



Introduction to

HALOPV 4.x

Guiding Slides on HALOPV

General Overview and Main Features

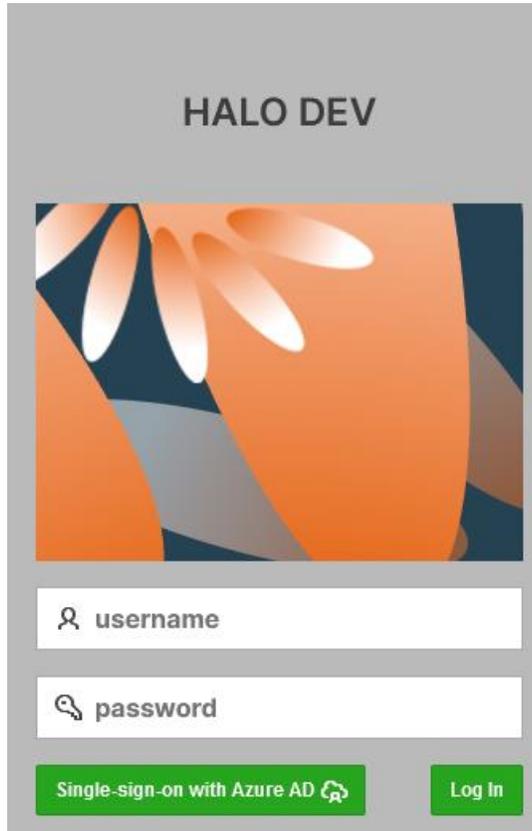
Introduction to



HALOPV

- › **Access to HALOPV**
- › **General Overview**
 - › Front Page, Widgets and Search
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 - › Record Worklist
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Accessing HALOPV using credentials or SSO



HALO DEV

username

password

Single-sign-on with Azure AD

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

Record's title



support@insife.com

To Michelle Romero Nørregaard



Annex H.1- List of Medicinal Products

Workflow and task

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

[Open record in HALO](#)

Link directly to application

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)

General Overview - Front Page

The screenshot shows the HALO front page. The left sidebar contains a menu with categories like Processes, My tasks, Active Tasks, Entities, and Products. The top navigation bar includes the HALO logo, system time (25-APR-2022 12:24:48 +00:00), a search bar, and the user's name (MICHELLE.NOERREGAARD@INSIFE.COM). The main content area features a 'Record search' widget, a 'User's menu' with options like Profile, My tasks, Help Center, and Log out, and a 'Widgets on home screen' section with various task-related widgets. At the bottom, there is 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.

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 shows the HALOPV front page with several key elements highlighted by yellow boxes and annotated with callouts:

- HALOPV version:** A box highlights "Release version 4.0.2" in the top-left sidebar.
- System time:** A box highlights "23-AUG-2022 13:34:20 GMT (Europe/Copenhagen)" in the top navigation bar.
- Search:** A box highlights the "Search" input field in the top navigation bar.
- Your username:** A box highlights the user email "MICHELLE.NOERREGAARD@INSIFE.COM" in the top navigation bar.
- My organization:** A box highlights "My organization" and "Root organization" in the main content area.
- Individual task ribbon:** A large box highlights the task overview section, which includes:
 - A toggle for "Allow assigning of tasks to me" set to "Yes".
 - A card for "My open assigned tasks" showing a count of 51.
 - A card for "My handled tasks last 24h" showing a count of 4.
 - A card for "My handled tasks last 7 days" showing a count of 5.
 - A card for "My handled tasks last 30 days" showing a count of 31.

Additional callouts include "Quick search" pointing to the search bar and "Processing compliance widget" pointing to the task ribbon area.

General Overview – Front Page

- Processes
- Dashboards and reports
- My settings
- Application management
- User administration

My top 5 open tasks

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

Refresh the list of your top 5 open tasks

Remove this widget

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 shows the HALOPV dashboard with a sidebar on the left containing navigation items like '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 includes a system time display (30-AUG-2022 10:28:31 GMT (Europe/Copenhagen)), a search bar, and a user profile (MICHELLE.NOERREGAARD@INSIFE.COM). Below this is a 'Welcome back' message and 'My organization' information. The 'Individual task ribbon' section provides a quick overview of tasks, including '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 search bar and a table of tasks.

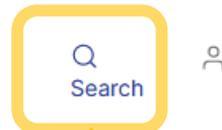
Priority	Title (identifier)	Task	Task due by	Assigned to	Organization	Territories	Workflow due by
1	ICSR-PROC14 (ICSR-Proce-14)	Medical Review	17-AUG-2021	ADMIN	Root organization	-	17-AUG-2021
1	Intake module: (ICSR-Proce-92738)	Medical Review	18-OCT-2021	ADMIN	Root organization	-	19-OCT-2021

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

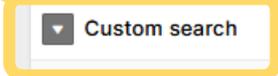
Days are allocated per step in the Application Management section.

29-AUG-2022
30-AUG-2022
12-SEP-2022

General Overview – ‘Search’ functionality



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.

The search interface includes a "Workflow filter" section with three input fields: "Search term (general search)" containing "8220930", "Search in module" containing "Entities", and "Search in workflow" containing "Entities (Internal)". A green "Search" button is located to the right of these fields. Below the fields, a note says "Separate multiple search strings with semicolon".A yellow callout box highlights an input field for "Search configuration name" with a green "+" button to its right. The text inside the field reads "Add a name to create a new stored Query".

Custom Search is used to store queries. To create a new query, add a new name in the Search configuration name and click on +

The "Custom search" configuration editor shows a "Saved Searches" dropdown with "Entities (2022-AUG-23)" selected. Below it is a "Search configuration name" input field with "Add a name to create a new stored Query" and a green "+" button. There are "Edit" and "Save" buttons. A table for criteria is visible with columns: Pre op., Keyword, Operator, Value, Post op. The table is currently empty. At the bottom right, there 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 ↑
(Patient sex	=	MALE)		1

patient

- !=
- <
- =
- >
- CONTAINS
- LIKE
- NOT CONTAINS
- NOT LIKE

Show detailed

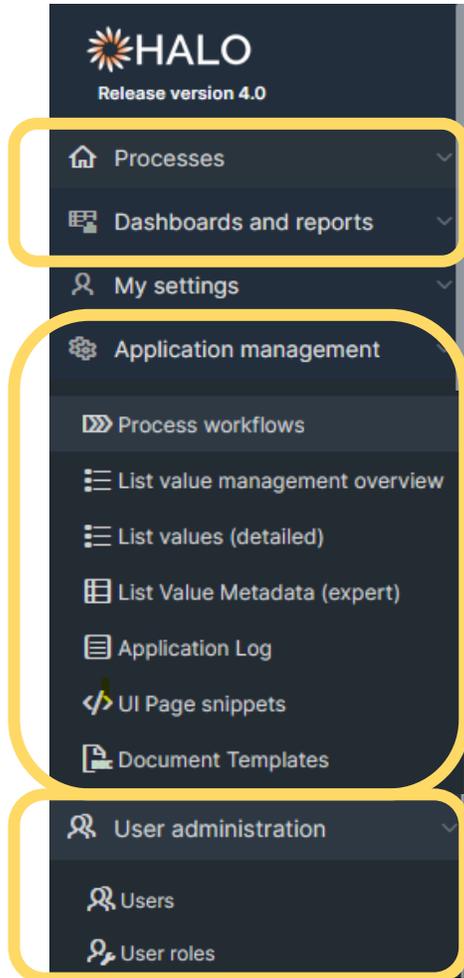
1-1 **Add criteria**

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 Hea 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-9303303	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, MMR ID: KR-Merck Healthcare KGaA-9303300	

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.

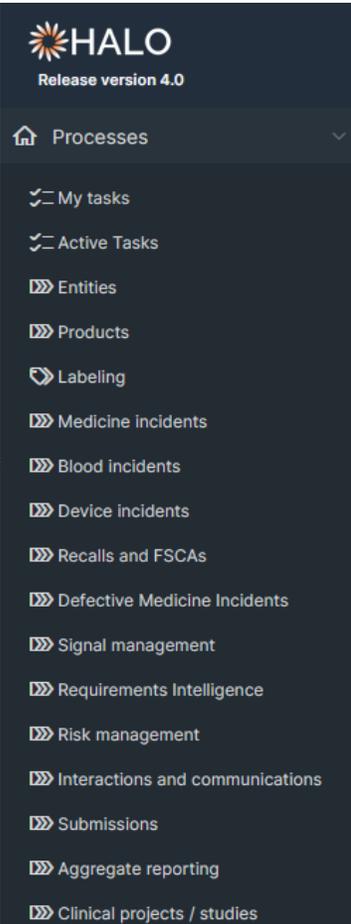
General Overview – Main Menu



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

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.

Workflow description. Wording is configurable.

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

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

General Overview – List of Workflows

The screenshot displays the HALOPV system interface. The top navigation bar includes the HALOPV logo, release version 4.0.2, system time (25-AUG-2022 13:42:15 GMT (Europe/Copenhagen)), a search bar, and the user name MICHELLE.NOERREGAARD@INSIFE.COM. The main content area is titled 'Products' and contains a description: 'Manage the company product repository, including handling of market authorizations from global to local markets.' Below this, there are two sections: 'Available workflows' and 'Functionality menu'. The 'Available workflows' section is highlighted with a yellow rounded rectangle and lists the following items: Product Families, Medicinal Products, Device Products (and constituents), Product Licenses (Authorizations), External Products, Substance Groups, and Scientific Ingredient groups. The 'Functionality menu' section lists: Product tree overview, Product index browser, Product faceted search, Product index faceted search (e), 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) | 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](#)
[Print](#)
[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-009507513-16111WN000170	Spontaneous Report			Drug-induced encephalopathy	PEMBROLIZUMAB; CISPLATIN; PEMBROLIZUMAB; 5-FLUOROURACIL; CISPLATIN; 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;	4	COMPLETED	-

Records (Products)

[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; Tris(hydroxymethyl)aminomethane; 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; ESCOMEPRAZOLE; 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			Bullos 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;	ZOFRAN; SYNTHROID; LIPITOR; ANTABUSE; CYMBALTA; XANAX; ZOFRAN; PRLOSEC; 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.

The screenshot shows the 'Process description' section with the text 'Manage partners, clients accounts or entities within the organization e.g. other geographic location.' Below this are four filter boxes: 'Completed records?' (checked), 'In workflow records?' (checked), 'Nullified records?' (unchecked), and 'Assigned to others?' (unchecked). To the right of these filters are buttons for 'Create from Wizard', a refresh icon, a print icon, 'Batch', and 'Auto-assign'. Below the filters is a search bar with a magnifying glass icon and a 'Go' button, followed by 'Rows 50' and an 'Actions' dropdown. The main area contains a table of records.

Record ID	Entity name	Priority	Orgentities Address	Orgentities Postal	Orgenti City					
ORG-INT-8221060	Insife	-	Gladsaxevej 384A, st., Søborg	2860	Gladsax					
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

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

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.

Select Columns

Do Not Display

- Created by
- Destination
- Master Description
- Master Notes
- Master Url
- Prefix
- Revision
- Wf Task Instance Id
- Wfcompletedflag

Display in Report

- Obs
- Record ID
- Parent record
- Intake record
- Type
- Active task
- Countries
- Organization
- 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.

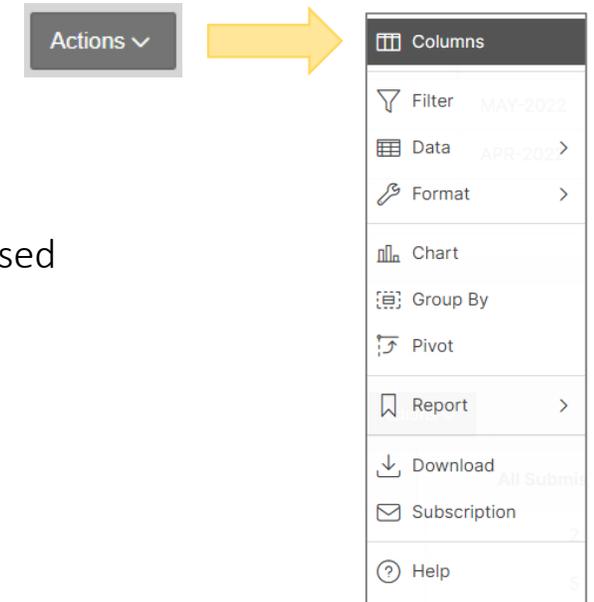
The screenshot displays a software interface for an interactive report. At the top, there are checkboxes for record statuses: 'Completed records?' (unchecked), 'In workflow records?' (checked), 'Nullified records?' (unchecked), and 'Assigned to others?' (unchecked). Below these are buttons for 'Create from Wizard', a refresh icon, a print icon, 'Batch', and 'Auto-assign'. The main area is titled 'Records (ICSRs)' and includes a search bar, a 'Go' button, a dropdown for '1. Primary Report', a 'Rows' dropdown set to '50', and an 'Actions' dropdown menu. A filter bar shows 'Type = Spontaneous Report' with a green filter icon and a close button. 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.' A table with columns 'Record ID', 'Title / Identifier', 'Type', 'Fatal/life Threatening Events', 'Serious Events', 'Non-serious Events', and 'Suspect Products' is shown. A dropdown menu is open over the 'Type' column, listing options: 'Not available to sender (unknown)', 'Other', 'Report from study', and 'Spontaneous Report'. Two 'Filter' dialog boxes are overlaid. The first dialog, titled 'Filter', has tabs for 'Column' and 'Row'. The 'Column' tab is active, showing a filter for 'Organization = Affiliate (Denmark)'. The second dialog, also titled 'Filter', has tabs for 'Column' and 'Row'. The 'Row' tab is active, showing a filter name 'WITHIN LAST 2 YEARS' and a filter expression 'D> SYSDATE - 730 OR D IS NULL'. Below the expression are two panels: 'Columns' (listing A. Last updated, C. Prefix, D. Overall due date, H. Workflow status, J. Assigned to, K. Organization, L. Master Url) and 'Functions / Operators' (listing !=, <, <=, =, >, >=, 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

The screenshot shows the 'Records' interface. At the top, there is a search bar, a 'Go' button, and a 'Rows' dropdown set to 50. The 'Actions' menu is open, showing options like Columns, Filter, Data, Format, Chart, Group By, and Pivot. The 'Report' option is highlighted, and a sub-menu is open showing 'Save Report' as the selected option. Below the menu, there is a table with columns 'Obs', 'Record ID', and 'Parent record'. The table contains several rows of data, including 'ICSR-IN-72', 'ICSR-IN-57', 'ICSR-IN-539', 'ICSR-IN-580', and 'ICSR-IN-147'. A yellow box highlights the 'Report' and 'Save Report' options in the menu.

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**.

The screenshot shows the 'Save Report' dialog box and the 'Records' interface. The dialog box has a 'Name' field with 'ABC Company Ltda.' and a 'Description' field. The 'Public' checkbox is checked. The 'Records' interface shows a table with columns 'ID', 'Parent record', 'In take', 'Active task', 'Countries', and 'Organization'. A dropdown menu is open, showing '1. Primary Report' as the selected option. A yellow box highlights the 'Public' checkbox in the dialog box and the dropdown menu in the interface.

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 shows the application interface for creating a new record. On the left, a dark sidebar contains a menu with 'Entities (organizations)' highlighted. The main content area shows the breadcrumb 'Entities / Entities (External) Records' at the top. Below this, there is a 'Process description' section and a 'Manage the global organization' section. A 'Create from Wizard' button is highlighted in a yellow box. Below the button, there are checkboxes for 'Nullified records?' and 'Assigned to others?'. A yellow callout box contains the following text:

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 screenshot shows a window titled "Create record Wizard" with a close button in the top right. Below the title bar is a header area with an information icon and the text "New record" and "You are about to create a new record. Please fill in the fields in this form to get started!". The main content area is divided into two panels. The left panel, titled "Enter basic information", contains three fields: "Record Title" with the value "Pharma ABC", "Record Type" with a dropdown arrow, and "Master Duedate" with a calendar icon. The right panel, titled "Static information", contains two fields: "Process" with the value "Entities" and "Workflow" with the value "Entities (External)". At the bottom left is a "Cancel" button, and at the bottom right is a green "Create" button. A yellow box highlights the "Record Title" field and the "Create" button.

The screenshot shows a window titled "Create record Wizard" with a close button in the top right. Below the title bar is a header area with an information icon and the text "New record" and "You are about to create a new record. Please fill in the fields in this form to get started!". The main content area is divided into two panels. The left panel, titled "Enter basic information", contains four fields: "Record Title" with the value "[The title will be auto-populated ...]", "Record Type" with a dropdown arrow, "Reporting to" with a dropdown arrow and a question mark icon, and "Master Duedate" with a calendar icon. The right panel, titled "Static information", contains two fields: "Process" with the value "ICSRs (Medicines Incidents)" and "Workflow" with the value "ICSR Processing". At the bottom left is a "Cancel" button, and at the bottom right is a green "Create" button. A yellow box highlights the "Record Title" field and the "Create" button.

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, Open 0; Data collection programs 1, Open 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, Set manually, Source (External) ID). A 'Save and close' button is at the bottom right.

Record's type.

User that is currently on the record.

Indicates in which workflow the record is stored in HALO.

Record's revision.

Description and Notes and linking can be enable/disable in Process Configuration.

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.

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

Task activities (red status means mandatory)

Data forms
External Partner form

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

Related Records

Title	Type	Workflow	Organization	Status	Territory	Reporting destination	Link Type	Reas
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 (6404231)	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.

The screenshot shows a 'View/edit record' window for a case titled 'ICSR-PROC6404881 - Report from study (Revision 8)'. The workflow is currently at the 'Medical Review' step. The interface includes a top navigation bar with steps: Register ICSR information, Medical Review, Submission, Send positive acknowledgment, Send ICSR for signaling, and Submit ICSR to source with updates. Below the navigation bar, there are buttons for 'Complete task', 'Send back task', 'Print', 'Alerts', 'Attachments', 'Save', and 'Close X'. The main content area is divided into sections: 'Task instructions', 'Task activities (red status means mandatory)', 'Data forms' (with sub-sections like Sender(s) and Case info, Patient / Parent, Reporter(s), Drug(s) information, Event(s), Drug(s)-reaction(s) / Event(s) Matrix, Narrative / Summary, and Safety information review), 'Associated records' (showing 'ICSR Submission (Manual) 1'), and 'Summary' (with details like Patient name/initials: John Doe, Age group: Adult, Reporter qualification: Physician, Country: GB, Events: Allergic Rash, Cardiac Arrest, Renal Failure, Seriousness: Fatal, Suspected products: Aspirin, Ibuprofen, Causal relation: Yes). There are also 'Tags' and 'Notes and linking' sections.

- 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

View/edit record

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

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 1

Reporter(s) 0

Drug(s) information 0

Event(s) 0

Drug(s)-reaction(s) / Event(s) Matrix 0

Narrative / Summary 0

Event listedness and datasheets 0

→ ⌚ 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

Complete task

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

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).

Pending actions

ICSR-PROC8219600 - Spontaneous Report (Revision 1)

Task instructions

Task activities (red status means mandatory)

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

Quality issues

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

The screenshot shows the 'Documents' interface. At the top left, there's a 'Folders' section with a 'REV1/' folder and an 'Add new folder' button. To the right is an 'Upload file(s)' section with a dashed box for dropping files and an 'Upload' button. Below these is a 'Documents' section with a table of documents. A green arrow points from the 'Upload file(s)' area to the 'File' column of the document table. The table has columns for 'File', 'Title', 'Description / type', 'Author', 'Comment', and 'Related Narr.'. One document is listed: 'Hello World.pdf' with the description 'Record attachment'. Below the table is a 'Working files (Sharepoint/Onedrive)' section with a search bar and a refresh button.

This close-up shows a toolbar with several icons: a printer icon, a notification bell icon with '0', a link icon with '3', a green 'Save' button with a checkmark, and a 'Close' button with an 'X' icon. There are also three dots indicating a menu.

- 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.

This close-up shows the 'Working files (Sharepoint/Onedrive)' table. It has columns for 'Object', 'Last Modified', and 'Action'. Two files are listed: 'Hello World.pdf' and 'Hello World.docx'. The 'Action' column for both files has a 'Load to HALO' button, which is highlighted with a yellow box.

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

Folders

- REV1/
- REV2/

Upload file(s)

Drop

Documents General/8220485/REV2/

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

1 rows selected

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

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.

View/edit record: Additional features

View/edit record

Complete task

Save Close

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

Task instructions
Enter relevant information pertaining to the product attributes

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 Nørregaard**

Countries: **Belgium (BE)**

Workflow history

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	

Audit 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

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

Keywords

Keyword	Context	Score	Modified By
QC Check	TAG	1	Automatic tag
Non-E2B	TAG	1	Automatic tag
Invalid	TAG	0	Automatic tag
Manual/Paper			
Non-Serious ICSR			

Records (ICSRs)

Record ID	Title / Identifier	Type	Fatal/life Threatening Events	Serious Events
ICSR- Proce- 8223503	ICSR- PROC8223503	Other		
ICSR- Proce- 8219600	ICSR- PROC8219600	Spontaneous Report		
ICSR- Proce- 8219544	ICSR- PROC8219544	Spontaneous Report		Headache; Nausea

Record info

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

Tags

QC Check Non-E2B Invalid Manual/Paper Non-Serious ICSR +

Delete Keywords

ICSRs (Medicines Incidents) / ICSR Processing Records

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 doc

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 Unknown

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

	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

	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}		

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}

(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

Go Actions

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

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



HALOPV Templates: Modify existing document templates

Upload a new document template

Document Templates

Search: Go Actions

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

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 1.2)	0
Generate document from template	0

Document link

Document link: Assign Document Template

Record Title: Annex C.1

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

Interactive report (Optional)

Template file (Optional)

Template file from working area (Optional)

Output format: **WORD**

Upload to working folder:

Print document

Template: PSMF Template Annex C.1

Format: PDF

Interactive report (Optional)

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

Generate Return

Generate Return

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 Insafe 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 right, a 'Create' button is highlighted with a yellow box. Below it is a table with columns: Id, Template, Name, Process, Workflow, Placeholders, Modified, and Modified by. A '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), and Type Mapping. A 'View/edit record' sidebar on the right shows task options like 'Complete task' and 'Send back task', 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 'Create' button is also highlighted at the bottom right of the form.

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

Template

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 box: [] 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

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

10

Modify Placeholder

Form on GOM_TEMPLATE_PARAMETERS

Placeholder ID

Template placeholder DATE

Placeholder type Single value (parameter)

Parameters (optional) System Timestamp (DD-MON-YYYY HH24:MI:SS)

SQL Example: select master_title where master_id = V('P119_MASTER_ID') and current_revision = 1

Create

HALO Public reports

Affiliates overview

Affiliate Name	Countries Covered By Affiliates	Address	
Affiliate (Denmark)	Denmark	-	-
Insafe	-	Gladsaxevej 384A, st., Soeborg	Glads

PSMF Annex C - Contact info

Placeholder type Table (Interactive Report)

Page ID HALO Public reports (86)

Region Name PSMF Annex C - Contact info

Return to record

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

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

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

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

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

Tags

Close Delete

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.

The screenshot shows the 'View/edit record' interface for 'Annex B.2 (PSMF-B.2-8223512) (Revision 1)'. It includes a task instructions section, a 'Task activities' section with a 'Generate document from template' button, and a 'Document link' section with an 'Assign Document Template' button. A workflow bar at the top shows 'Update Annex B.2' and 'Generate Annex B.2'.

2

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

The 'Document link' configuration form shows the 'Document Template' set to 'PSMF - Annex B.2' and the 'Output format' set to 'PDF'. The 'Generate' button is highlighted at the bottom right.

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

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
<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

Template **1**

[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**

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

Correspondence Contents

Manage templates 

Generate from template 

Paragraph  **B** *I* U ~~S~~        

Dear receiver

Please have a look at this record..

Best regards,

Insife

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.