management	Annex B.2 - Contact Details of Data Entry Sites			

HALOPV Templates: Create a new document template

4

Click on **Choose file** and select your new Word document template from your local computer.

5

Click on **Save**

6

Close the **Modify template** window

7

Search for your newly created template using the search box and proceed to update the placeholders.

Modify Template

Template

View/edit placeholders

Choose File

Template

View/edit placeholders

Annex B.2.docx

Template name

PSMF - Annex B.2

Filename

Annex B.2.docx

Process mapping

PSMF Management

Workflow mapping

Annex B.2 - Contact Details of Data Entry Sites

Type Mapping

Modified

20-AUG-2022 13:02:30

Modified by

MICHELLE.NOERREGAARD@INSIFE.COM

Save Save a Copy Delete Close

Document Templates

Search: Go Actions

Row text contains 'Annex B.2' Process = 'PSMF Management'

	Id	Template	Name	Process	Workflow	Placeholders
	1884	Download	PSMF - Annex B.2	PSMF Management	Annex B.2 - Contact Details of Data Entry Sites	Edit Placeholders (0)

HALOPV Templates: Create a new document template

How to create a placeholder

8

To create a new placeholder, click on **Create**.

9

Create placeholders based on types:

- **Single value (parameters)** allow users to select preexisting values
- **Table (Interactive report)** allows users to select data from Public reports
- **Table (JSON)** allows users to create a SQL parameters
- **HTML Letter Template** allows users to create a correspondence template

10

The screenshot shows the 'Template Placeholders' interface. At the top, there's a 'Placeholders' section with a 'View/edit template' link and a 'Template' dropdown set to '1884'. To the right, the 'Template name' is 'Annex B 2.docx'. A green 'Create' button is highlighted with a yellow box. Below this is the 'Modify Placeholder' form. It has a 'Placeholder ID' field with '3606' and a 'Template placeholder' dropdown set to 'DATA'. The 'Placeholder type' dropdown is set to 'Table (Interactive Report)' and is highlighted with a yellow box. Below it, the 'Page ID' is 'HALO Public reports (86)' and the 'Region Name' is 'PSMF Annex C - Contact info', both highlighted with yellow boxes. The 'Parameters (optional)' dropdown is set to 'System Timestamp (DD-MON-YYYY HH24:MI:SS)'. The 'SQL' field contains an example query: 'Example: select master_title where master_id = V('P119_MASTER_ID') and current_revision = 1'. A green 'Create' button is at the bottom right of the form. To the right of the form is a 'HALO Public reports' section. It has a 'PSMF Annex C - Contact info' report highlighted with a yellow box. Below this is a table with columns 'Affiliate Name', 'Countries Covered By Affiliates', 'Address', and 'City'. The table has two rows: 'Affiliate (Denmark)' and 'Insife'. A yellow box highlights the 'Affiliate Name' column. To the right of the table is a 'Saved Report' section with a 'Report Details' section. It lists 'REPORT FILTERS' and 'Document Placeholder / Column name' with a list of columns: {COL1}: Affiliate Name, {COL2}: Countries covered by affiliates, {COL3}: Address, {COL4}: City, {COL5}: Postal code, {COL6}: Business telephone, {COL7}: Mailbox (Marketed), {COL8}: Mailbox (Clinical), {COL9}: Mailbox (Unblinded), {COL10}: master_id. A yellow box highlights the 'Affiliate Name' column in this list. A yellow box also highlights the 'PSMF Annex C - Contact info' report. A yellow box highlights the 'Create' button at the bottom right of the form. A yellow box highlights the 'Create' button at the top right of the form. A yellow box highlights the 'Create' button at the bottom right of the form. A yellow box highlights the 'Create' button at the bottom right of the form.

Template Placeholders

Placeholders

View/edit template

Template 1884

Template name Annex B 2.docx

Go Actions

Create

Modify Placeholder

Form on GOM_TEMPLATE_PARAMETERS

No

Placeholder ID 3606

Template placeholder DATA

Placeholder type Table (Interactive Report)

Page ID HALO Public reports (86)

Region Name PSMF Annex C - Contact info

Return to record

HALO Public reports

Affiliates overview

PSMF Annex C - Contact info

Saved Report

Tip: Leave blank to get the latest saved report

Report Details

REPORT FILTERS:

Document Placeholder / Column name:

{COL1}: Affiliate Name

{COL2}: Countries covered by affiliates

{COL3}: Address

{COL4}: City

{COL5}: Postal code

{COL6}: Business telephone

{COL7}: Mailbox (Marketed)

{COL8}: Mailbox (Clinical)

{COL9}: Mailbox (Unblinded)

{COL10}: master_id

Affiliate Name	Countries Covered By Affiliates	Address	City
Affiliate (Denmark)	Denmark	-	-
Insife	-	Gldsaxevej 384A, st., Soeborg	Glad

Create

Column names should match columns in the public report, e.g., {COL1} corresponds to the first column in the Public Report, 'Affiliate Name.'

HALOPV Templates: Create a new document template

How to create a placeholder: Single value (parameter)

A **single value (parameter)** allows you to select existing parameters like revision, date, record title, etc. To create this type of placeholder, select **Single value (parameter)** and select a value from the **Parameters (optional)** drop-down list. Another option is to insert a SQL parameter in the **SQL** field.

Data Lock Point {DATE}, {REVISION}

Example of a Word document template including two single value placeholders; {DATE} and {REVISION}

Modify Placeholder

Form on GOM_TEMPLATE_PARAMETERS

Placeholder ID
3603

Template placeholder
DATE

Placeholder type
Single value (parameter)

Parameters (optional)

SQL
select to_char(sysdate, 'DD-MON-YYYY HH24:MI:SS') from dual

Close Delete

Example of two template placeholders; DATE and REVISION

Modify Placeholder

Parameters

Template placeholder
REVISION

Placeholder type
Single value (parameter)

Parameters (optional)

PSMF Notes - Header 3
PSMF Notes - Header 4
PSMF Notes - Header 5
PSMF Notes 1
PSMF Notes 2
PSMF Notes 3
PSMF Notes 4
PSMF Notes 5
QPPV_PAGE119
RECORD DESCRIPTION
RECORD TITLE
REVISION
REVISION (prefixed with version)
SYSTEM DATE (DD MON YYYY)
SYSTEM DATE (DDMonYYYY)
System Timestamp (DD-MON-YYYY HH24:MI:SS)
UNBLINDINGMAILBOX_PAGE119
WF_LOCK_ON_COMPLETE
WORDTEST
WORKFLOW

HALOPV Templates: Create a new document template

How to create a placeholder: Table (Interactive report)

You can pull data from an existing public report using the option **Table (Interactive report.)** For instance, **Annex C – contact info** public report, shows a set of columns. If you select, **Public report PSMF Annex C – Contact info**, for your {DATA} placeholder. The tags sequence will be {COL1}, {COL2}, {COL3}, etc. Place the tags on your word template in the order that you want, but remember that the data table should always start with {#DATA} and finish with {/DATA}

Annex B.2 - Contact Details of Data Entry Site

Affiliate Name	Countries (Covered by Affiliate)	Address	Telephone	Safety Mailbox
{#DATA}{COL1}	{COL2}	{COL3} {COL5} {COL4}	{COL6}	{COL8} {/DATA}

Example of a Word document template including placeholder and tags



HALO Public reports

Public Report

Affiliates overview

PSMF Annex C - Contact info

Q

Go

Actions

Affiliate Name	Countries Covered By Affiliates	Address	City	Postal Code	Business Telephone
Affiliate (Denmark)	Denmark	-	-	-	-
Insafe	-	Gladsaxevej 384A, st., Soeborg	Gladsaxe	2860	+45123456789

Modify Placeholder

Form on GOM_TEMPLATE_PARAMETERS

Placeholder ID 3606

Template placeholder DATA

Placeholder type Table (Interactive Report)

Page ID HALO Public reports (86)

Region Name PSMF Annex C - Contact info

Tip: You can only select reports saved as public reports

Saved Report

Tip: Leave blank to get the latest saved report

Report Details

REPORT FILTERS:

Document Placeholder / Column name:
{COL1}: Affiliate Name
{COL2}: Countries covered by affiliates
{COL3}: Address
{COL4}: City
{COL5}: Postal code
{COL6}: Business telephone
{COL7}: Mailbox (Marketed)
{COL8}: Mailbox (Clinical)
{COL9}: Mailbox (Unblinded)
{COL10}: master_id

Close Delete

Tags

Output of the document template

Affiliate Name	Countries (Covered by Affiliate)	Address	Telephone
Affiliate (Denmark)	Denmark		
Insafe		Gladsaxevej 384A, st., Soeborg 2860 Gladsaxe	+451234567

HALOPV Templates: How to test your new template

1

To review your newly created template. Go to the workflow and use **Generate document from template**, the Print icon or the **Print** option in the extended menu.

3

Once the document is generated, click on the attachment icon, download the file and review the output.

2

Select the **Document template**, **Output format** and click on the **Generate** button.

The first column {COL1} 'Affiliate Name' data is transferred to your first column

View/edit record

Update Annex B.2 → Generate Annex B.2

Complete task

Send back task

Annex B.2 (PSMF-B.2-8223512) (Revision 1)

Annex B.2 - C

Task instructions

Fill in the PSMF details form available in the Task Activities section. Generate the annex document using the Generate document from template button. Upon checking the PDF document, please click on Generate Task.

Task activities (red status means mandatory)

Data forms

PSMF details form (populates 1.2)

Generate document from template

Verify data - Affiliates

Status

Document link

Action

Assign Document Template

Document Template

PSMF - Annex B.2

Interactive report (Optional)

Template file (Optional)

Template file from working area (Optional)

Output format

PDF

Upload to working folder

Generate

Return

Annex B.2 - Contact Details of Data Entry Site - expression

Affiliate Name	Countries (Covered by Affiliate)	Address	Telephone
Affiliate (Denmark)	Denmark		
Insife		Gladsaxevej 384A, st., Soeborg 2860 Gladsaxe	+451234 67



HALOPV Templates: Create Correspondence Template

Sample template - Notepad

File Edit View

2

```
<b>Dear receiver</b>
<p>Please have a look at this record..</p>
<p>Best regards, </p>
<p>Insife</p>
<p><b>Case reference: </b>{TITLE}</p>
<p><b>Patient: </b>{PATIENT}</p>
<p><b>WWUID: </b>{WWUID}</p>
```

Modify Template

1

Template

[View/edit placeholders](#)

Template

Choose File

Download

Template name

Letter sample

Filename

Letter

Process mapping

ICSRs (Medicines Incidents)

To create a Correspondence template:

1. Go to **Application Management > Document Templates** and click on **Create**.
2. Create an HTML template and upload it to HALO as explained in the section **Create a new document template**.
3. Proceed to create the **Placeholders**.

Placeholders

[View/edit template](#)

Template

1521

Template name

Letter

Q Go Actions Create

	Template Id	Id	Placeholder Type	Placeholder Name	Placeholder SQL (Custom)
	1521	3618	Single value (parameter)	PATIENT	select decode(upper(D_1),'UNK',D_1,decode((select NVL(child_num_6, 1) from gom_process_child where child_id = V('P119_MASTER_ID') and child_Revision = V('P119_REVISION') and page_id = 116),1,'PRIVACY',substr(D_1,1,10))) from GOM_E2BR3_D where (revision, master_id) IN (SELECT revision, MASTER_ID FROM GOM_PROCESS_MASTER WHERE CURRENT_REVISION = 1 AND MASTER_ID =v('P119_PARENT_RECORD_ID'))
	1521	2721	HTML Letter template	TITLE	select master_title from gom_process_master where master_id = V('P119_MASTER_ID') and current_revision = 1
	1521	2761	HTML Letter template	WWUID	select c_1_1 from gom_e2br3_c c join gom_process_master m on m.revision = c.revision and m.master_id = c.master_id and m.master_id = V('P119_MASTER_ID')

1 - 3

HALOPV Templates: Create Correspondence Template

View/edit record

ICSR-Proce-6404881 → Author correspondence → Intake review Correspondence → Send correspondence

Complete task

MICHELLE.NOERREGAARD@INSIFE.COM

Save Return

Close

Inquiry on ICSR-PROC6404881 (Correspond-8223522) (Revision 1) Medicine Incident Correspondence

Task instructions

Use the contents field to create a correspondence

Add recipient

Add Related record

Task activities (red status means mandatory)

Data forms	Status	Links / other activities
Generate document from template		Manage attachments Letter template

Correspondence Contents

1 Manage templates

Generate from template

Paragraph B I U S @ := 1= " " v ↶ ↷

Print the template on the correspondence contents using the button **Generate from template**.

A new window will open, select the **Template** from the drop-down list and click on **Generate**.

Print document

Template Parameters to include

Template Letter sample

Format


Interactive report (Optional)


Generate Return







2

HALOPV Templates: Create Correspondence Template

Correspondence Contents

Manage templates 

Generate from template 

Paragraph **B** *I* U     

Dear receiver

Please have a look at this record..

Best regards,

Insafe

Case reference: Inquiry on ICSR-PROC6404881

Patient: MND

WWUID: 001-00345

The template will upload and pull the placeholder’s data in the content area. Feel free to customize it as needed.