Introduction to HALOPV 4.x

Guiding Slides on **HALO**PV

General Overview and Main Features

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Introduction to HALOPV

- **Access to HALOPV**
- **General Overview**
  - Front Page, Widgets and Search
  - Main Menu, Process and workflow
  - Record Worklist
- **Record view**
  - How to create a record
- **Interactive Reports**
  - Sort, filter, enable data
  - Save a new Public Report
  - Advanced functionalities
- **Templates**
  - Modify existing document templates and placeholders
  - Download template file
  - Duplicate templates
  - Create new document templates and placeholders
  - Create correspondence templates

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Accessing HALOPV using credentials or SSO

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.

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Access record(s) via email

EU PSMF - Annex H.1 List of Medicinal Products

Record's title

S

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!

Workflow and task

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)

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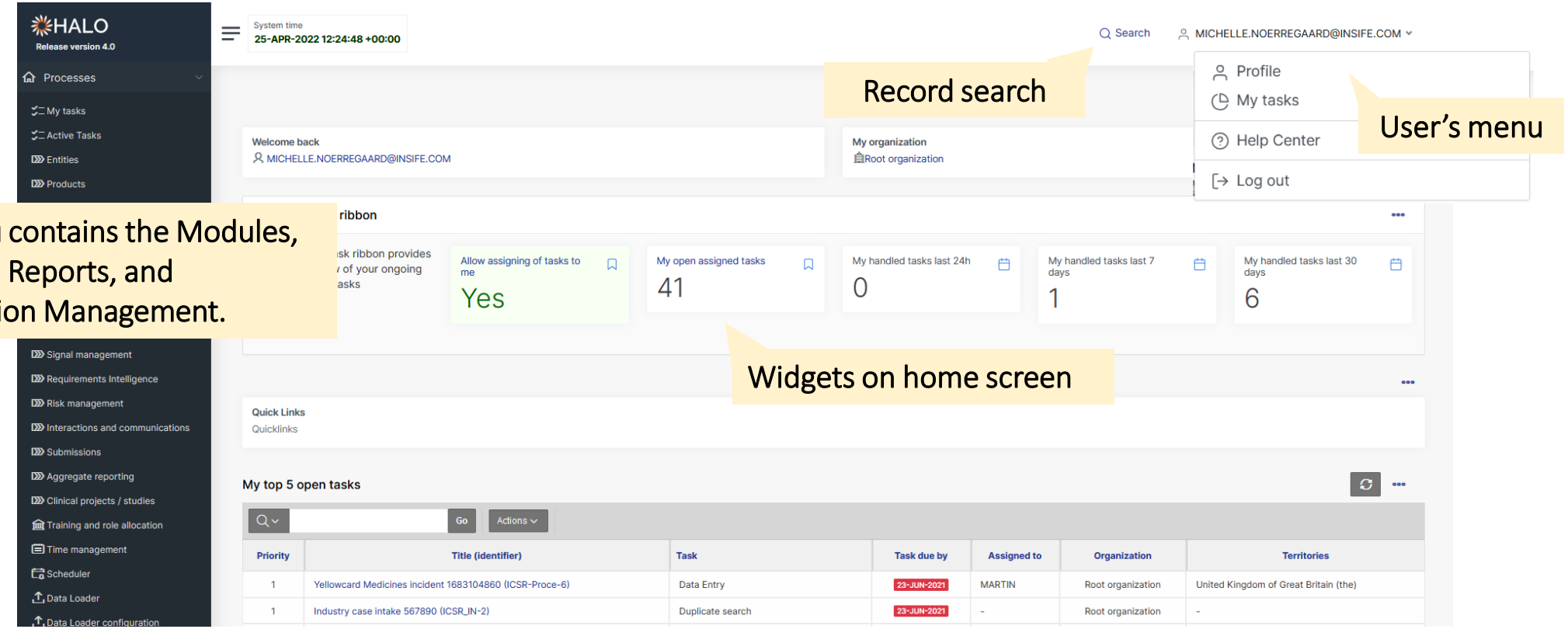
General Overview - Front Page



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

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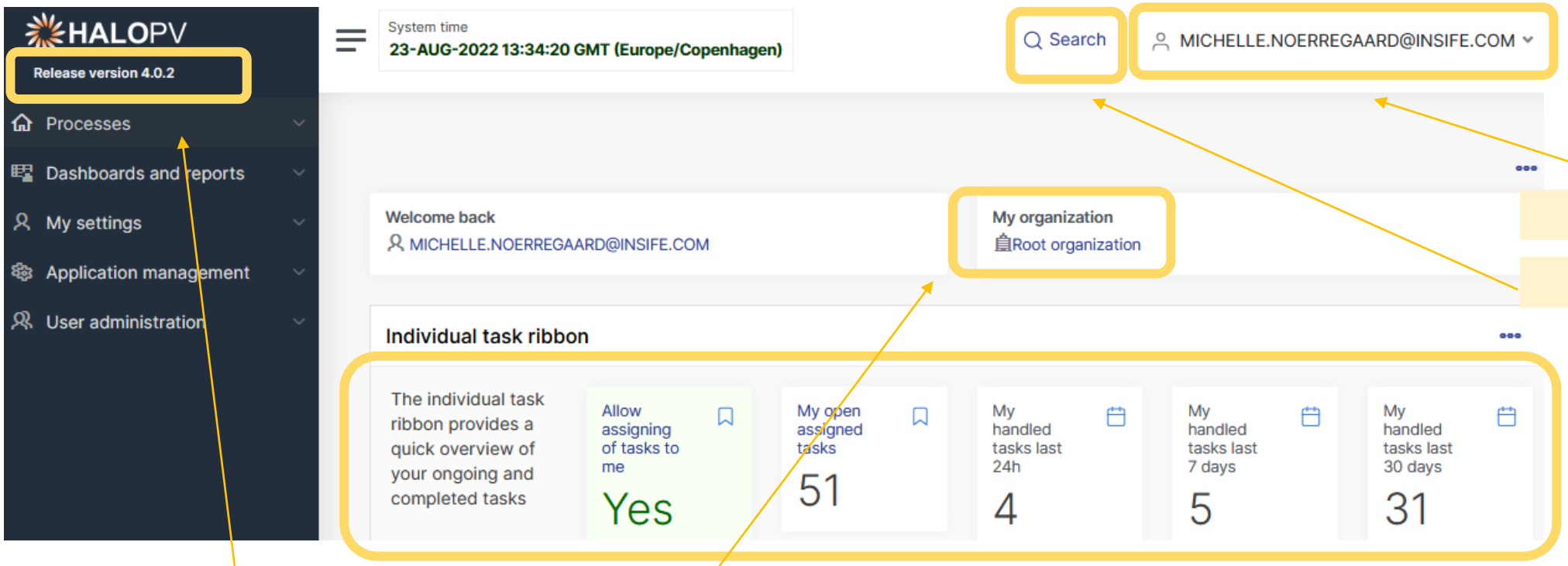
General Overview - Front Page



Your username

Quick search

HALOPV version

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

Processing compliance widget

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General Overview – Front Page

Refresh the list of your top 5 open tasks

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	28-OCT-2021	MARTIN.HOLM-PETERSEN@INSIFE.COM	Root organization	-	27-OCT-2021
1	Intake module: (ICSR-Proce-92822)	Register ICSR information	28-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

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.

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General Overview – Task due by

HALOPV
Release version 4.0.2

System time
30-AUG-2022 10:28:31 GMT (Europe/Copenhagen)

Search | MICHELLE.NOERREGAARD@INSIFE.COM

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
- Submissions

Welcome back
MICHELLE.NOERREGAARD@INSIFE.COM

My organization
Root organization

Individual task ribbon

The individual task ribbon provides a quick overview of your ongoing and completed tasks

Allow assigning of tasks to me	My open assigned tasks	My handled tasks last 24h	My handled tasks last 7 days	My handled tasks last 30 days
Yes	51	3	25	45

Quick Links
Quicklinks

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

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

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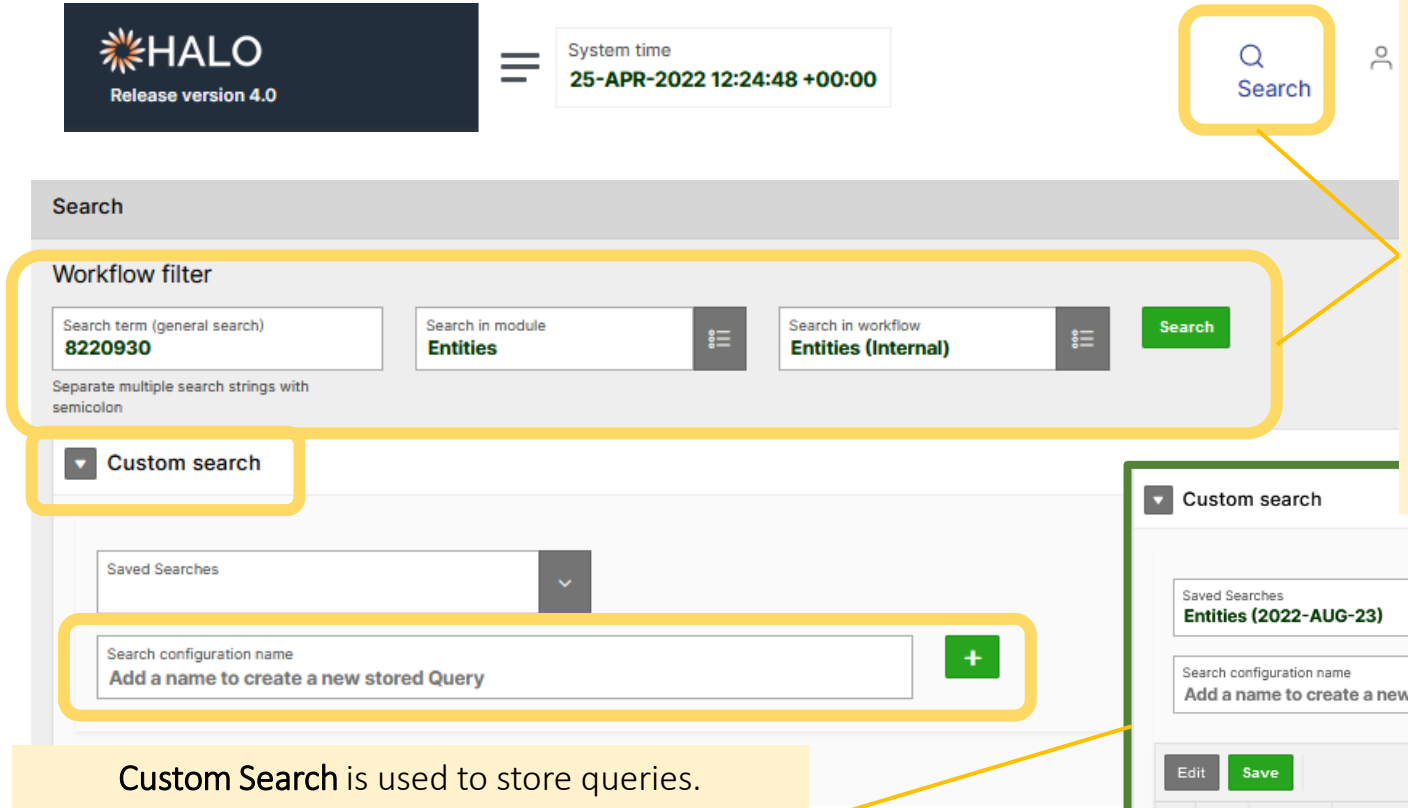
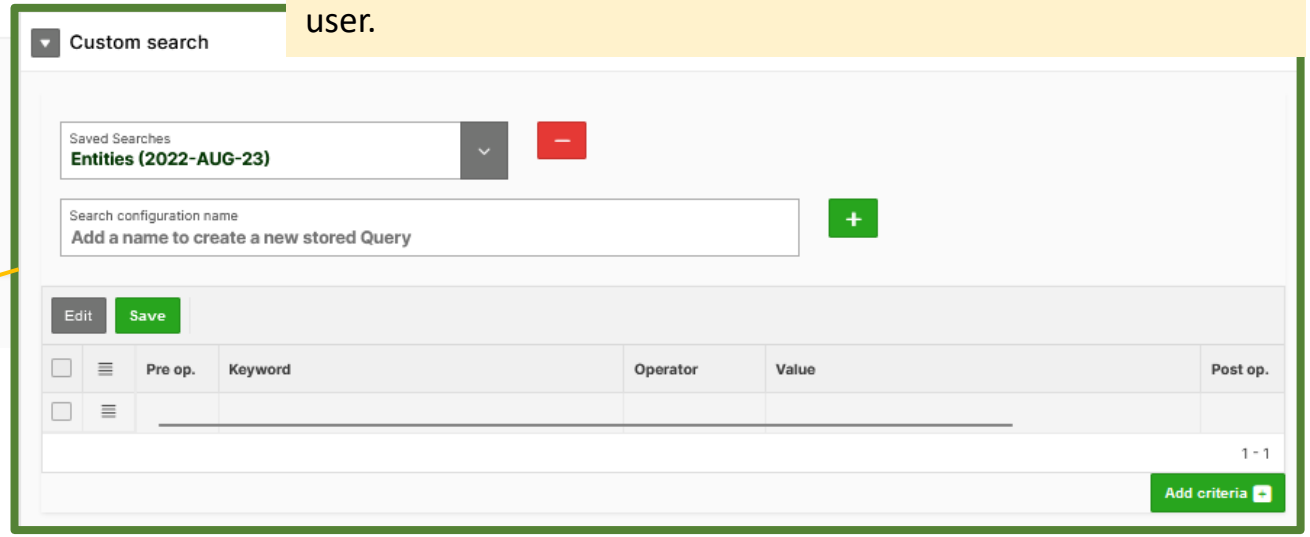
General Overview – ‘Search’ functionality



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.



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

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General Overview – Custom search: Saved Searches

Duplicate search

Workflow filter

Search term (general search)

Separate multiple search strings with semicolon

Search in module

Search in workflow

Search

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

1 - 1

patient

Patient age
Patient age group
Patient initials
Patient sex

!=
<
=
>
CONTAINS
LIKE
NOT CONTAINS
NOT LIKE

Add criteria

Show detailed

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-2 KR-Merck Healthcare KGaA-9303303, Safety report ID: KR-Merck Healthcare KGaA-9303303, Medicine Incident Title: GB-MHRA-ICSR3729514	
3729513	KR-Merck Healthcare	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	

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.

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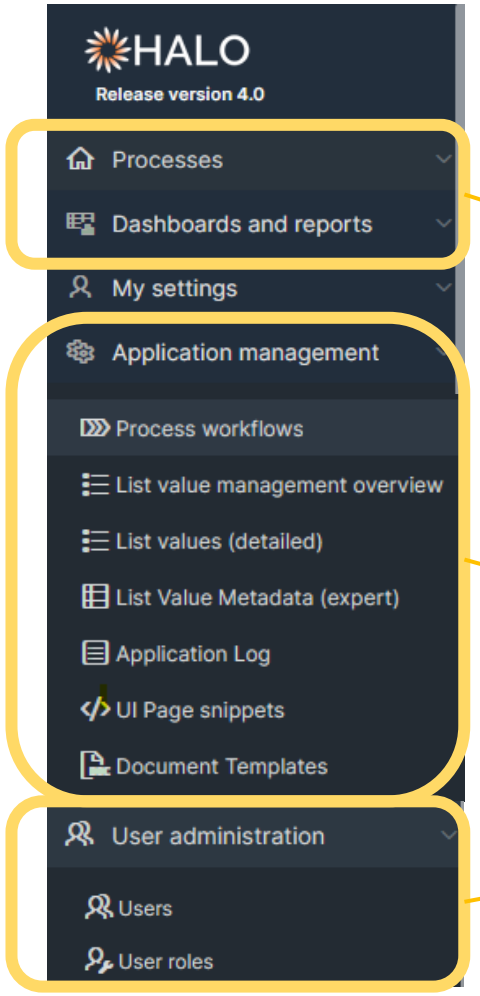
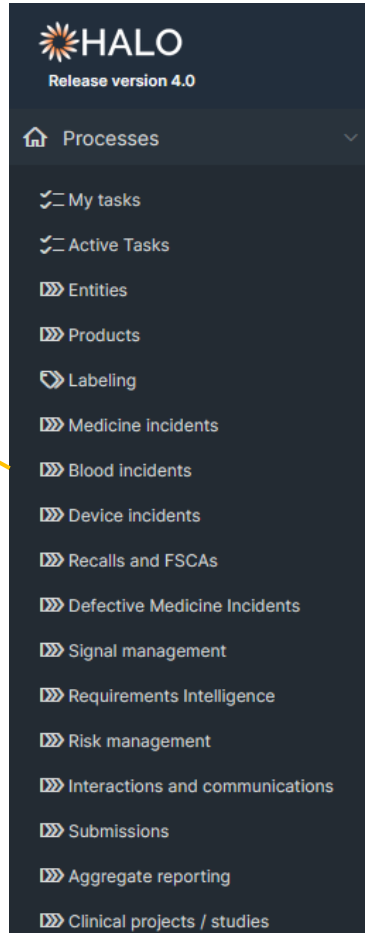
General Overview – Main Menu



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.



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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

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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.

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 prod

Workflow description. Wording is configurable.

Records updated after 02-APR-2021 | Completed records? | Nullified records? | Assigned to others?

Records (Products families)

Go | Rows 50 | Actions

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

View/edit record

Create/Update Product Family

Complete task

Parcetamol (PRODFAM-37) (Revision 1) Product families

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

About

Task activities (red status means mandatory)

Data forms

Product Family details

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

Note: Access is segregated by role. User will need different roles to access the processes, workflows, and step(s).

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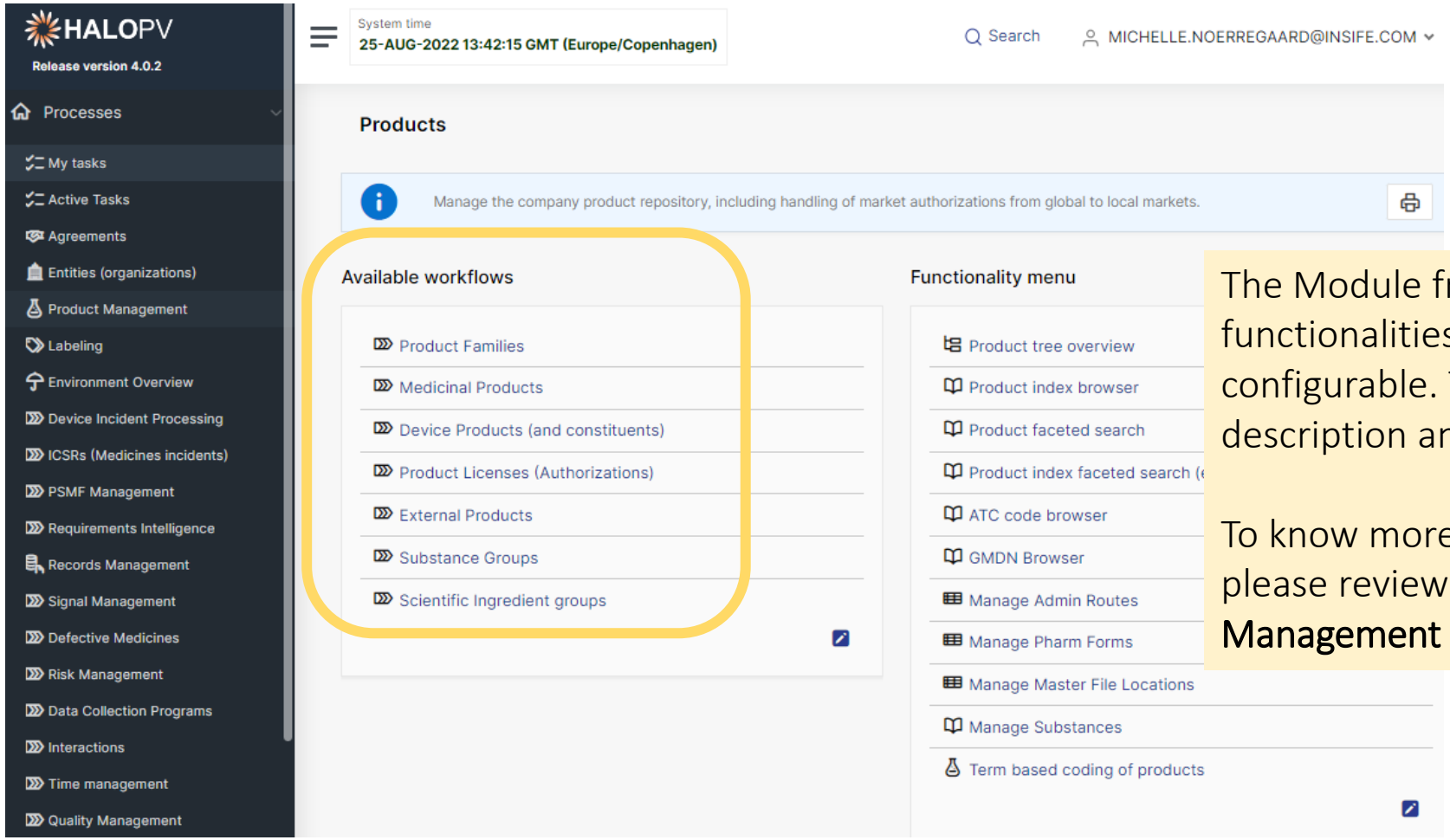
General Overview – List of Workflows



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.**

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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 | 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;	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	Efective 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	-	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).

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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 | Batch | Auto-assign

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;	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.**

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Record Worklist

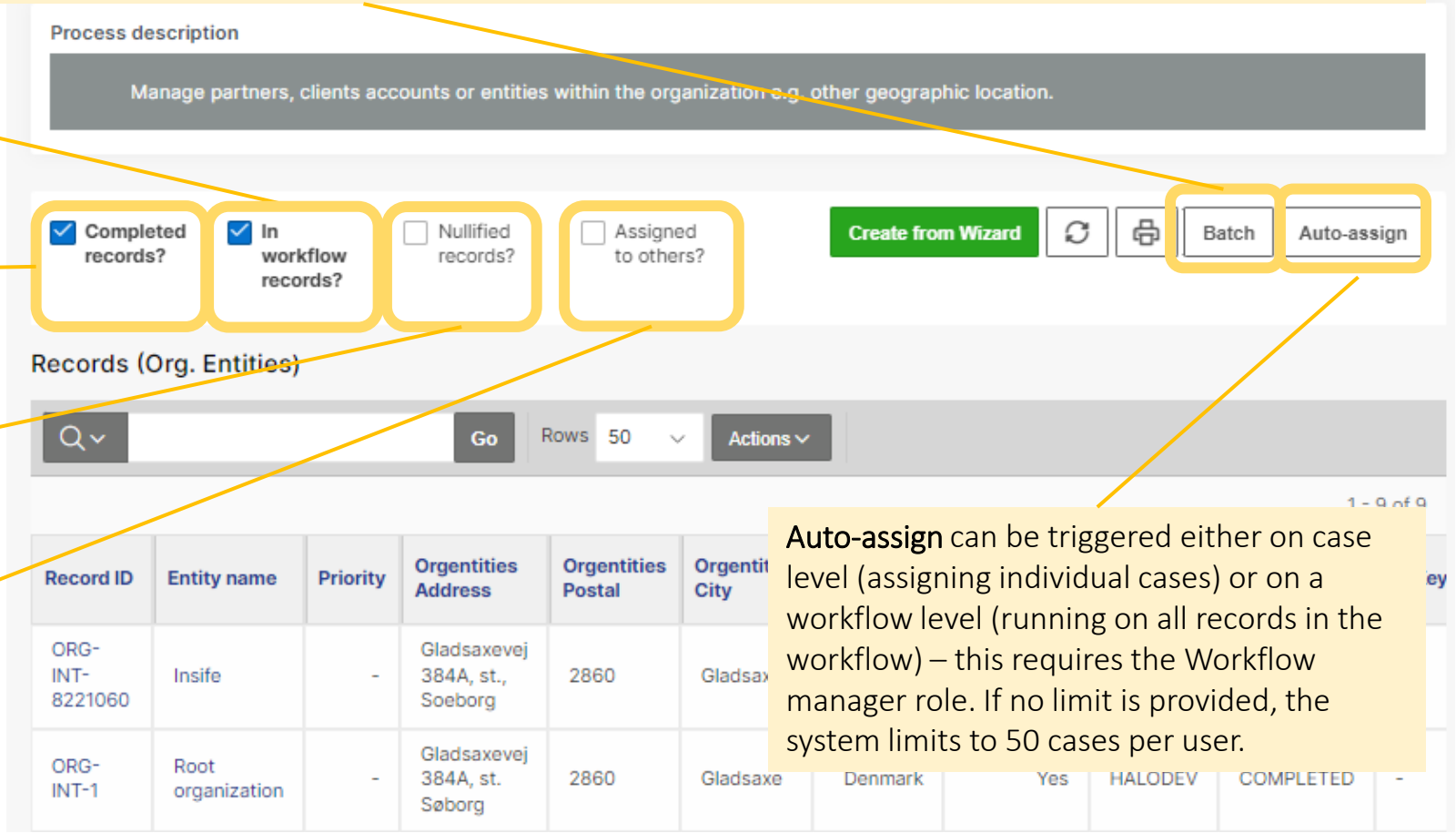
Batch allows the user to batch update multiple records. It is possible to perform Batch actions, including re-assignment of the cases, changing case priority, changing workflow status (routing), and addition/ removal of Tags from cases.

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.



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.

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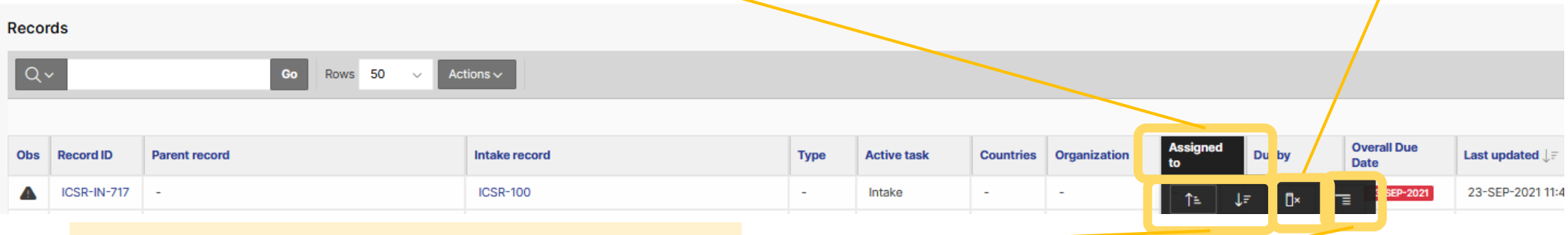
Interactive Report - Hide and Sort columns

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

Hide the column from the list



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.**

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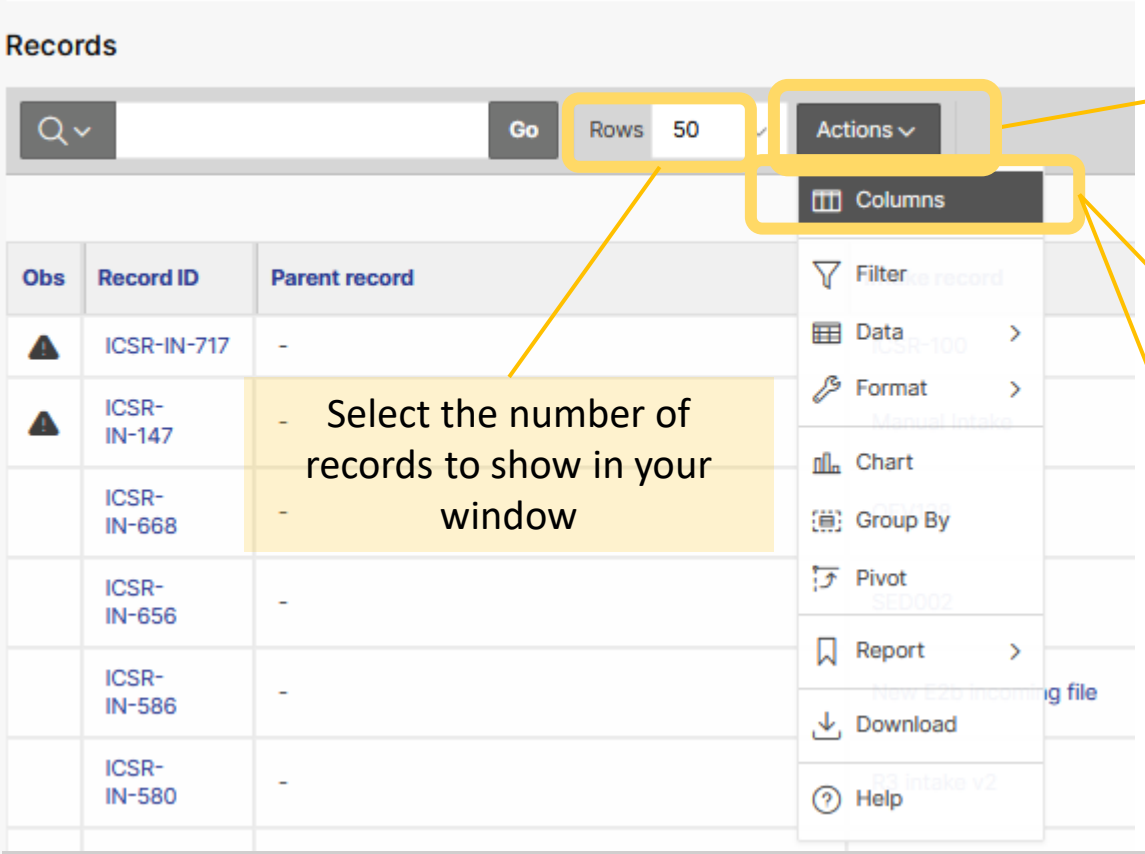
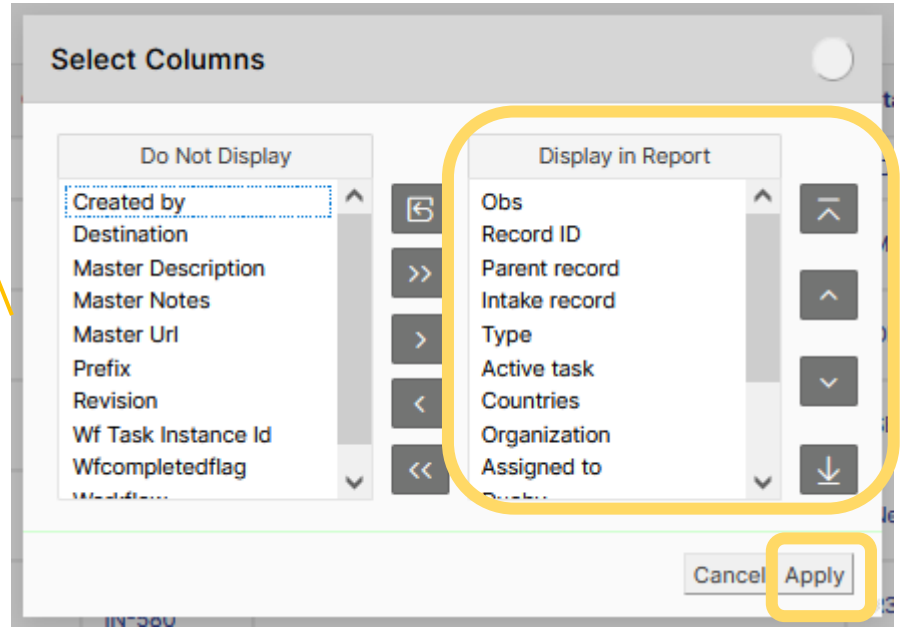
Interactive Report - Enable columns



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.**

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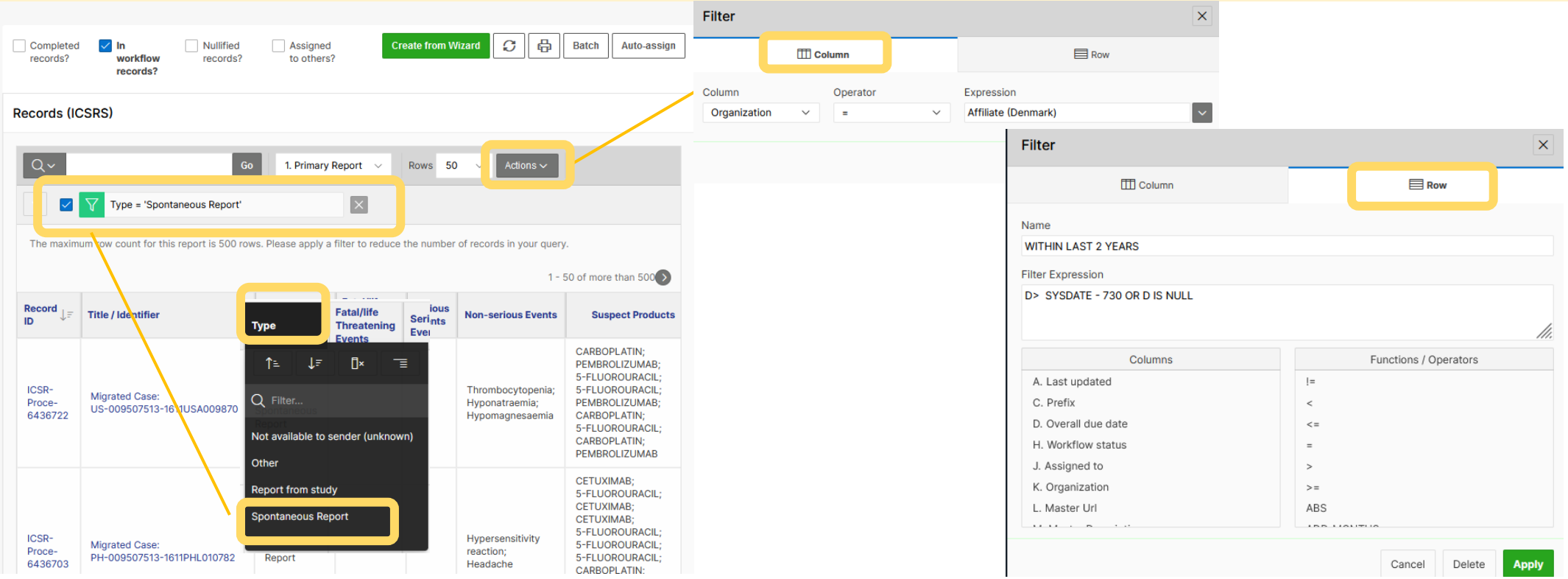
Interactive Report - Filter Data in Columns

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.



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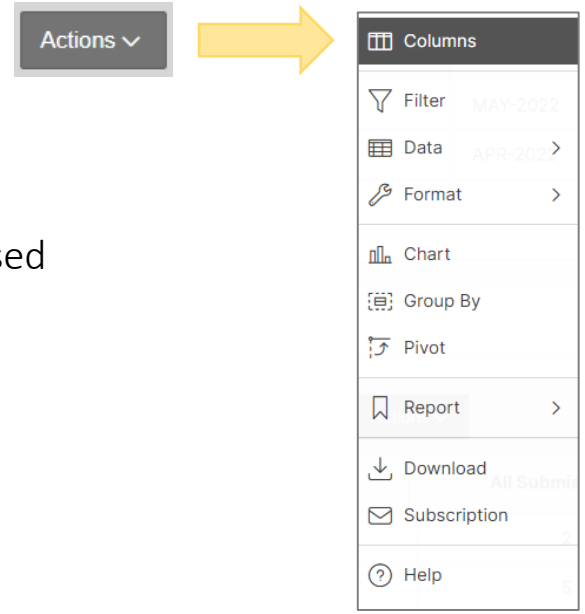
Interactive Report – Additional functionalities

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

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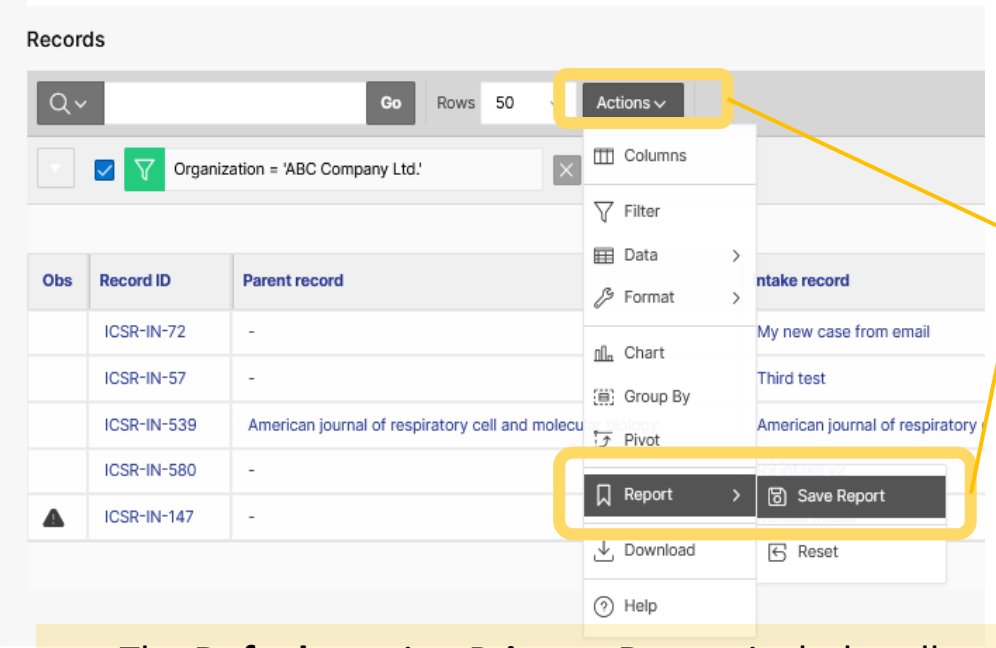
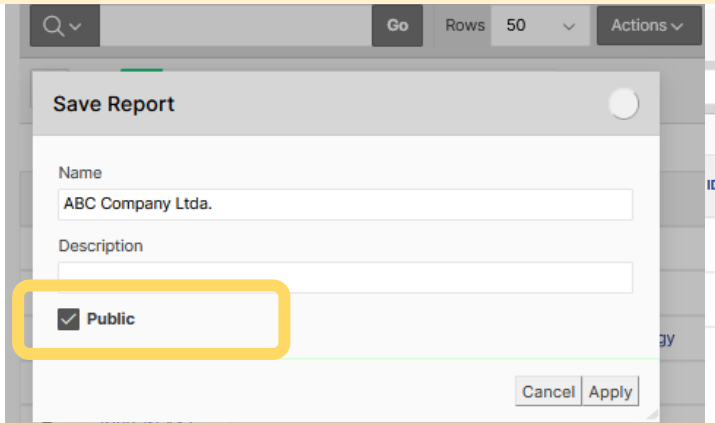
Save your new Public Report

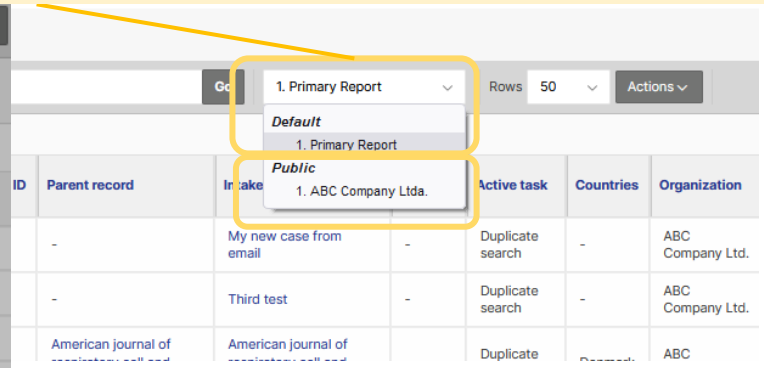


The **Default** section **Primary Report** includes all entries stored in that specific process.

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**.





***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.*

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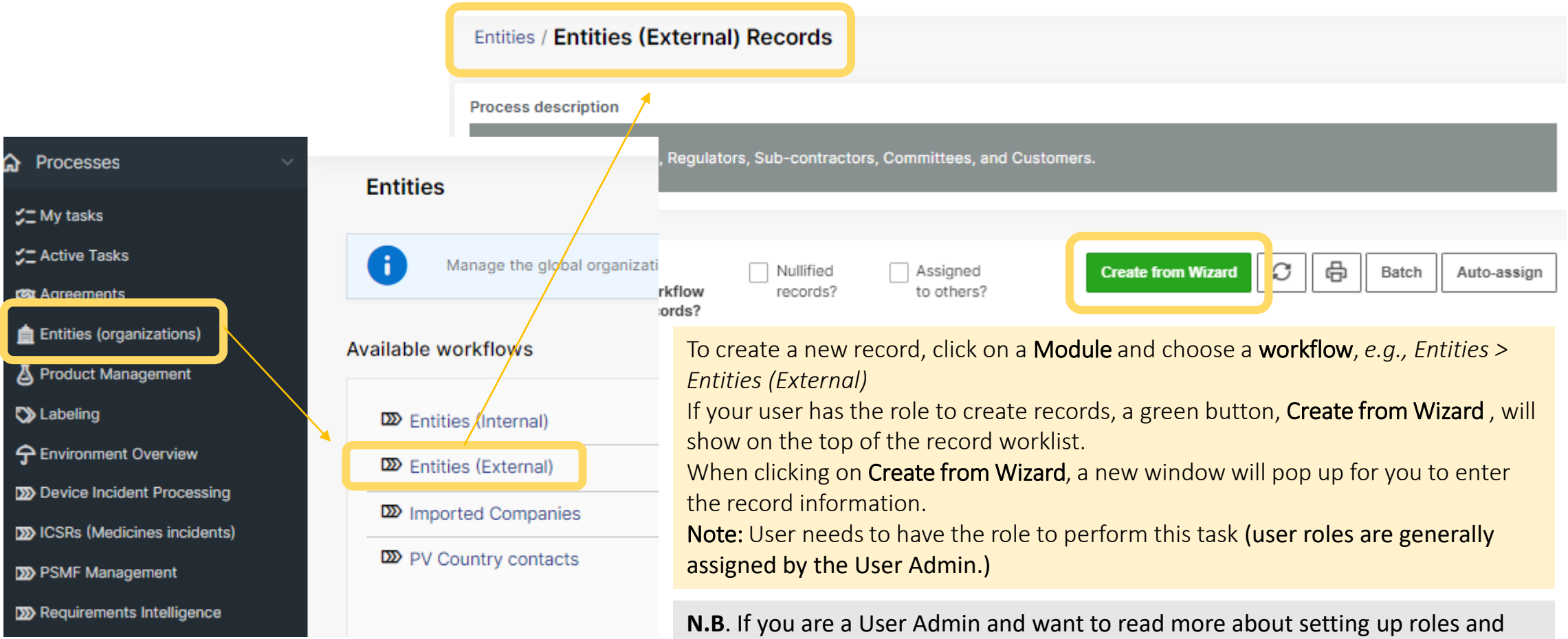
Creating a new Record



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.)**

N.B. If you are a User Admin and want to read more about setting up roles and permissions, please consult the separate **Admin Manual: Application Management and User Admin.**

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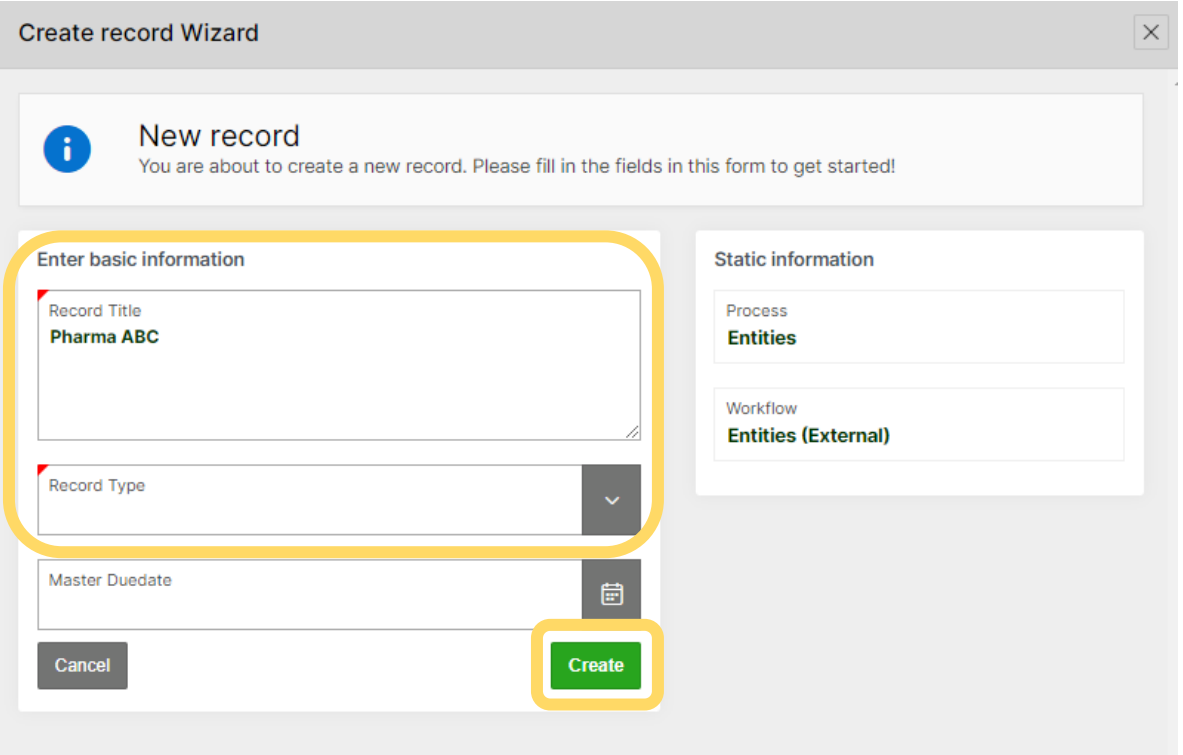
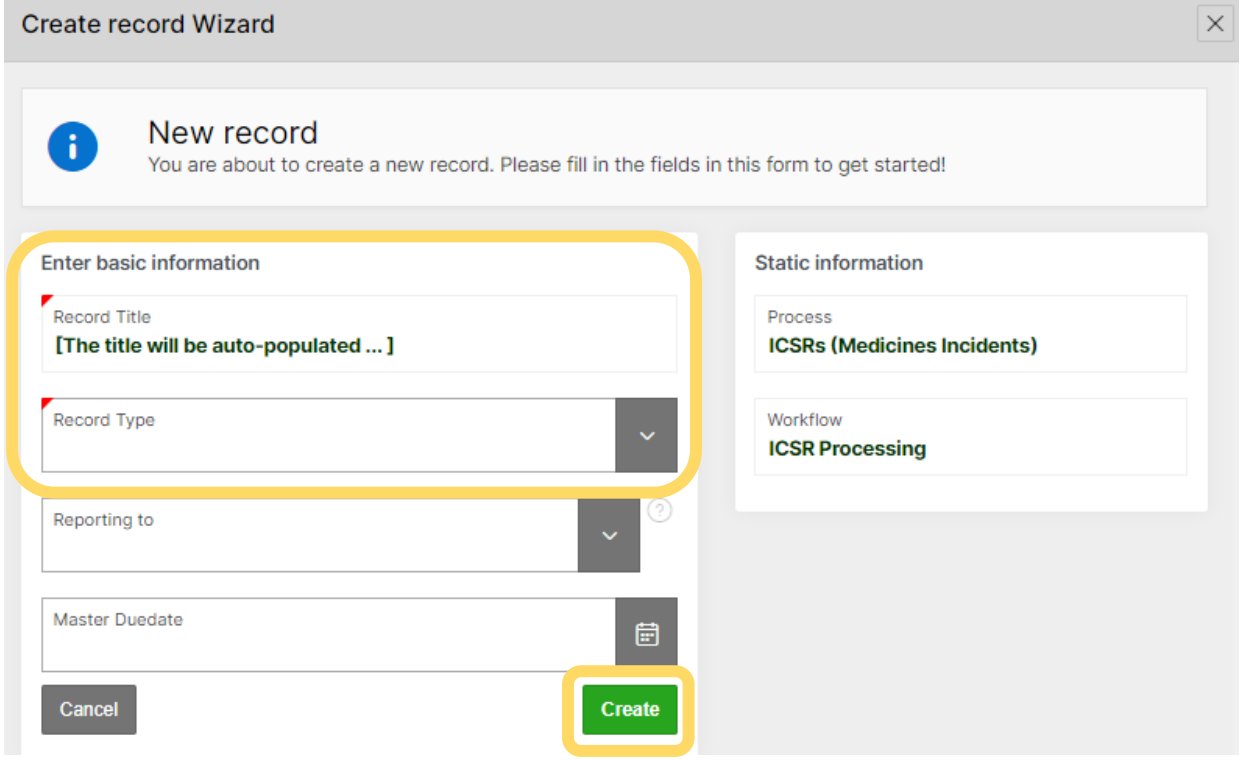
Creating a new Record: Record Title





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.

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View/edit record: Main features

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

Record's title.

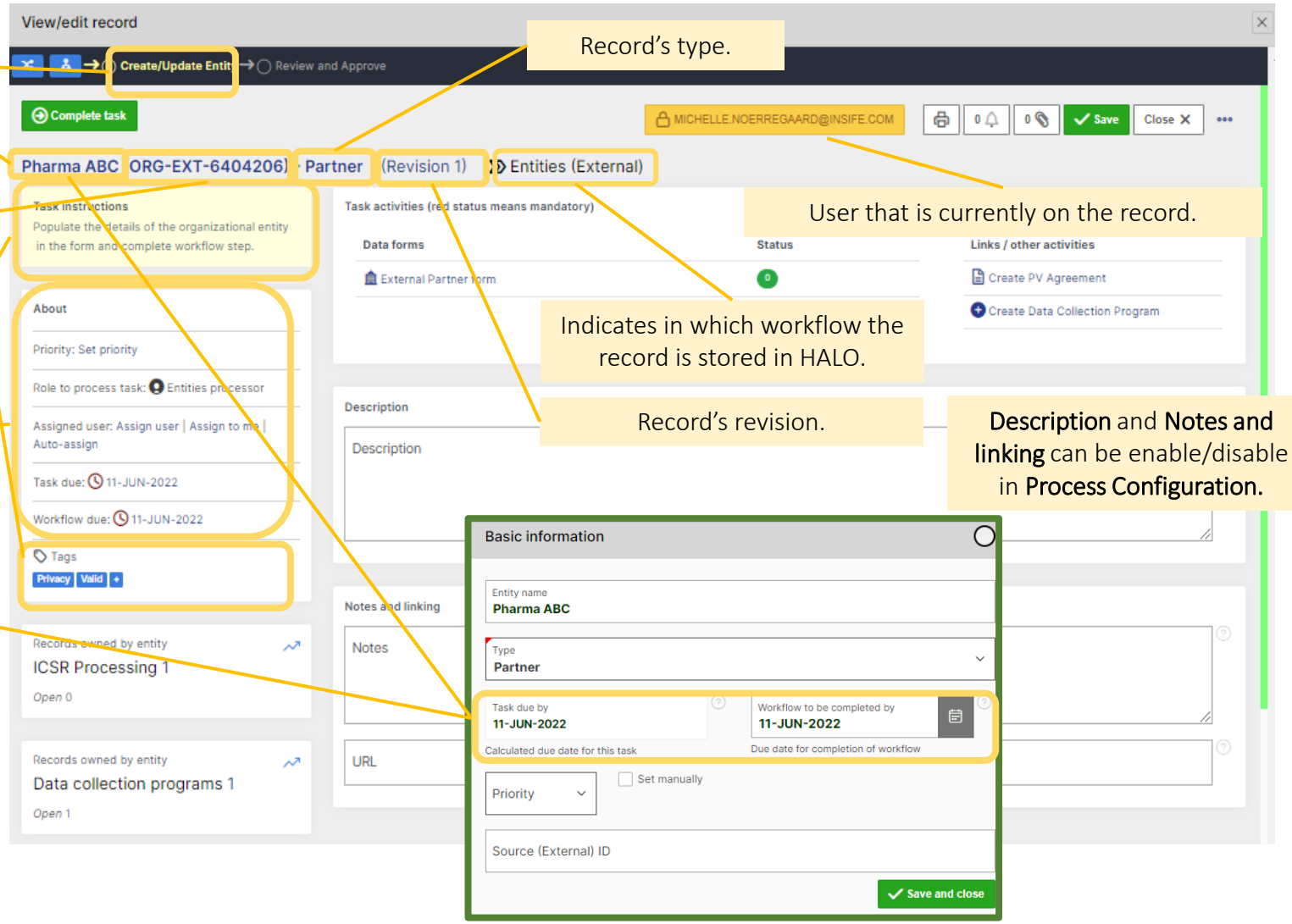
Prefix accompanied by a unique HALO record ID.

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.

<u>About</u>

- **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.'



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.**

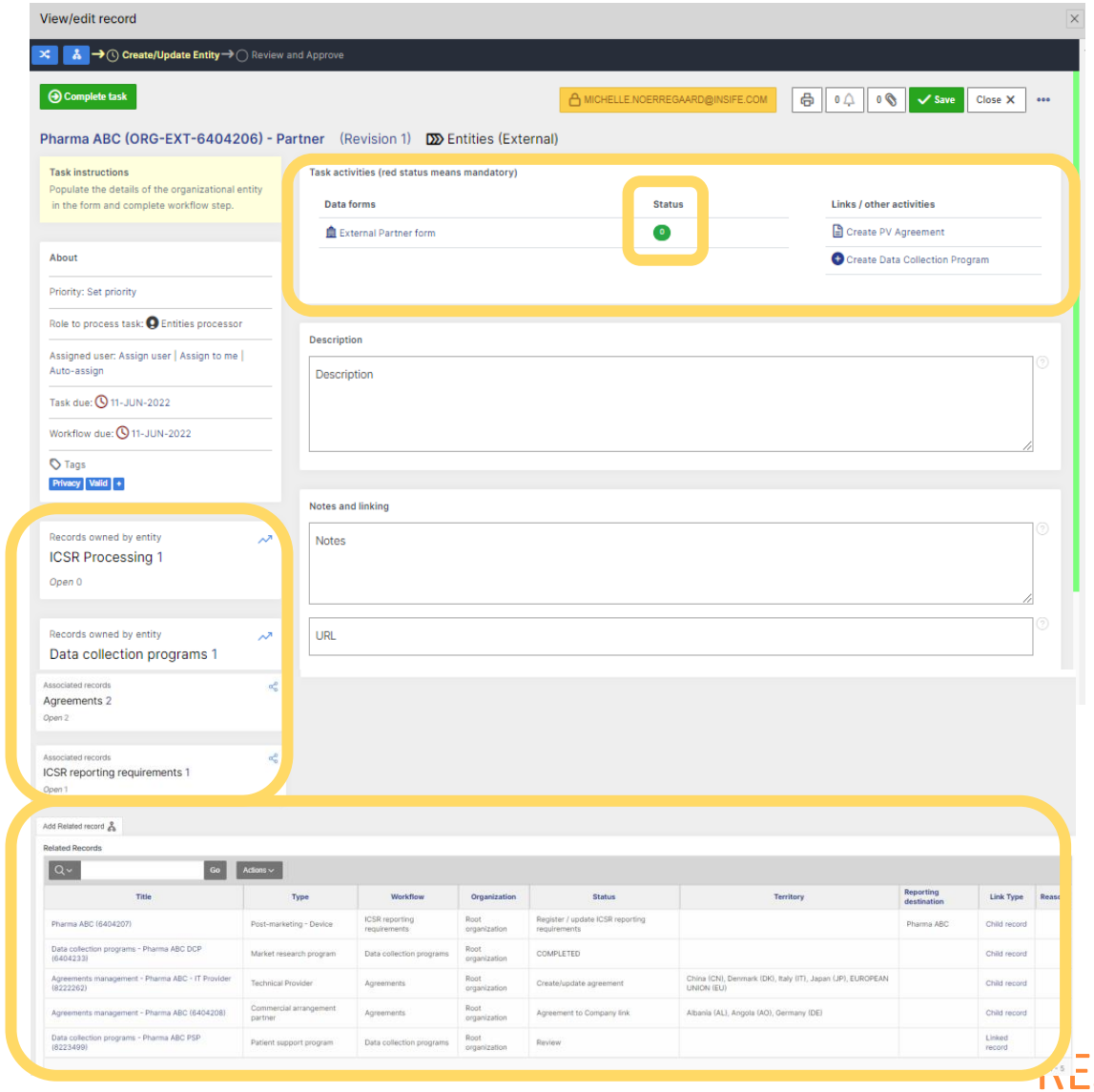
insife

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.



insife

View/edit record: Main features

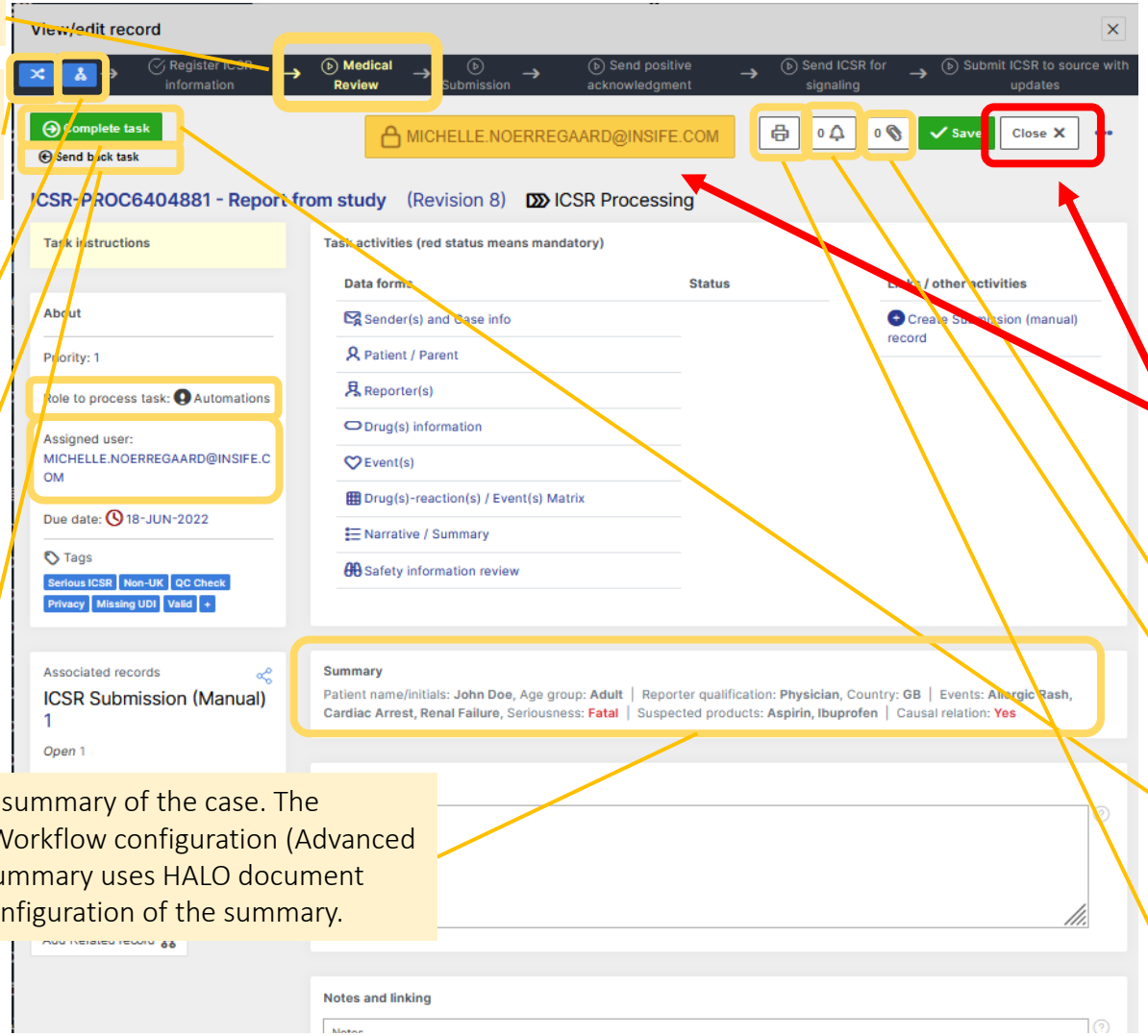
Example of an active step.

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.

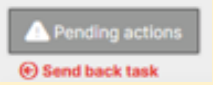
- A Workflow shows a graphical representation of an active and inactive step, your role, the tasks assigned to that role, and the due date.
- Some sections are configurable and might not be available in all workflows, e.g., Summary, Description, Notes, and linking.

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.

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View/edit record: Workflow steps

View/edit record

Register ICSR information → Medical Review → Quality control → Submission → Send positive acknowledgmen

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 1

Reporter(s) 0

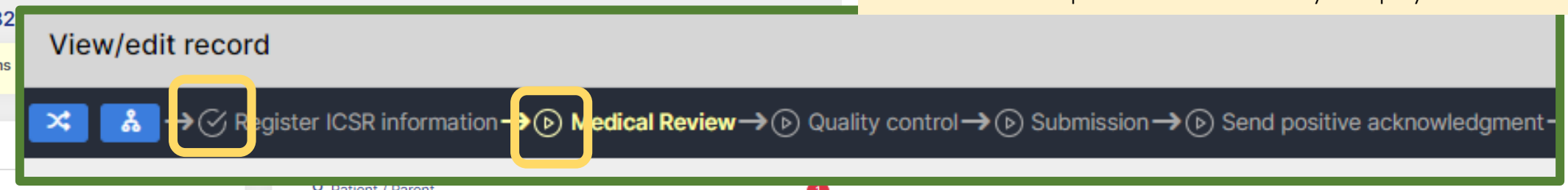
Drug(s) information 0

Event(s) 0

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

Narrative / Summary 0

Event listedness and datasheets 0



- 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**.

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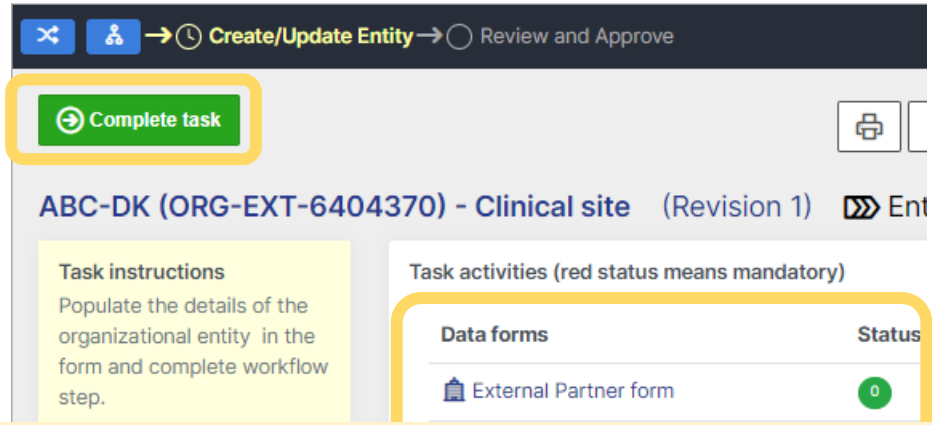
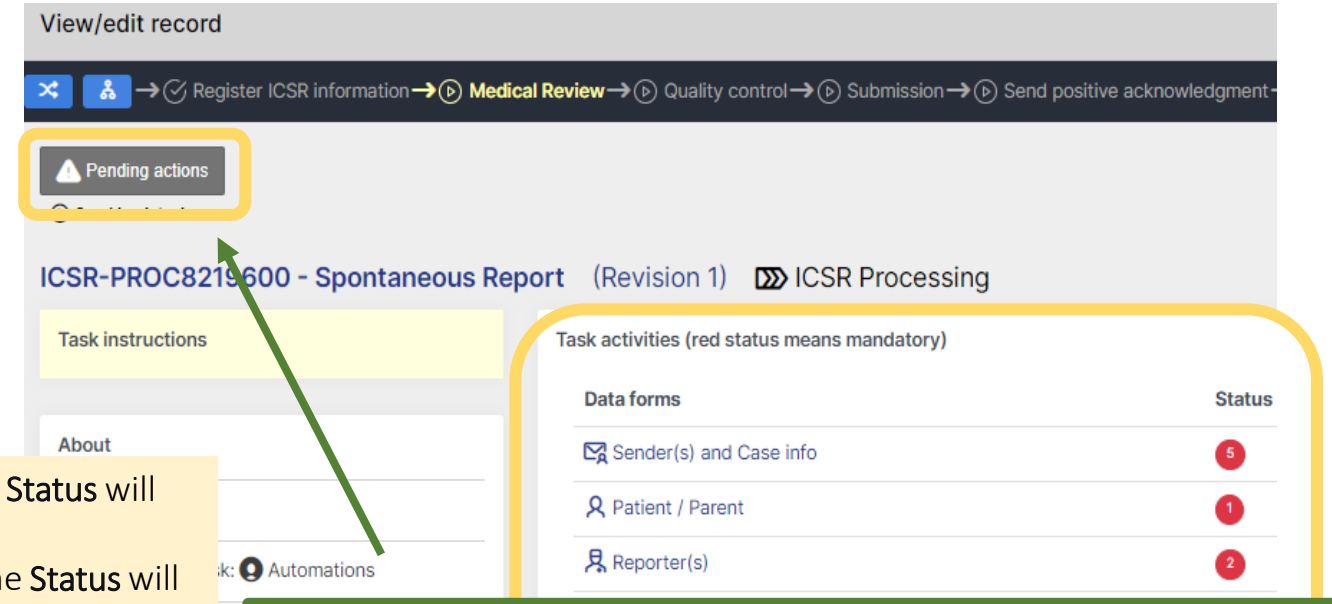
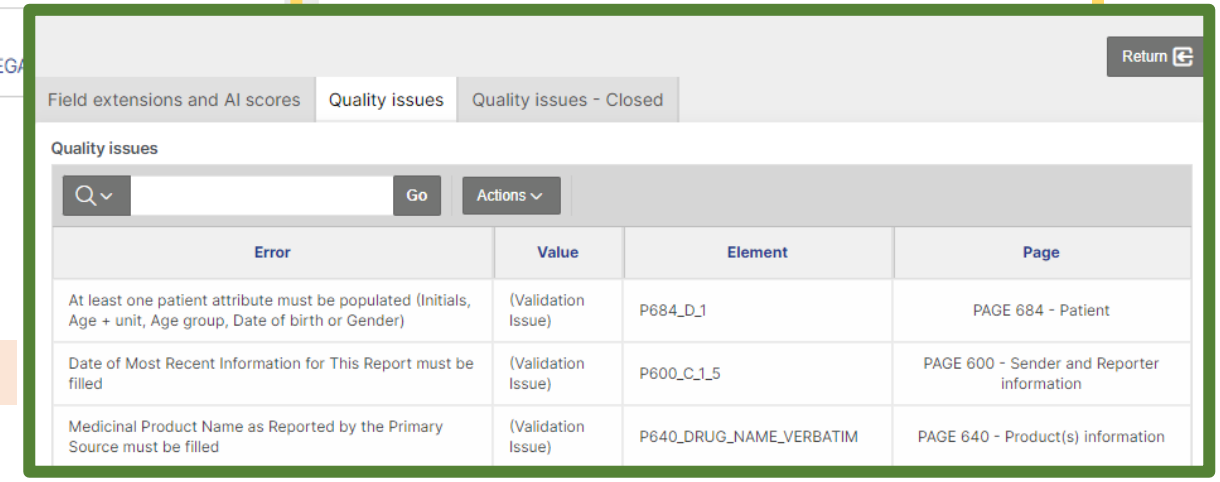
View/edit record: Pending task







- 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).

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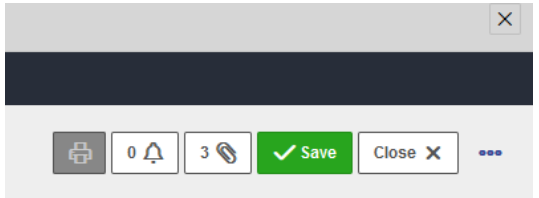
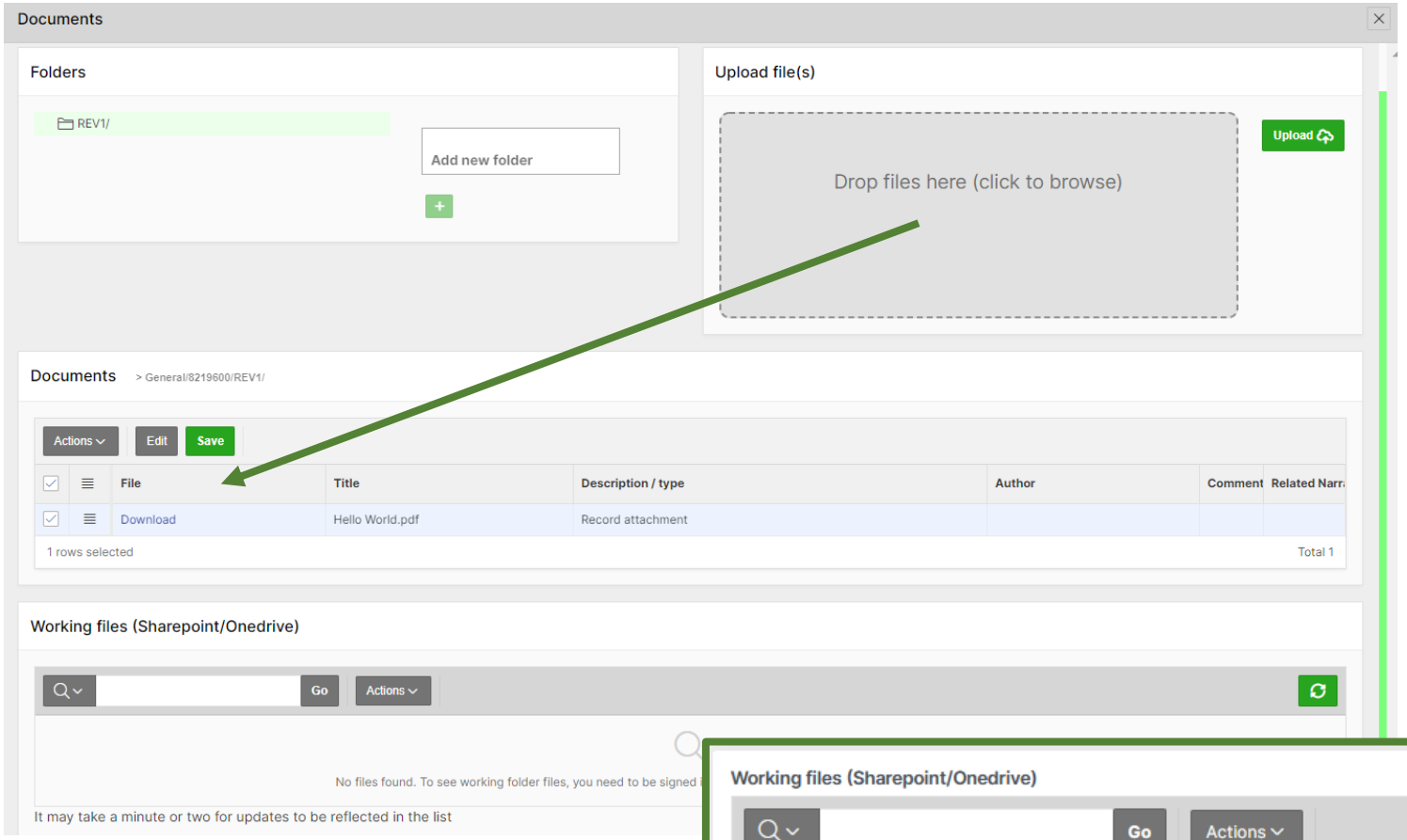
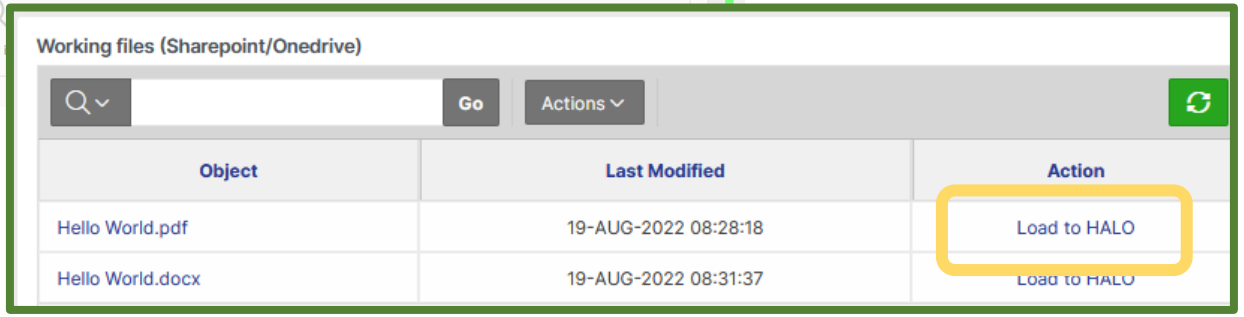
View/edit record: Attachment area





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.



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View/edit record: Attachment area

Folders

REV1/
REV2/

Actions | Edit | Save

File
Download
Single Row View
Delete Row
Refresh Row
Revert Changes

Add new folder

Upload file(s)

Documents General/8220485/REV2/

Actions | Edit | Save

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

1 rows selected

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

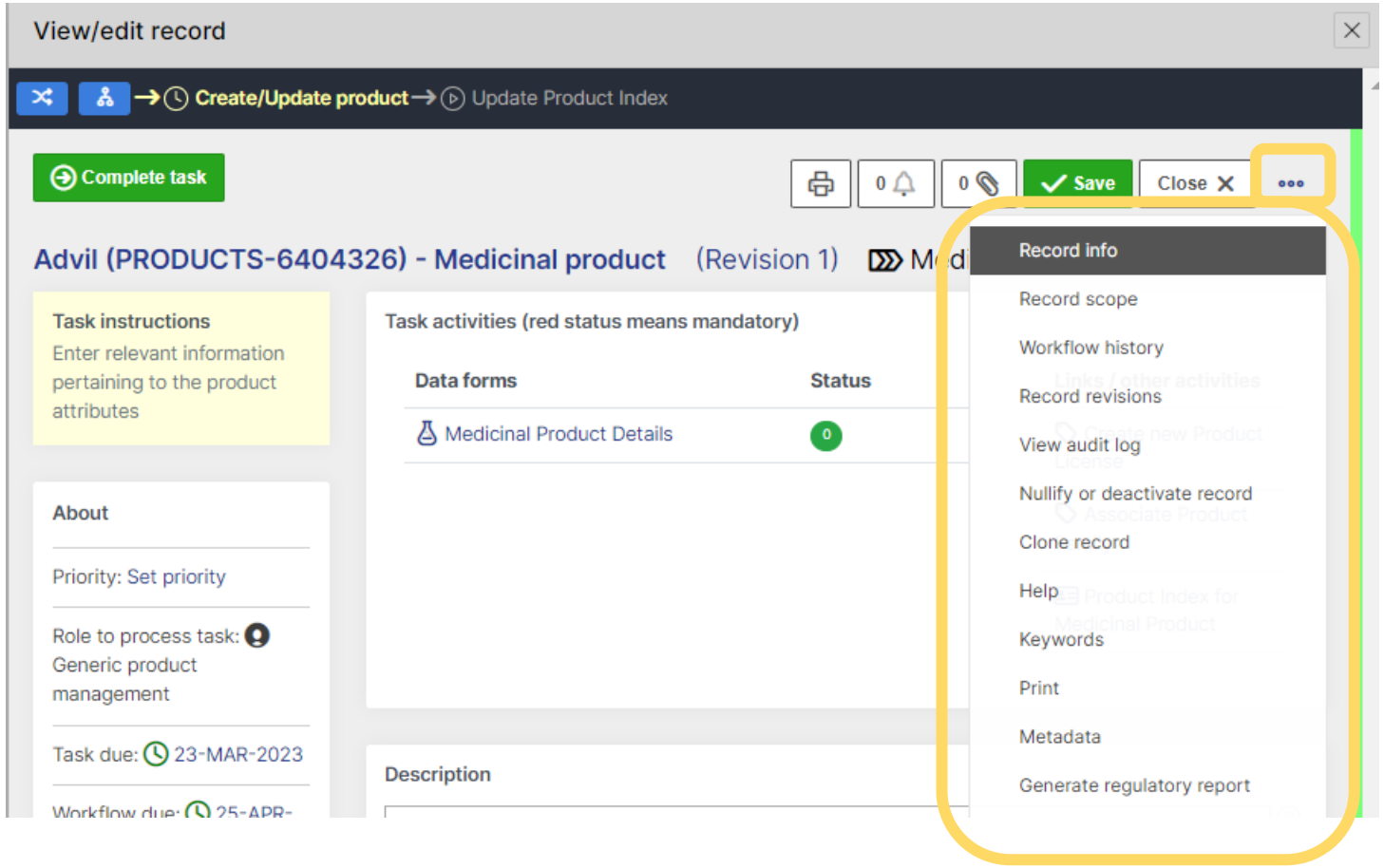
PSMF-MAIN-5633570 → Upload Document → Review final PDF

Complete task | MICHELLE.NOERREGAARD@INSIFE.COM | 0 | 1 | Save | Close

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

insife

View/edit record: Additional features



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

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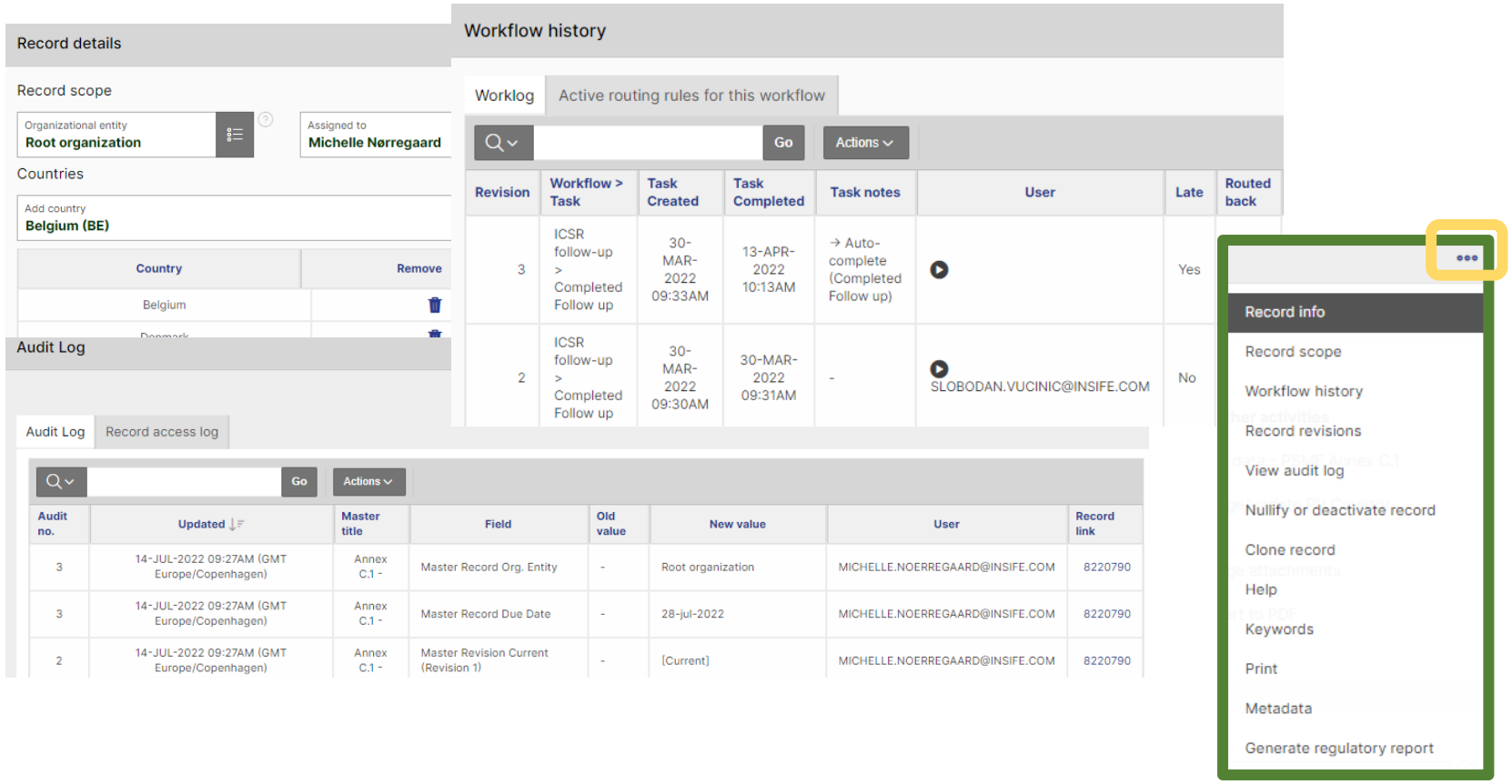
View/edit record: Additional features



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.

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Additional features: Keywords and tags

View/edit record

Register ICSR information → Medical Review

Complete task

ICSR-PROC8223503

Task instructions

Data entry of essential ICSR in

About

Priority: 4

Role to process task: Gener

Assigned user: Assign user | A

Task due: 28-AUG-2022

Tags

QC Check | Non-E2B | Invalid | Manual/Pape | Non-Serious ICSR | +

Keywords

Add a predefined Tag

Save

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			

Delete Keywords

ICSRs (Medicines Incidents) / **ICSR Processing Records**

Completed records? | In workflow records? | Nulli

Records (ICSRS)

Go | 1. Primary Report | Rows 50 | Actions

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

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.

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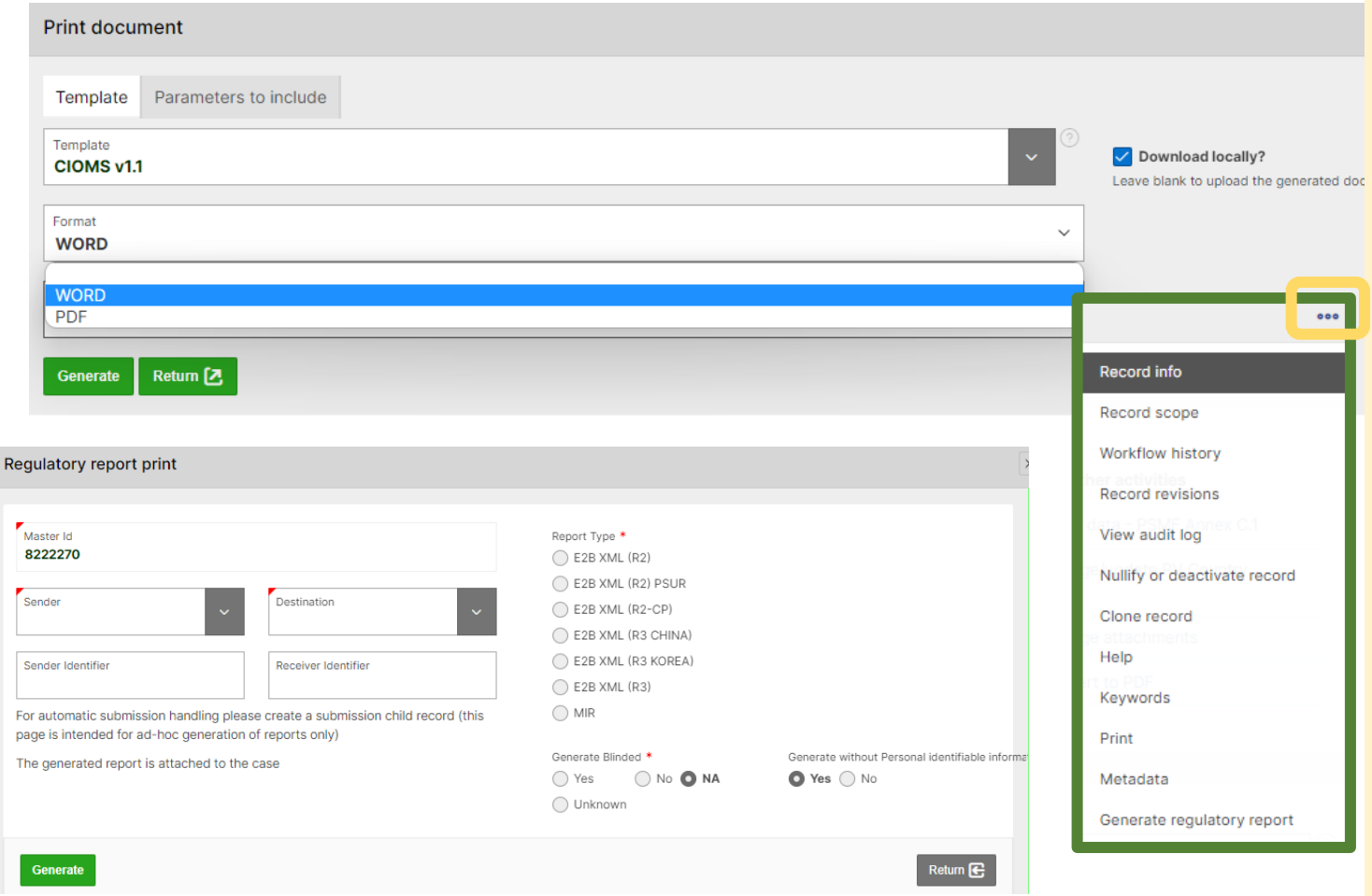
View/edit record: Additional features



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 an 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)

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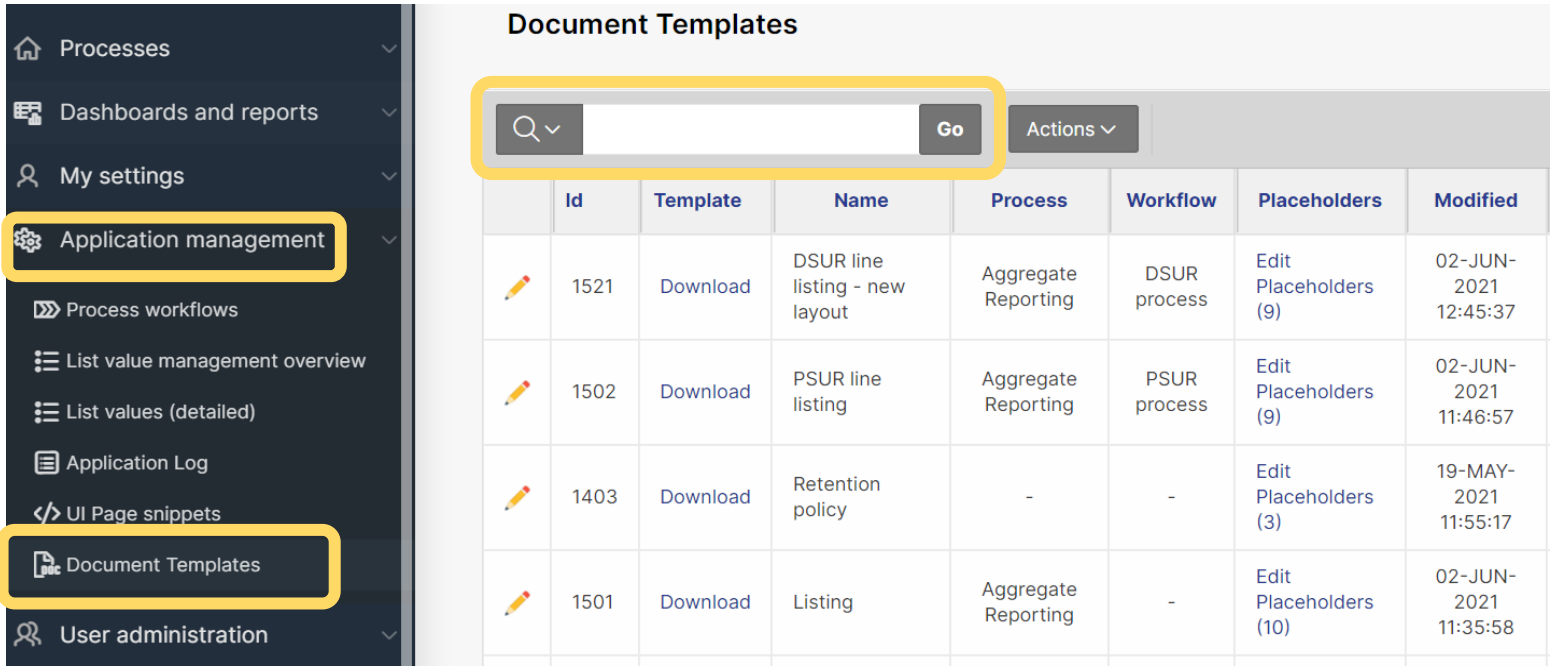
HALOPV Templates



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

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HALOPV Templates: Modify existing document templates

2

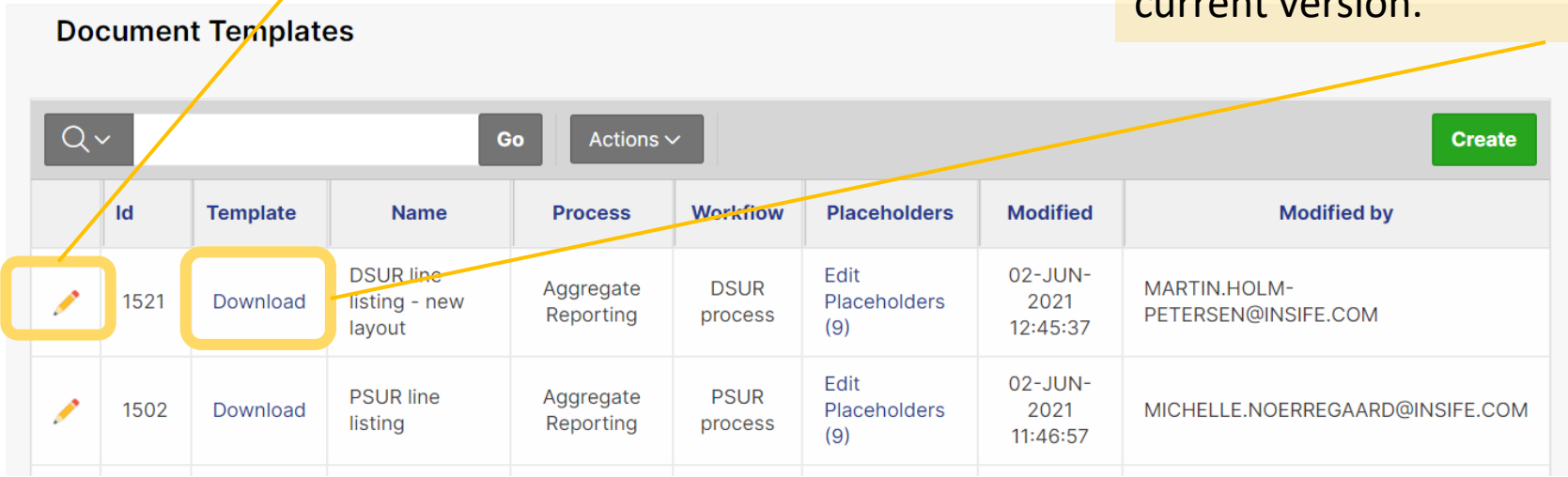
The pencil icon allows you to edit the name or upload a new template

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.



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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)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6. REACTION ONSET		
{PATIENTINITIALS} {PATIENTWEIGHT} {PATIENTHEIGHT}	{COUNTRY}	Day {DDDOB}	Month {MMDOB}	Year {YYDOB}	{AGE}	{SEX}	Day {DDONSET}	Month {MMONSET}	Year {YYONSET}

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)

{#NARRATIVE1}
{@NARRATIVE1}

Example of a validated template.

Note: *Validated templates should not be changed.*

Single values placeholders

Table (Interactive Report) placeholders

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}{COL1}	{COL2}	{COL3}{/DATA}

Template Placeholders

Placeholders

View/edit template

Template
1884

Go Actions

	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)	REVISON	-	-	-
	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

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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 | Create

	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

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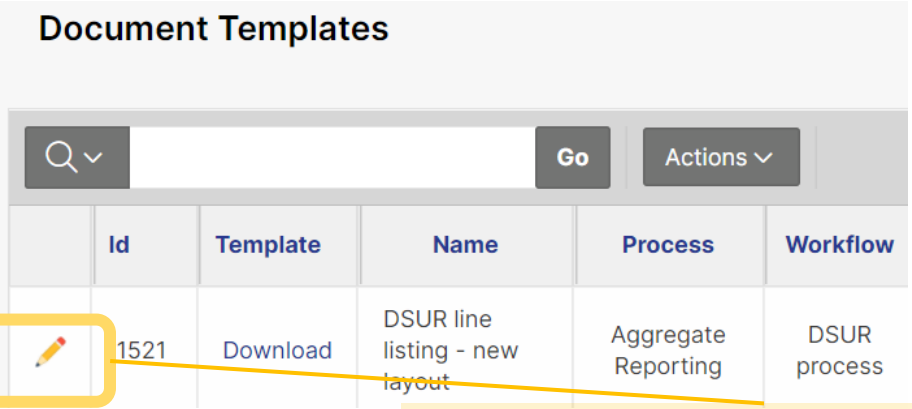
HALOPV Templates: Modify existing document templates

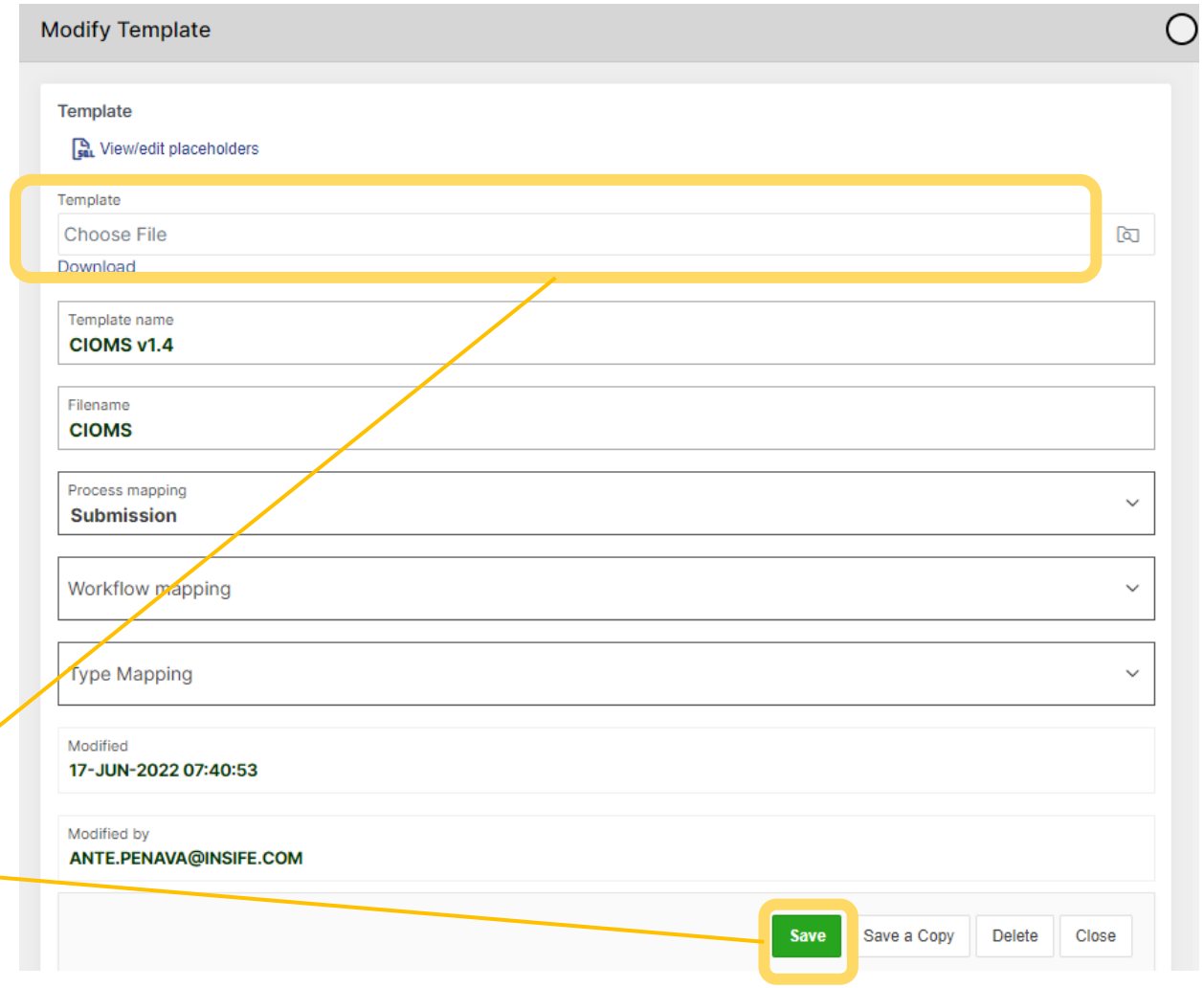
Upload a new document template



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



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RESTRICTED

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

0 | 3 | Save | Close

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	Links / other activities
PSMF details form (populates I.2)	0	Verify data - PSMF Annex C.1
Generate document from template	0	Manage/update PV Country

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

Generate | Return

Record Info

Record scope

Workflow history

Record revisions

View audit log

Nullify or deactivate record

Clone record

Help

Keywords

Print

Metadata

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

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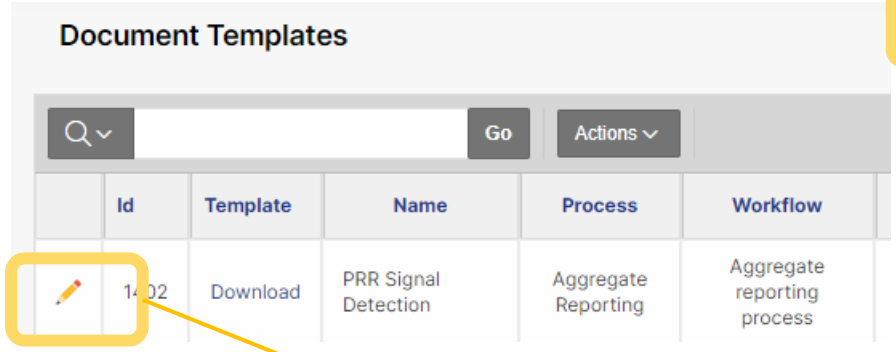
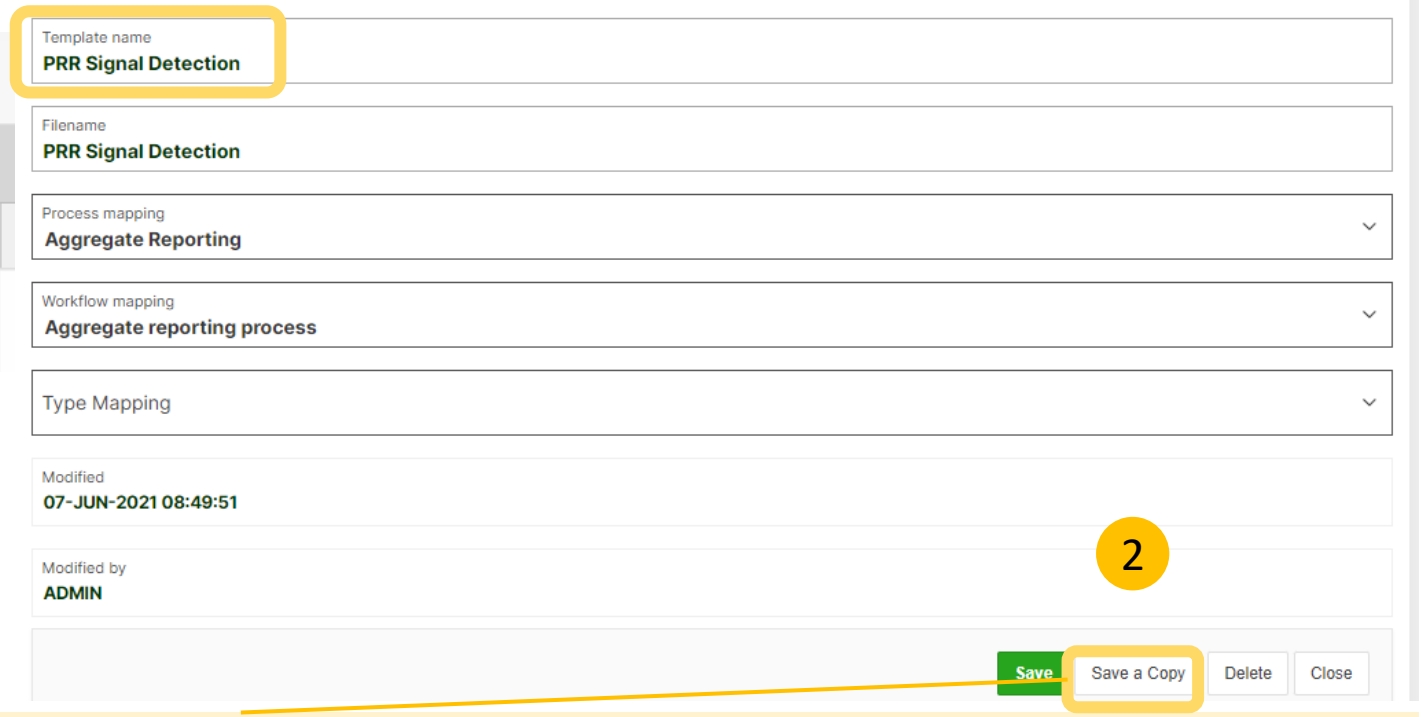
HALOPV Templates: Duplicate a template



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



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.

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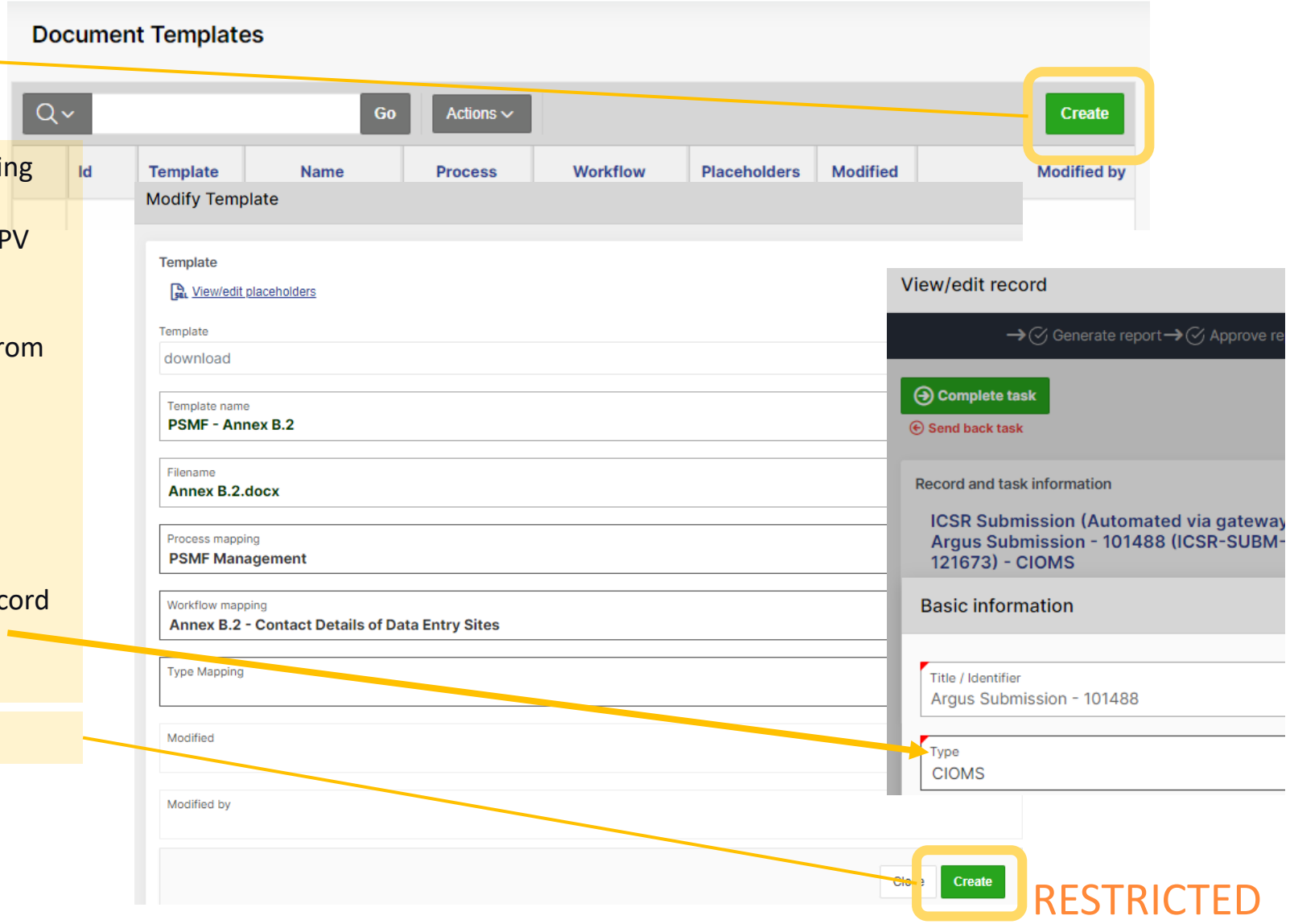
HALOPV Templates: Create a new document template

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**



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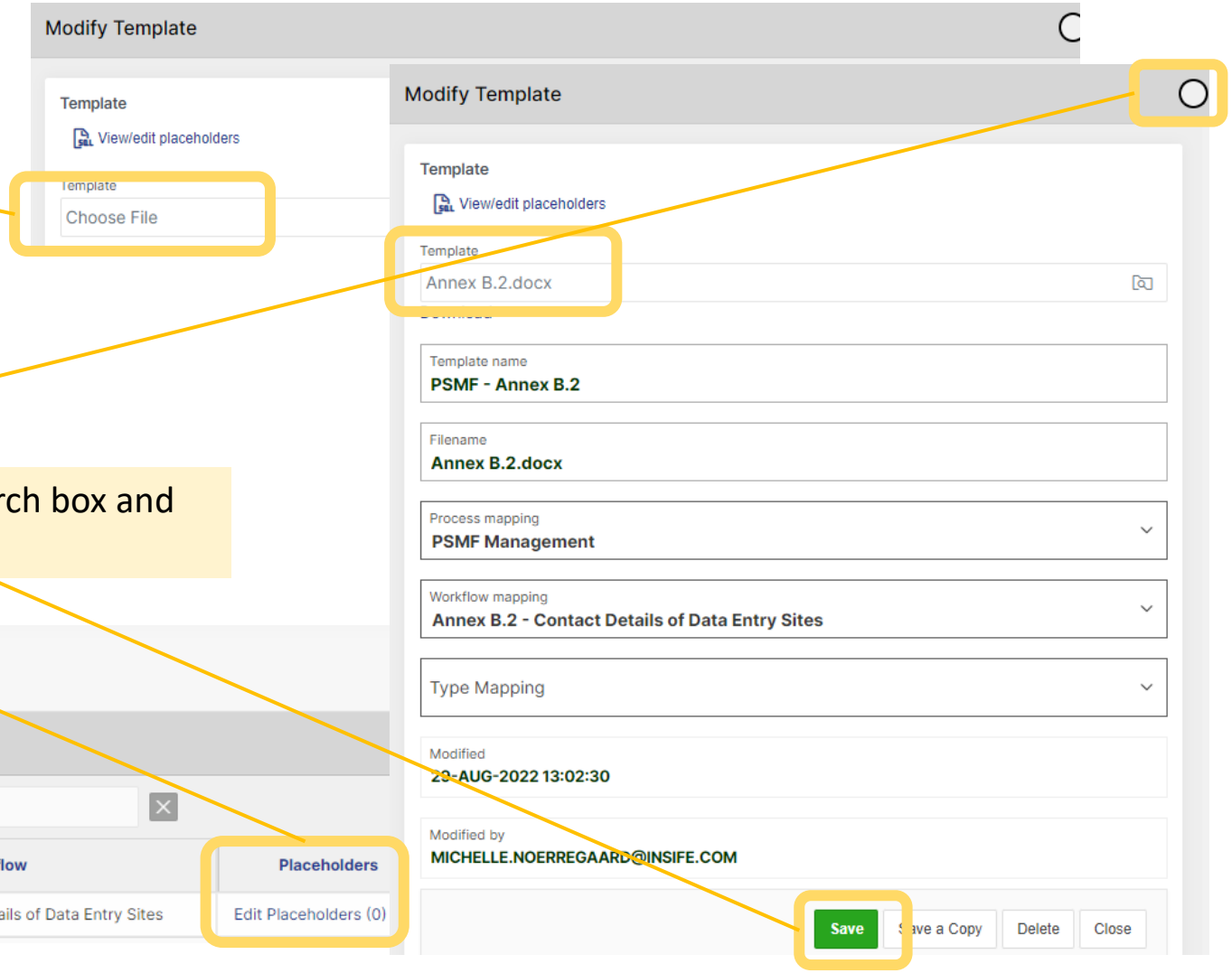
HALOPV Templates: Create a new document template

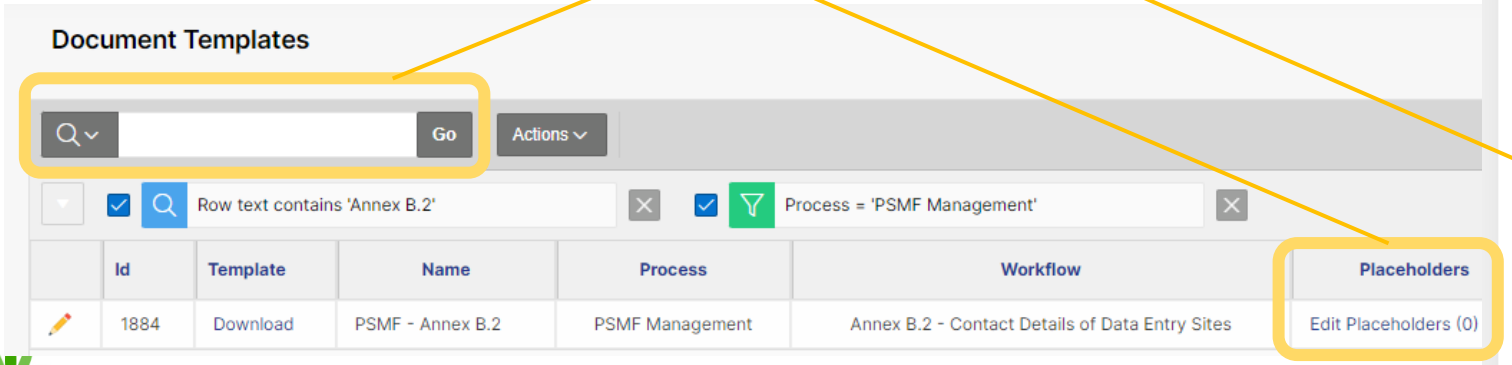
4 Click on **Choose file** and select your new Word document template from your local computer.

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.





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HALOPV Templates: Create a new document template

How to create a placeholder

8

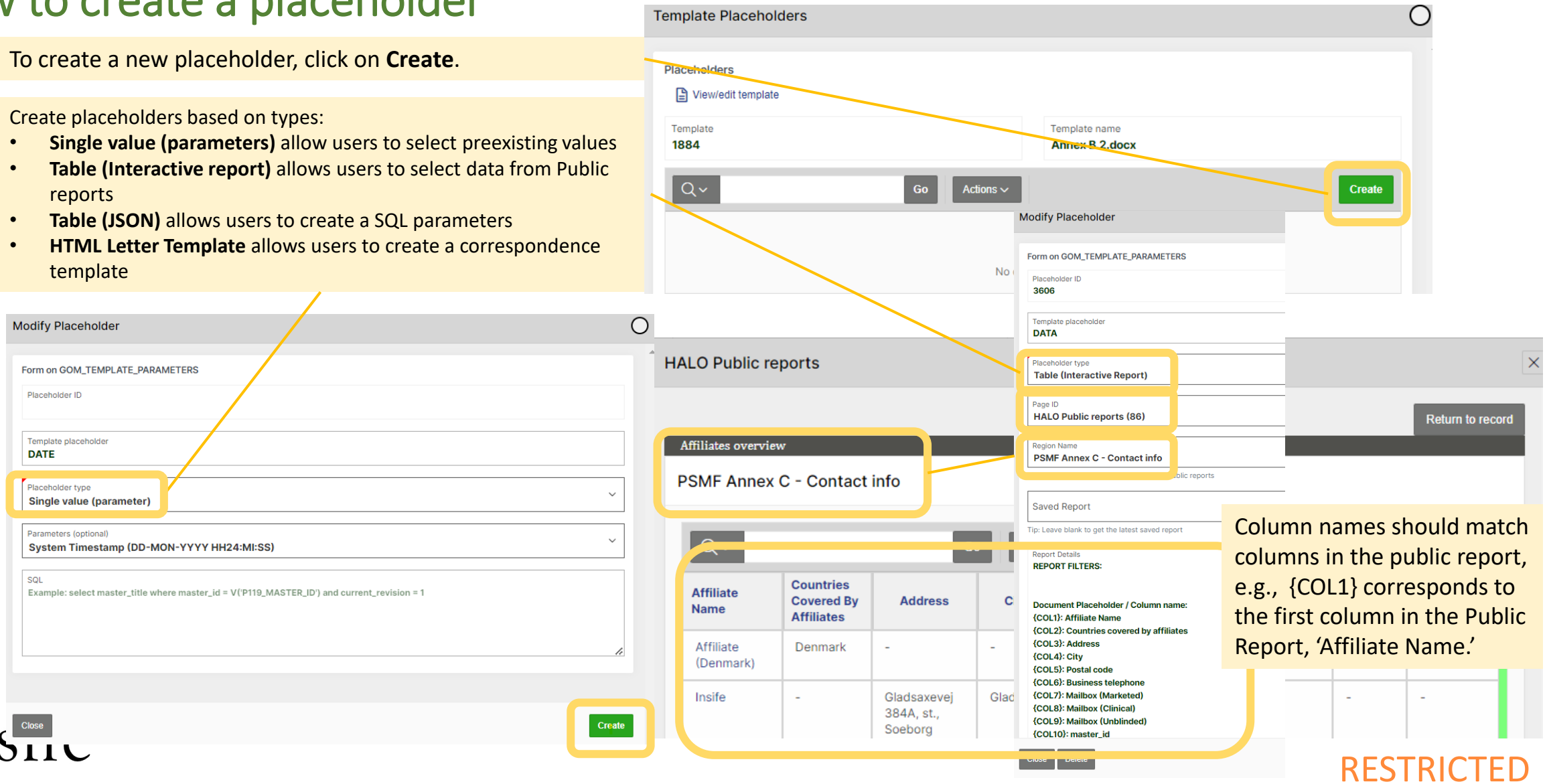
To create a new placeholder, click on **Create**.

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



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

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HALOPV Templates: Create a new document template

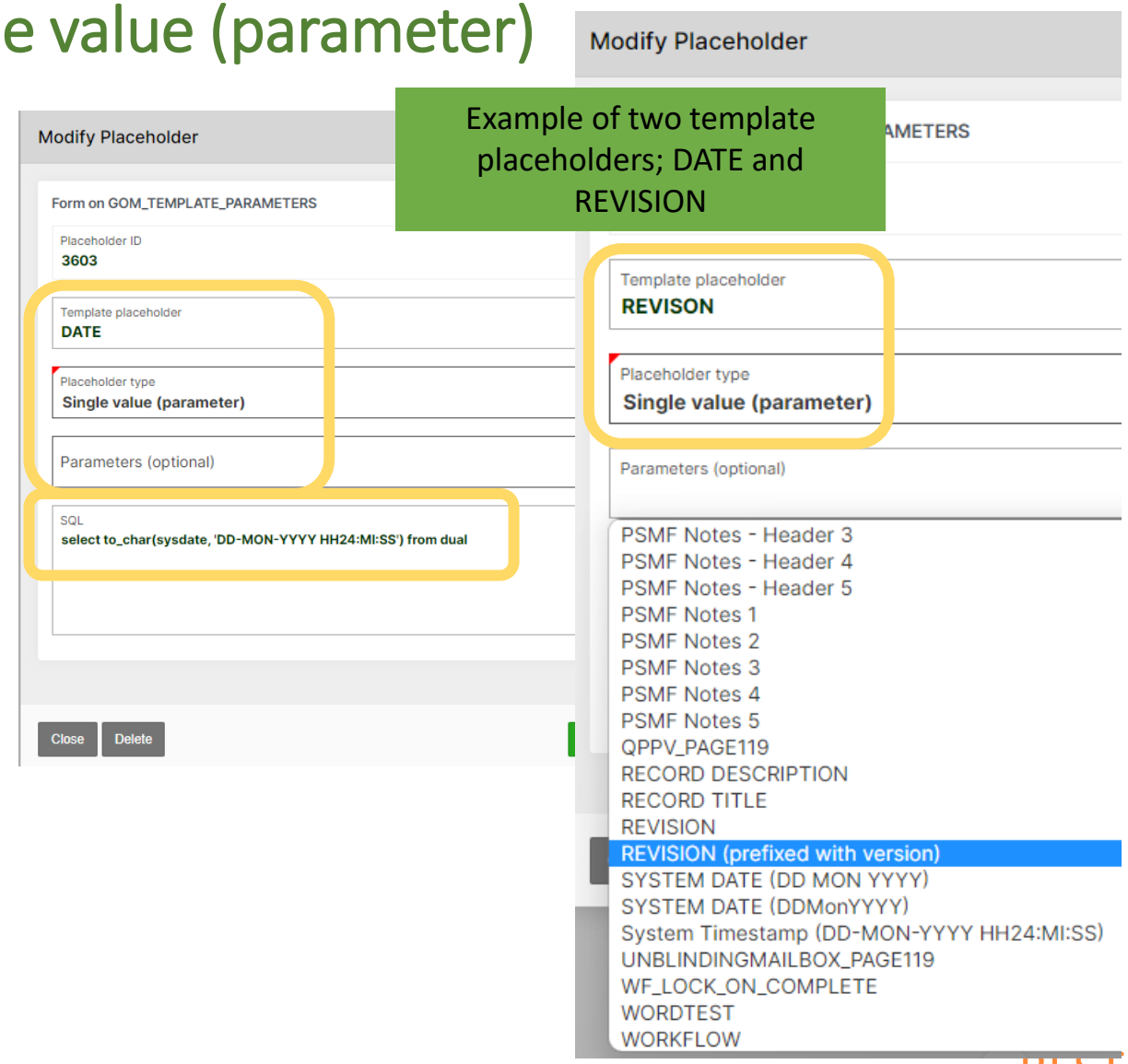
How to create a placeholder: Single value (parameter)

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}

Example of two template placeholders; DATE and REVISION



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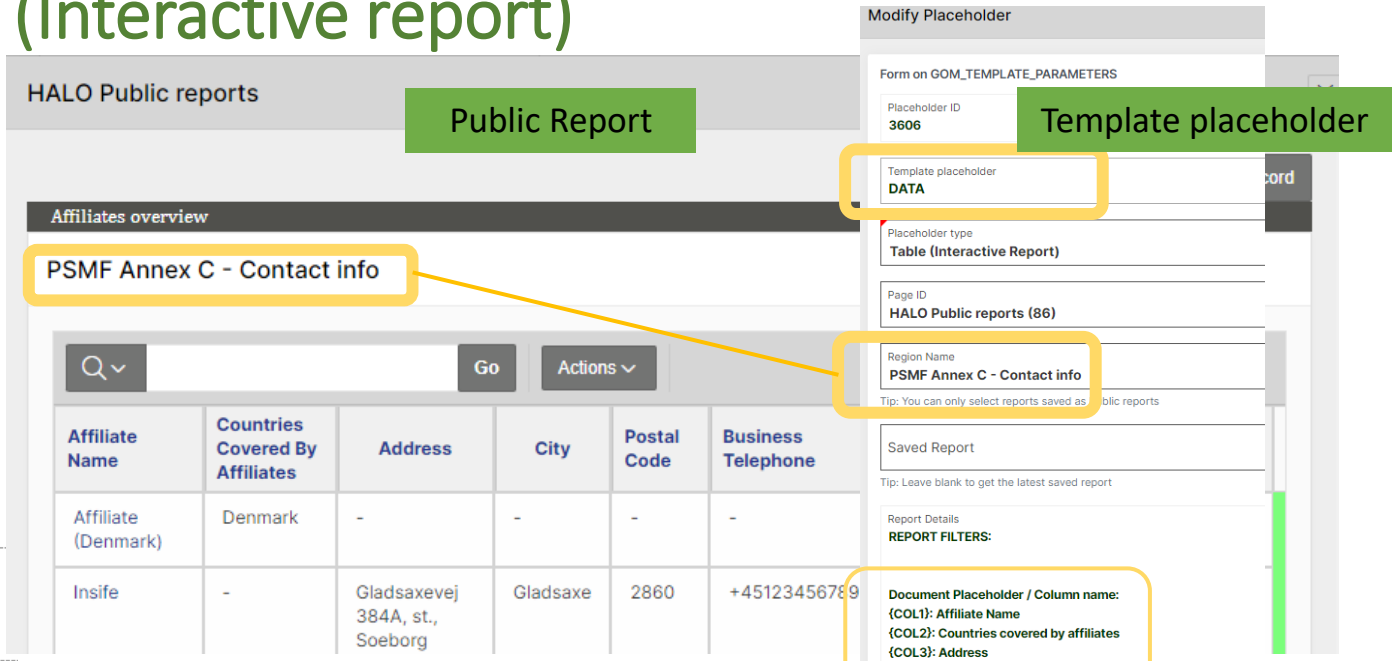
HALOPV Templates: Create a new document template

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

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

Output of the document template

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

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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.

2

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

3

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

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

0 | 0 | Save | Close | •••

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

Task activities (red status means mandatory)

Data forms	Statu
PSMF details form (populates I.2)	0
Generate document from template	0
Verify data - Affiliates	0

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	+45123 67

Document link

Document link

Action: Assign Document Template

Record Title: Annex B.2

Document Template: PSMF - Annex B.2

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: PDF

Upload to working folder

Generate | Return

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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

Template

View/edit placeholders

1

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

3

	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

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HALOPV Templates: Create Correspondence Template

View/edit record

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

Complete task | 0 | Save | Return | Close

MICHELLE.NOERREGAARD@INSIFE.COM

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

Task instructions
Use the contents field to create a correspondence

Task activities (red status means mandatory)

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

Add recipient

Add Related record

Correspondence Contents

1

Manage templates | Generate from template

Paragraph

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

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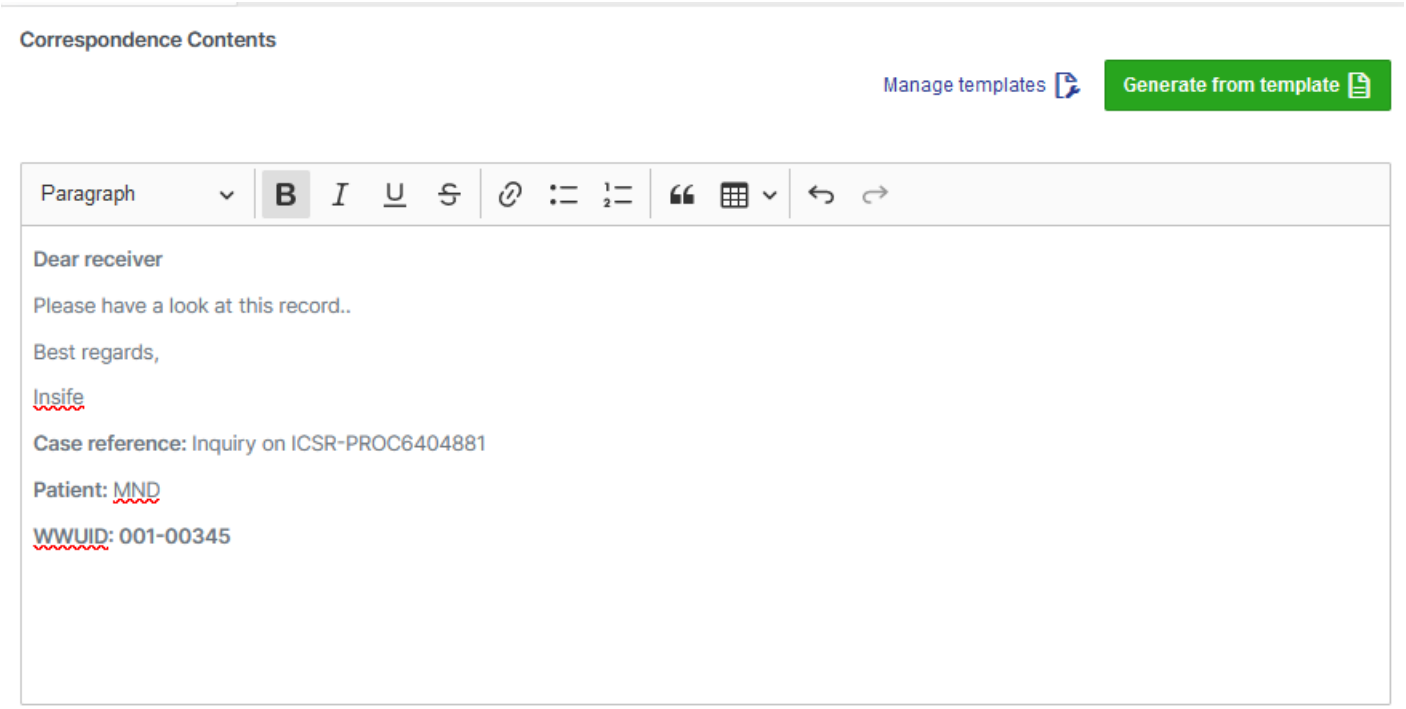
HALOPV Templates: Create Correspondence Template



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

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