Signals

HALOPV / PROHALO 4.X USER GUIDE

This is an end-user guide for the Signals module of the drug safety solution HALOPV / PROHALO.

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1. HALOPV / PROHALO Signals module user manual

User Manual - Release 4.X (4.X first released March 2023)

2. Preface

The latest product information including release notes for HALOPV and multi-tenant HALOPV (branded as PROHALO) is available at

https://insife.com/halopv

Insife Support:

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

3. Introduction

3.1. Purpose of this document

This User Manual describes the Signals module features of HALOPV. It is intended as a module guide, which should be considered one of the general manuals. You will find a manual for each Module separately on https://insife.com/halopv-user-guides-tutorials.

The overall guide for using general features is available online on General features (insife.com)

3.2. Modules of HALOPV

At the time of writing this manual, the HALOPV Modules comprise:

- Aggregate Reporting Module
- Agreements Module
- Clinical Trials Module
- Complaints Module
- Data Collection Programs Module
- Device Incidents Processing Module
- Entities Module
- ICSRs (Medicine and Vaccine Incidents) Module
- Literature Monitoring Module
- Labelling (Dictionaries and terms) Module
- Medical Information and Communications Module
- Pharmacovigilance System Master File (PSMF) Module
- Products Module
- Quality Module
- Requirements Intelligence Module
- Risks Module
- Signals Module
- Submissions Module

Besides the modules, you will also find a separate manual for application administration and user administration in Admin Guide (insife.com)

3.3. About HALOPV (incl. PROHALO)

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

4. Navigating the Signals module

Once you log into HALOPV with your user credentials, on the left Menu, you will find the list of Modules to which your user has access. Otherwise, please refer to our General Features user manual. If you can log in but do not have access to the Module, please consult section 4.2.

The **Signals module** will appear if your user profile has access to the Module.

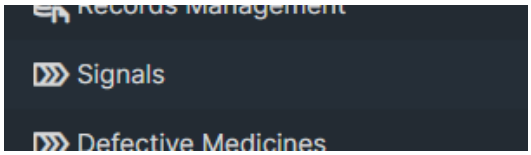


Figure 1 Left menu, Signals is available for users with the appropriate access role

4.1. Module Main Screen

The Main screen displays the list of process workflows available in the Module Labelling – including the Functionality Menu.

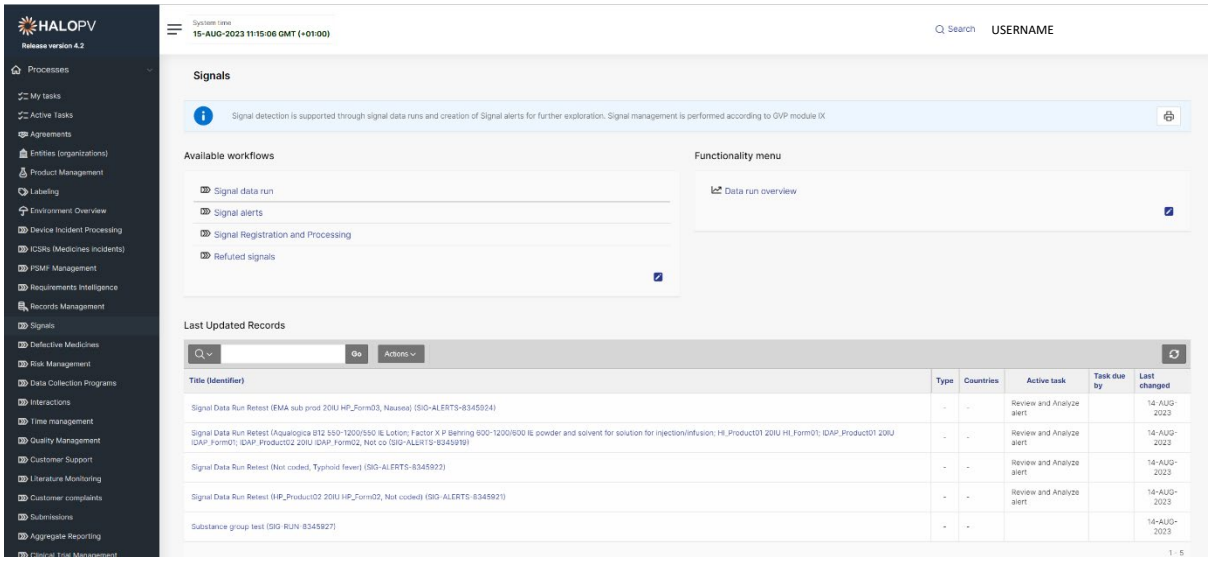


Figure 2 The standard list of Workflows and Functionality Menu items for the Signalsmodule

Click on a workflow or functionality to access it.

4.2. User roles relevant for the Module

Users must be assigned roles to access the relevant modules. Furthermore, user roles can allow access or editing rights for a record when it is in a specific workflow task step. Please consult the table below for

standard user roles that are provided with the system. Other user roles may have been configured by your administrator. For a description on how to administer users and user roles, please refer to the Admin Guide (insife.com)

User role	Description
Signals Module	Provides access to the Signals Module in the navigation.
Signals processing	Main processing role for the Module. The role can create records and assign a due date.
Signals reviewer	Users with this role can review the information/data available in the relevant workflow step.

Table 1 Default User roles for the Signals module

5. Standard Workflows

The Module comes pre-configured with several standard workflows. These are described in the following sections, including tasks and associated actions.

It is important to note that the workflows may be configured to local requirements in your HALOPV / PROHALO setup. Hence the workflows may look different from the standards, and some workflows and menus might not be available to the user view.

Users can access the record worklist by clicking on one of the available workflows. **Clicking on a workflow** takes you to the records worklist. See Figure 2 The standard list of Workflows and Functionality Menu items for the Labelling module and 3.

The Records worklist may have different columns, depending on the selected workflow. However, the principle is the same for all workflows. The standard list displays the ***Record ID, Title of the Record, the Type, Current task, Overall Due date*** *(the date the task is due to comply with set timelines),* etc.

Clicking on the "Record ID" or "Requirement Title" takes you to the individual record. See Figure 3 When clicking on a workflow, the following screen displays the Process and workflow description (if configured) as well as a worklist of records, where the Record ID and title can be clicked to access the record.

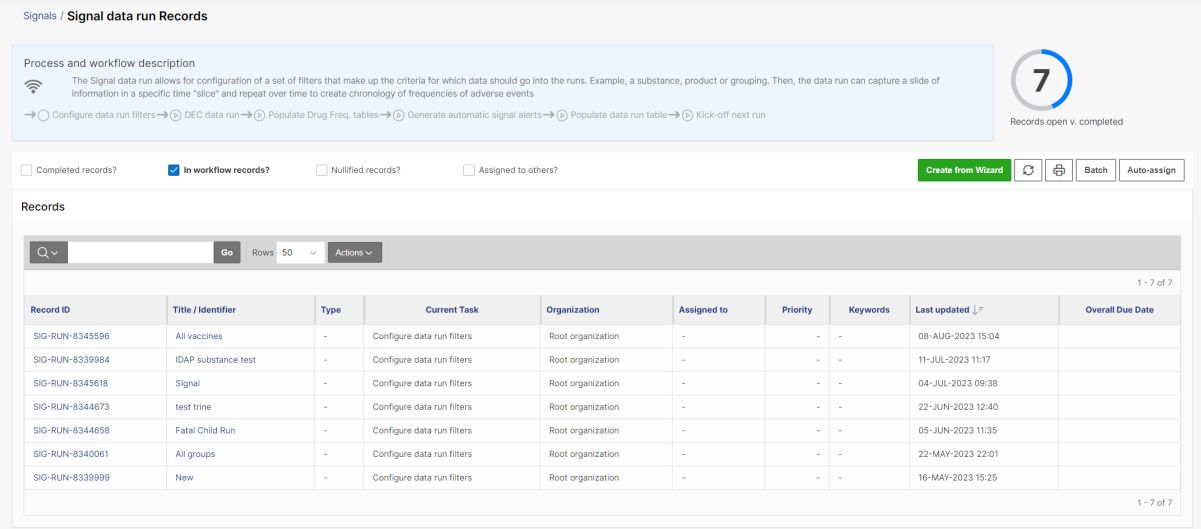
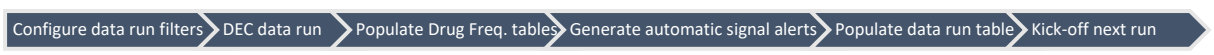


Figure 3 When clicking on a workflow, the following screen displays the Process and workflow description (if configured) as well as a worklist of records, where the Record ID and title can be clicked to access the record.

End users can update interactive reports such as this worklist, using the **Actions** button**.** Please consult the **User Guide - Interactive Reports**.

Please note that access to Records is restricted to the user role assigned to you, e.g., if ***you have read-only access to the current workflow***, the user cannot create or nullify records. Still, it might have the roles to access and execute the task(s) assigned within the Record.

5.1. Signal data run workflow



The purpose of the Signal data run workflow is to allow for configuration of a set of filters that make up the criteria for which ICSR and device data should go into the runs. Example, a substance, product or grouping. Then, the data run can capture a slide of information in a specific time "slice" and repeat over time to create chronology of frequencies of adverse events.

The workflow consists of two task steps:

- *Configure data run filters (5.1.1)*
- *DEC data run (5.1.2)*
- *Populate Drug Freq. tables (5.1.3)*
- *Generate automatic signal alerts (5.1.4)*
- *Populate data run table (5.1.5)*
- *Kick-off next run (5.1.6)*

The following sections will explain the tasks in further detail:

5.1.1. Configure data run filters (Step 1)

The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

Task instructions (as shown in the application):

A signal is information arising from one or multiple sources which suggest a new potentially causal association, or a new aspect of a known association, between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action.

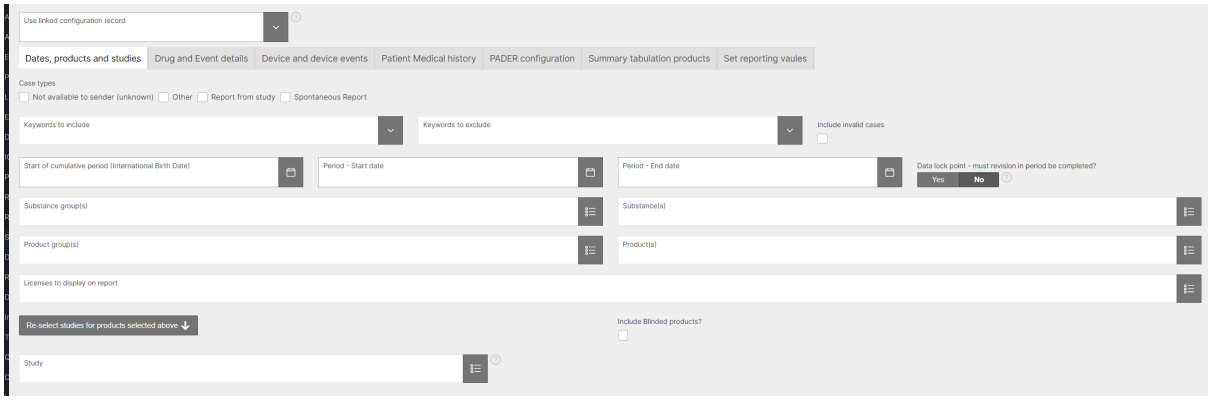
The Configure data run filters task allows you to set a number of criteria for which you are going to monitor for any potential causal association

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step. The first task step contains three actions:

5.1.1.1. Action: Data query configuration form

The first form in the configuration is a series of filters. These are ordered in tabs.

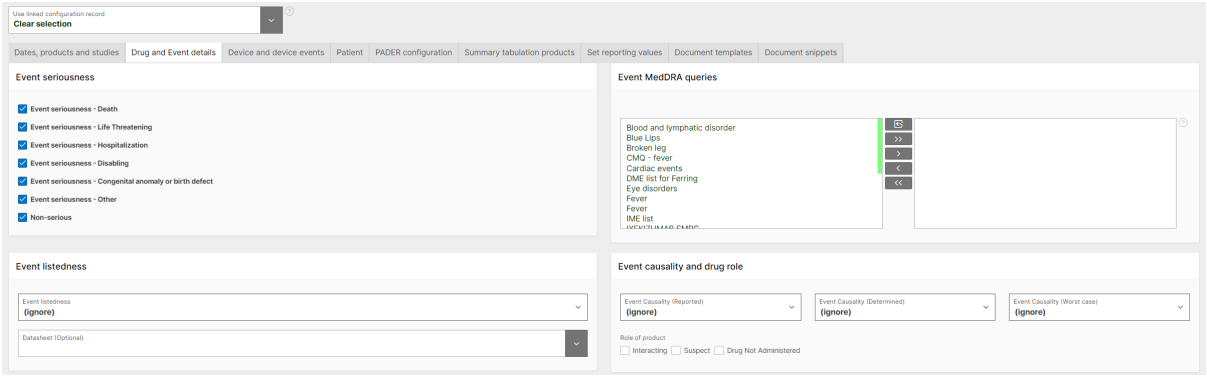
Data, products and studies tab



Here, you can set filters as per table below:

Case type	Options are based on a configurable list of values (default is E2BR3 values)
Keywords to include, Keywords to exclude	Options (multiselect) are based on configured keywords set on the ICSR / device case records. Include invalid cases is a shortcut to a commonly used keyword for tagging invalid cases.
Start of cumulative period	Defines the first data where signal run will commence from (can be used or else can be defined by Period – Start date and end date as the first data slice
Period – Start date	Defines the start date of the first data slice
Period – End date	Defines the end date of the first data slice
Data lock point	If Yes, then the latest completed revision will be included (if within the period), if no, then latest current revision will be included also if in workflow
Substance group(s)	Options (multiselect) are based on all available substance groups in the Products module
Substance(s)	Options (multiselect) are based on all available substances in the Products module
Product group(s)	Options (multiselect) are based on all available product groups/families in the Products module
Product(s)	Options (multiselect) are based on all available medicinal products in the Products module
Licenses to display on report	Not in use for Signals
Study	Options (multiselect) are based on all available Clinical Studies in the Clinical Studies module. Furthermore, clicking the Re-select studies for products selected above allows for shortlisting the studies for which the products selected are included in their configuration. Include blinded products option is not applicable for Signals

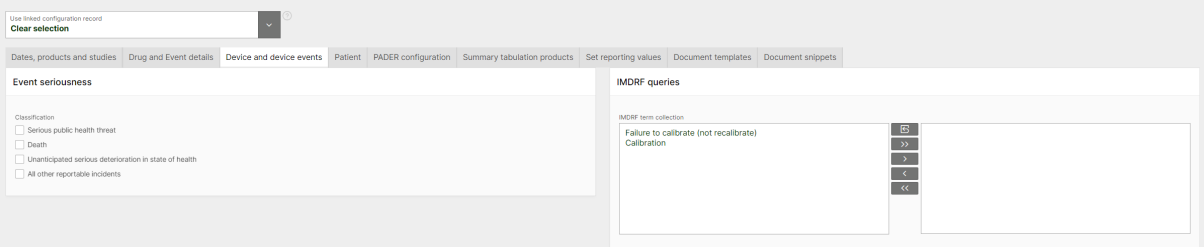
Drug and event details tab



Here, you can set drug and event filters as per table below:

Event causality (reported, determined, worst case)	Options are based on a configurable list of values.
MedDRA Term collection	Options (multiselect) are based on all available MedDRA term collections created in the Labelling (Dictionaries and Terms module)
Role of product	Options are based on a configurable list value (default is E2BR3 values)
Event listedness	Options are based on a configurable list value
Datasheet	The above listedness can be specified to a specific datasheet (default is ignore)
Event seriousness	Options include event seriousness's as well as non-serious events (based on E2BR3)

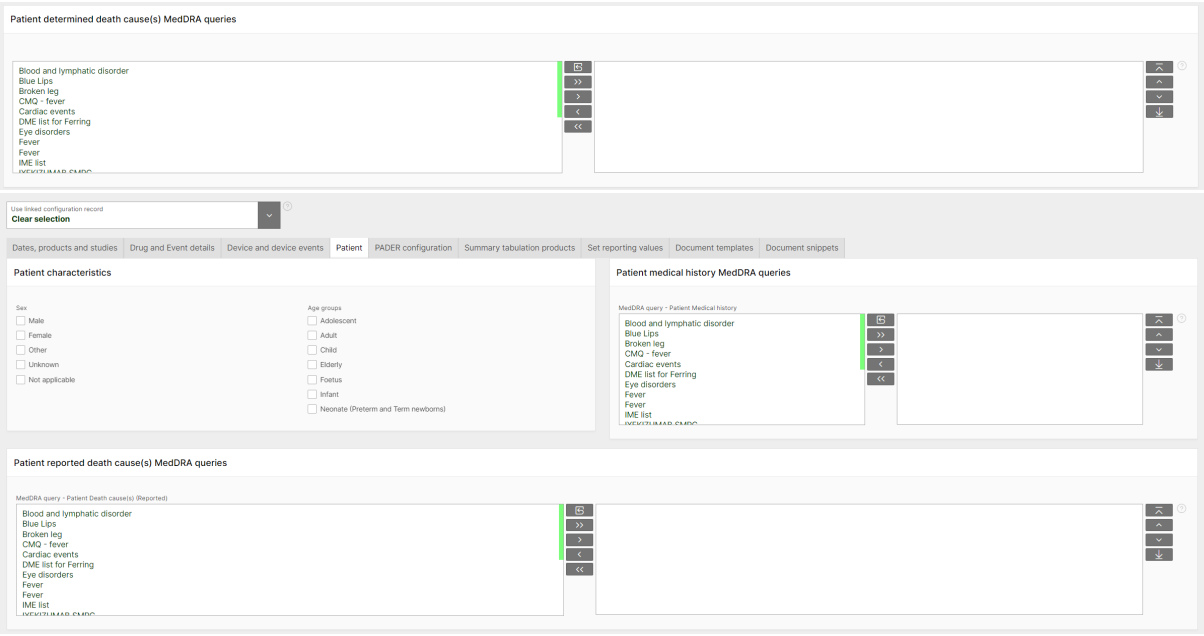
Device and device events details tab



Here, you can set device and device event filters as per table below:

Event seriousness	Options include event classifications (based on EU MIR)
IMDRF Queries	Options (multiselect) are based on all available IMDRF term collections in the Labelling (Dictionaries and Terms) module

Patient tab



Here, you can set device and device event filters as per table below:

Patient sex	Options (multiselect) are based on a configurable list of values (default is E2BR3)
Patient age groups	Options (multiselect) are based on a configurable list of values (default is E2BR3)
Patient medical history MedDRA queries	Options (multiselect) are based on all available MedDRA term collections created in the Labelling (Dictionaries and Terms module)
Patient reported death cause(s) MedDRA queries	Options (multiselect) are based on all available MedDRA term collections created in the Labelling (Dictionaries and Terms module)
Patient determined death cause(s) MedDRA queries	Options (multiselect) are based on all available MedDRA term collections created in the Labelling (Dictionaries and Terms module)

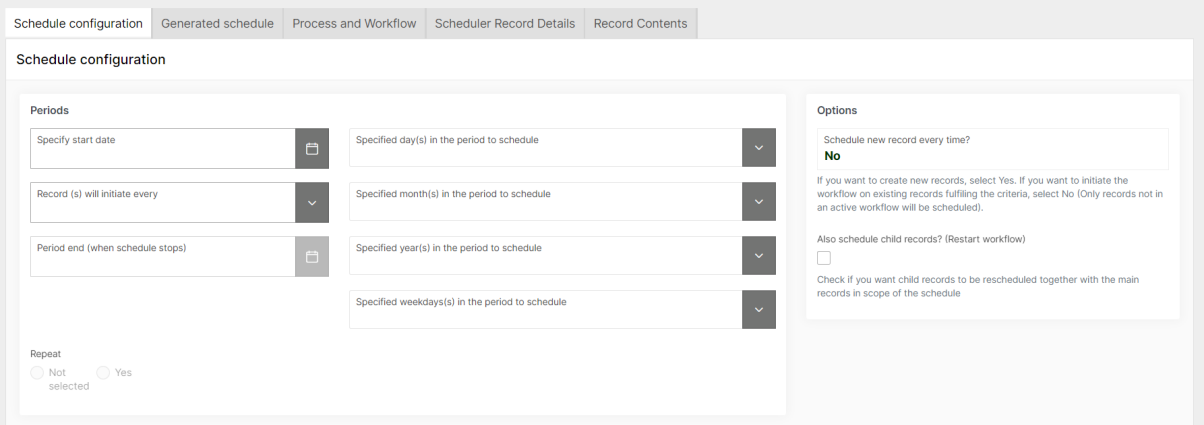
Further tabs on the configuration form are not used for Signals.

Then you can click Save and then Return to get back to the data run.

5.1.1.2. Action: Setup task scheduler form

The second form in the configuration is a series of filters for scheduling. These are ordered in tabs.

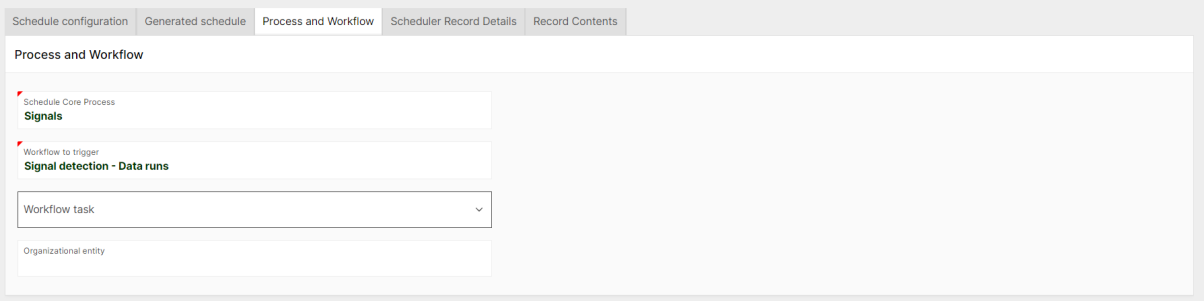
Schedule configuration tab



Here, you can set scheduling details filters as per table below:

Specify start date	The first date you want to schedule a data run (slice). This is mandatory.
Record(s) will initiate every	Options are based on list of values (configurable) (daily, weekly, monthly etc.)
Period end (when schedule stops)	The last date you want to schedule a data run (slice). This must be filled in as the schedule would else create an infinite amount of schedules
Specific day(s) in the period to schedule	This option is only available if “Record(s) will initiate every” is set to other. Options (multiselect) include all weekdays
Specific month(s) in the period to schedule	This option is only available if “Record(s) will initiate every” is set to other. Options (multiselect) include all months
Specific year(s) in the period to schedule	This option is only available if “Record(s) will initiate every” is set to other. Options (multiselect) include all years
Specific weekdays(s) in the period to schedule	This option is only available if “Record(s) will initiate every” is set to other. Options (multiselect) include all days in the month
Schedule new record every time?	Currently always set to No
Also schedule child records? (Restart workflow)	Keep unticked for Signals. Allow for also reopening subordinate records associated to the data run, which will not be desirable

Process and workflow tab

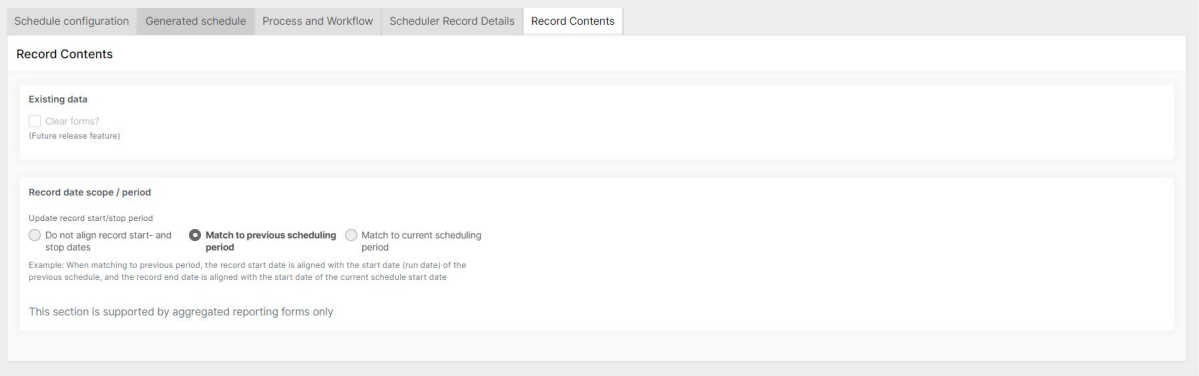


Here, you can set which workflow and task to initiate as per table below:

Schedule Core Process	This is currently always set to Signals
Workflow to trigger	This is currently always set to the workflow of the data run
Workflow task	Options include the workflow tasks that have been configured for the data run workflow. To achieve automatic operations, the correct selection is normally “Case series data run”

Organizational entity	Options include all entities that you as a user have access to. It will per default be the entity of the user setting it up

Record contents tab



Here, you can set the logic for the scheduling dates, as per table below:

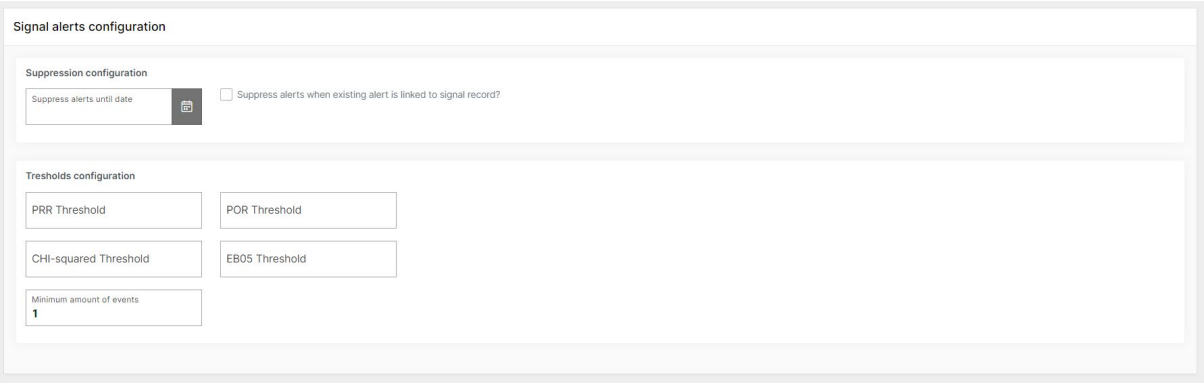
Existing data	Is currently not enabled
Record date scope / period	Please select “Match to previous scheduling period” in order to schedule record in sequential periods as is required for Signals data slices.

Other tabs are not used for Signals.

Once the data has been populated, first click the “Create” button then click “Activate/update schedule” to set the list of dates for automatic scheduling. Then you can click Return to get back to the data run.

5.1.1.3. Action: Signals alert configuration form

The third form in the configuration is a set of filters for setting up when Signal alerts should be raised automatically.



Here, you can set the configurations, as per table below:

Suppression configuration	Options include setting a date until when no automatic alerts will be created. A tickmark can further specify that new Signal alerts will be suppressed if an alert on the drug-event combination has already exists
Threshold configuration	Options include setting decimal number for either one or multiple statistical methods, including PRR, ROR, CHI-squared and EB05. Furthermore, minimum amount of events can be set in combination with

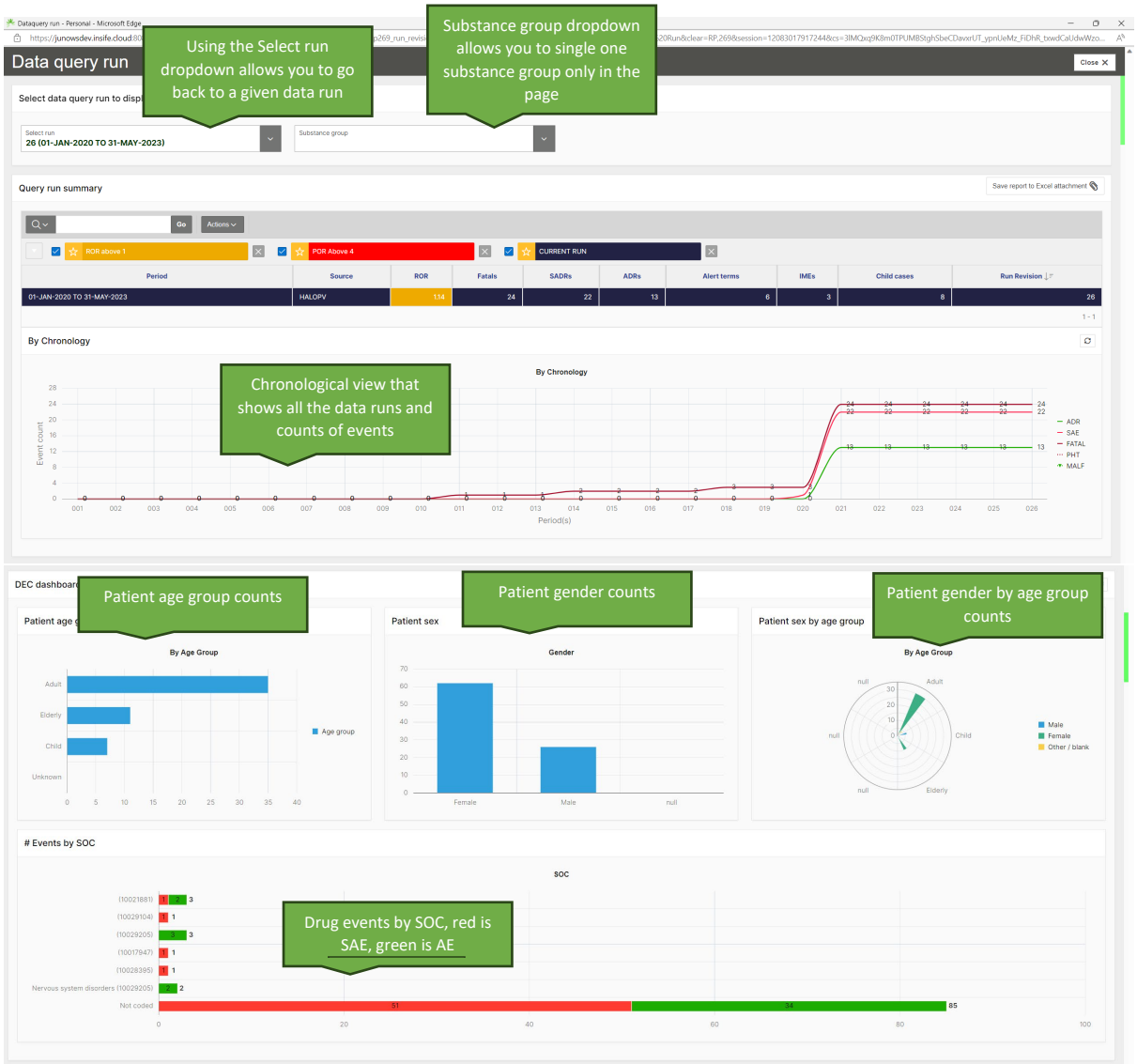
	the threshold, to only allow alerts to be generated if both threshold and number of drug-event-combinations are fulfilled

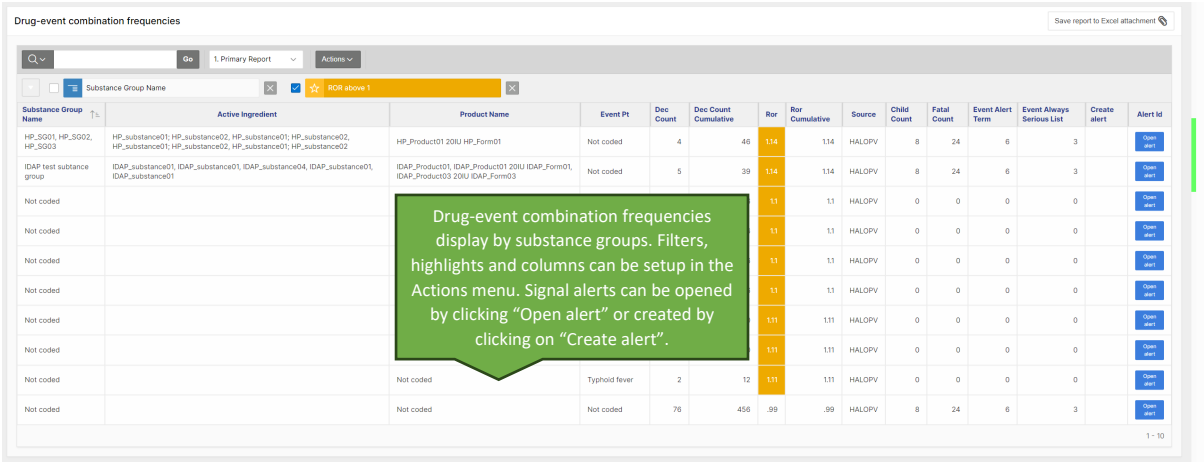
Save the form. Then you can click Return to get back to the data run.

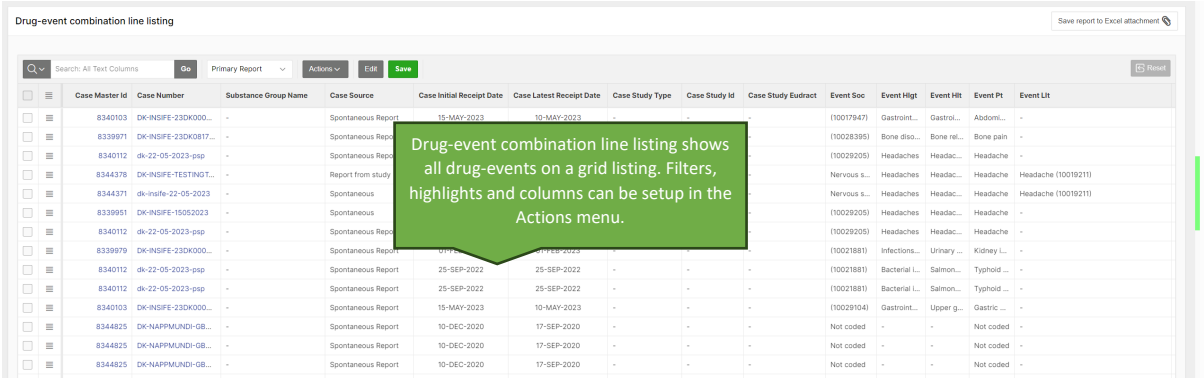
5.1.1.4. Action: View data query run

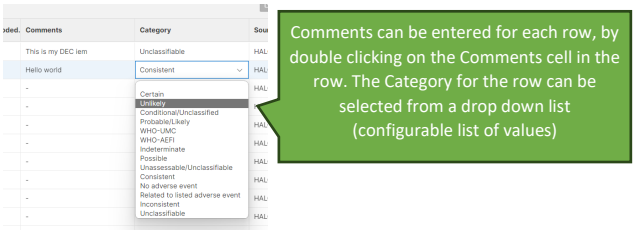
The View data query run is a pop-up window that in dashboards and reports show all the signal data run data that has been generated by the automators that are described in the sections: 5.1.2, 5.1.3, 5.1.4, 5.1.5 and 5.1.6.

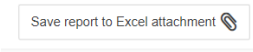
The view allows comparing frequencies with the cumulative data. The following screenshot shows the detailed contents:









When a user wants to save the grid / listing to the data run record, you can click on the Save report to Excel attachment button. 

. In case you would like to download the listing, please go to the Actions menu and select Download.

5.1.2. DEC data run (Step 2)

This task is an automated calculation of the dataset based on the configured filters, please refer to 5.1.1.1.

The task will automatically complete when done and the record will proceed to the next task once data extraction is done.

5.1.3. Populate Drug Freq. tables (Step 3)

This task is an automated calculation of the dataset based on the extracted data in the previous step, the drug frequencies tables are holding the statistical information related to the data slice as well as cumulative data throughout all slices.

The task will automatically complete when done and the record will proceed to the next task once data statistical calculations are done.

5.1.4. Generate automatic signal alerts (Step 4)

This task is an automated assessment calculation based on the frequency table in the previous step, the alerts are using the configuration explained in 5.1.1.3 to determine if any new alert should be created for the data slice If an alert is created, it will appear as a record in the Signal alerts workflow, see 5.2 .

The task will automatically complete when done and the record will proceed to the next task once alert calculations are done.

5.1.5. Populate data run tables (Step 5)

This task is an automated calculation of the dataset based on the extracted data in the previous steps, the data run table is a high-level summary of the data run, including some counts of how many events were identified and the worst-case statistical scores.

The task will automatically complete when done and the record will proceed to the next task once calculations are done.

5.1.6. Kick-off next run (Step 6)

This task is an automated.

The task will automatically step that will assess and either re-initiate or schedule the record in the workflow in a new revision when relevant, based on the configuration in 5.1.1.2. As it is automatically progressing, it will complete the workflow without any human interaction.

Note: The Signal data run will create a new revision for each data run (slice) of information it generates. You can review all the data slices in the

5.2. Signal alerts workflow

The purpose of the workflow is to review and analyze the Signal alert that was opened.

The workflow consists of a single step:

- *Review and Analyze alert (5.2.1)*

The following sections will explain the task in further detail:

5.2.1. Review and Analyze alert (Step 1)

The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

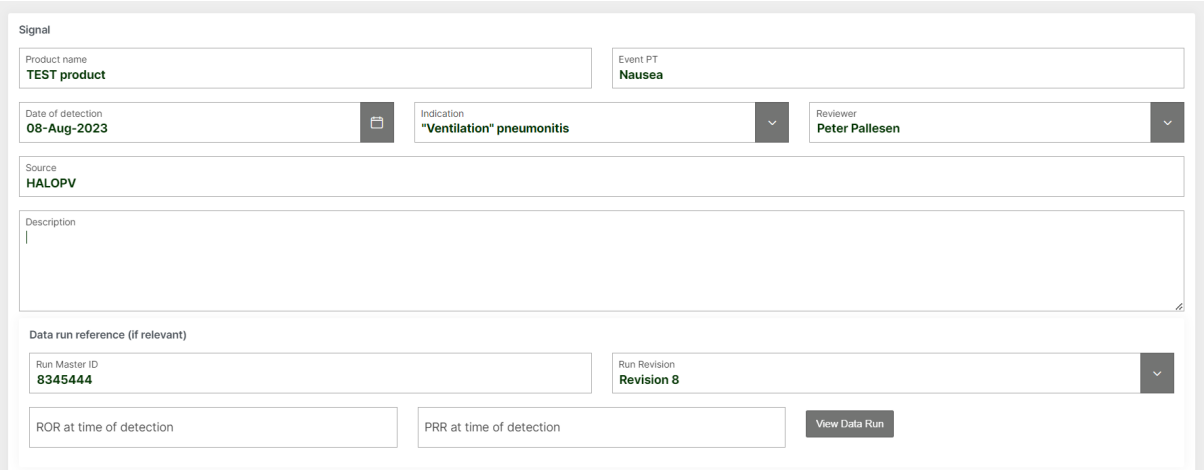
Task instructions (as shown in the application):

The Signal alert should be analyzed and considered for further activities. Use the notes to add context to your analysis

As with any other task in the application, you must have the corresponding role assigned in order to be able to process the record in the task step. The first task step contains two actions:

5.2.1.1. Action: Signal alert and registration details form

The form is a series of data points that can be captured. Provided the Signal alert was created from the Signal alert automation (5.1.1.3) or manually created from the view data query run screen (5.1.1.4), data will automatically have been added where possible.



Here, you can enter the data, as per table below:

Product name	Product, substance or substance group name
Event PT	The Preferred Term from MedDRA in question
Date of detection	Option to add date
Indication	Option to select a Preferred Term
Reviewer	Option to select a user in HALOPV
Source	If data source is HALOPV, system will default to HALOPV. Other text can be entered
Description	Data can be entered
Data run reference	Run Master ID, Run revision, ROR at time of detection, PRR of time of detection can only be set automatically. The view data run button allows for the user to jump to the View data query page of relevance, see 5.1.1.4

Then you can click Save, then Return to get back to the Signal alert record.

N.B. The data provided in this form will be retained if a user chooses to promote a Signal alert to a Signal, in the Signal registration and processing workflow, see 5.3.

5.2.1.2. Action: Task relocation (Move to Signal Registration and Processing)

This action allows for promoting a Signal alert into an actual Signal. This should only be done if the assessor of the Signal alert is considering it relevant to initiate a Signal process.

5.3. Signal registration and processing

The purpose of the workflow is to process Signals according to the EU GVP Module IX guidelines.

The workflow consists of five task steps:

- *Signal registration (5.3.1)*
- *Signal validation and prioritization (5.3.2)*
- *Signal assessment (5.3.3)*
- *Signal/risk action confirmation (5.3.4)*
- *Action/information exchange (5.3.5)*

The following sections will explain the tasks in further detail:

5.3.1. Signal registration (Step 1)

The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

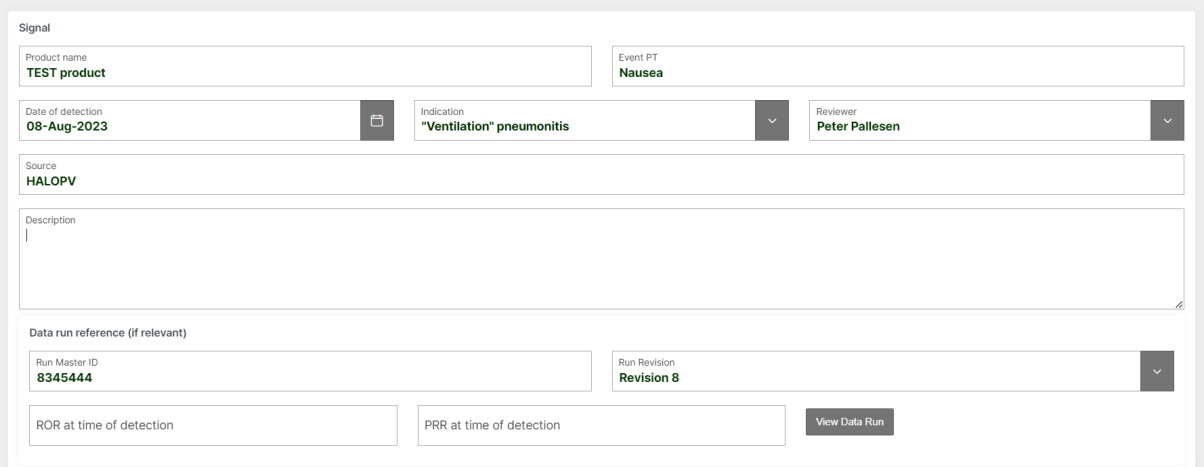
Task instructions (as shown in the application):

Registration of a Signal with documentation of Terms and product details in the Signal alert and registration Form.

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step. The first task step contains one action:

5.3.1.1. Action: Signal alert and registration details form

The form is a series of data points that can be captured and it is the same form as used for the Signal alert registration, see 5.2.1.1. Provided the Signal was promoted from a Signal alert, data will automatically have been added where possible.



Here, you can enter the data, as per table below:

Product name	Product, substance or substance group name
Event PT	The Preferred Term from MedDRA in question
Date of detection	Option to add date
Indication	Option to select a Preferred Term
Reviewer	Option to select a user in HALOPV
Source	If data source is HALOPV, system will default to HALOPV. Other text can be entered
Description	Data can be entered
Data run reference	Run Master ID, Run revision, ROR at time of detection, PRR of time of detection can only be set automatically. The view data run button allows for the user to jump to the View data query page of relevance, see 5.1.1.4

Then you can click Save, then Return to get back to the Signal record. Once the signal has been registered, and if relevant, supporting attachments have been added, then click Complete task.

N.B. For more information about the Signal alert process, see 5.2.

5.3.2. Signal validation and prioritization (Step 2)

The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

Task instructions (as shown in the application):

Validation includes analysis of the data supporting the detected signal in order to verify that the available documentation contains sufficient evidence demonstrating the existence of a new potentially causal association, or a new aspect of a known association, and therefore justifies further analysis of the signal.

Prioritization of Validated Signals can be done at the same time as Validation. Prioritization should take place as soon as possible, no later than 2 calendar days after Validation (24hrs if Signal is a potential ESI.)

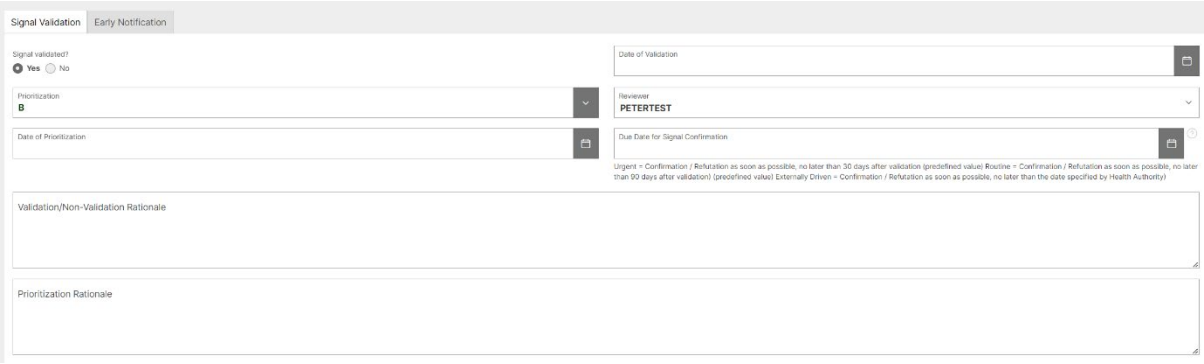
Validation and prioritization is documented in the "Signal Validation and Prioritization Form" with rationale.

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step. The task step contains three additional action to be performed:

5.3.2.1. Action: Signal prioritization form

The form is a series of data points that can be captured for signal validation and prioritization. The form is dynamic, I.e. will expand with options and fields depending on your choices. The form also consists of two tabs, each one explained in the below:

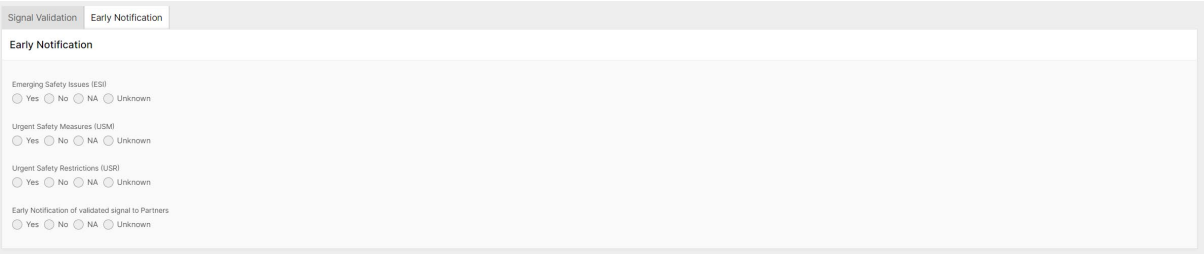
Signal Validation tab



Here, you can enter the data, as per table below:

Signal validated?	Option Yes/No
Date of validation	Option to add date
Prioritization	Option to select value from list of values (configurable)
Date of prioritization	Option to add date
Reviewer	Option to select a user in HALOPV
Due date for Signal Confirmation	Option to add a user defined date for when the signal must be confirmed. If added, it will overwrite the due date of the record in the workflow. If left blank, as standard due date based on workflow task configuration will be used
Validation/non-validation rationale	Option to add text about the reasoning of the validation decision
Prioritization rationale	Option to add text about the reasoning of the prioritization decision

Early Notification tab



Here, you can enter the data, as per table below:

Emerging Safety Issues (ESI)	Option to select Yes, No, NA, Unknown
Urgent Safety Measures (USM)	Option to select Yes, No, NA, Unknown
Urgent Safety Restrictions (USR)	Option to select Yes, No, NA, Unknown

Early Notification of validated signal to Partners	Option to select Yes, No, NA, Unknown

Then you can click Save, then Return to get back to the Signal record. Once the signal has been assessed for validation and prioritization, and if relevant, supporting attachments have been added, then click Complete task. If the signal has not been found to be validated, then you can use the following action to refute the Signal record.

5.3.2.2. Action: Task relocation (Refuted signal)

This action is intended to remove the Signal from its workflow and place it under Refuted signals. The signal record and its' contents will not be deleted, but placed in a non-active workflow, where it can reside for documentation purposes. Please see 5.4 for more information.

When relocating the record to a new workflow/task a reasoning must be provided (mandatory). Click Confirm to execute the relocation or Return to cancel.

5.3.2.3. Action: End workflow

This action is intended to complete the workflow, without following the pre-designated tasks of the Signal workflow. This could be for instances where expedited investigations have been happening outside the normal process, or if very urgent activities warrant a completion of the signal process at once.

When ending the workflow/task, no data is deleted, but the record will proceed to a completed state. Click Complete workflow to complete or Cancel to cancel.

Once the signal has been validated / prioritized, and if relevant, supporting attachments have been added, then click Complete task.

5.3.3. Signal assessment (Step 3)

The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

Task instructions (as shown in the application):

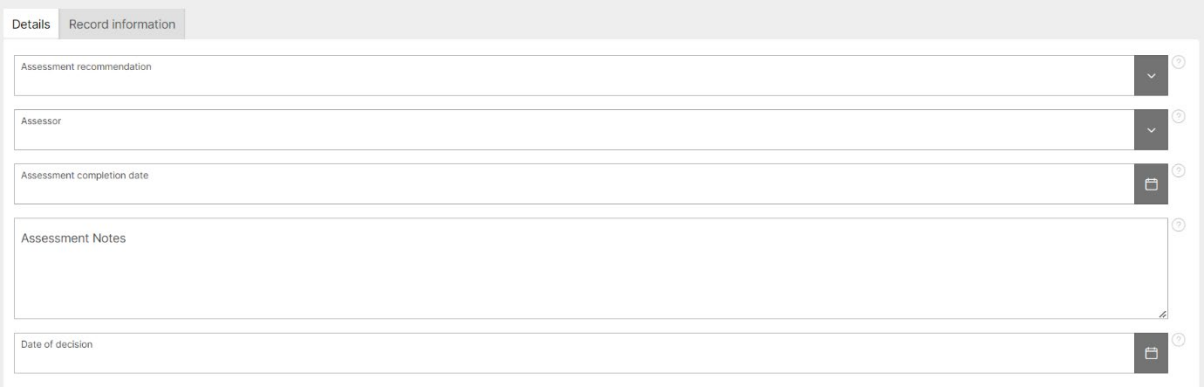
Further evaluation of a validated signal taking into account all available evidence to determine whether there are new risks causally associated with the active substance or medicinal product or whether known risks have changed. This review may include non-clinical and clinical data and should be as comprehensive as possible regarding the sources of information.

Document Signal Assessment in Signal Assessment Form.

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step. The task step contains one additional action in addition to previous steps:

5.3.3.1. Action: Signal assessment form

The form is a series of data points that can be captured specific to the signal assessment.



Here, you can enter the data, as per table below:

Assessment recommendation	Option to select from a list of values (configurable)
Assessor	Option to select a user in HALOPV
Assessment completion date	Option to add date
Assessment notes	Option to enter text
Date of decision	Option to add date (this is the date that will be officially stamped for the activity)

Then you can click Save, then Return to get back to the Signal record. Once the signal has been assessed, and if relevant, supporting attachments have been added, then click Complete task.

5.3.4. Signal/risk action confirmation (Step 4)

The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

Task instructions (as shown in the application):

Safety Governance decides that new or changed risks is a "Confirmed Signal" or "Not-Confirmed (Refuted) Signal".

Update Signal Assessment Report (SAR), as needed and Approve SAR.

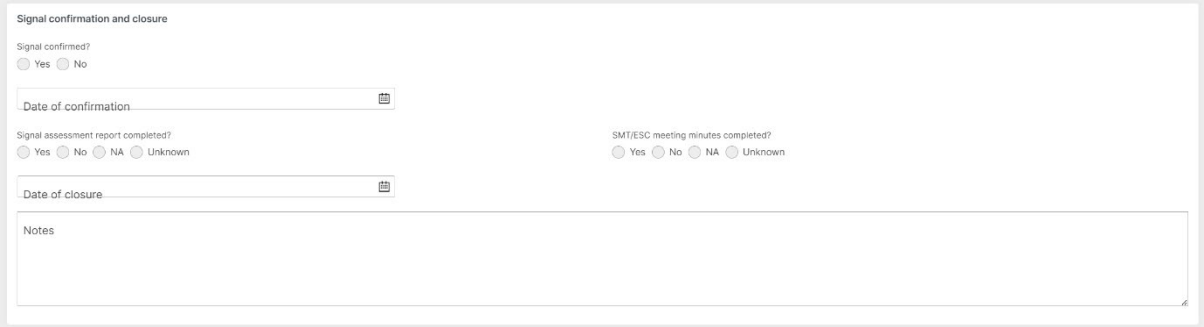
Create, Review and Approve SMT and ESC Minutes.

Signal Closed = Date of Approval of Governance Meeting Minutes in which the Confirmed / Not-Confirmed decision was made. Status changes from "Ongoing" to "Closed".

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step. The task step contains one additional action in addition to previous steps:

5.3.4.1. Action: Signal confirmation form

The form is a series of data points that can be captured for signal confirmation. The form is further explained in the below:



Here, you can enter the data, as per table below:

Signal confirmed?	Option Yes/No
Date of confirmation	Option to add date
Signal assessment report completed?	Option Yes/No/NA
SMT/ESC meeting minutes completed?	Option Yes/No/NA
Signal closed date	Option to add date. This is the date of Approval of Governance Meeting Minutes in which the Confirmed / Not-Confirmed decision was made.
Notes	Option to add text

Save and return to the Signal record.

Once done, and if relevant, supporting attachments have been added, then click Complete task.

5.3.5. Action/information exchange (Step 5)

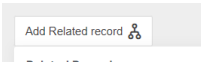
The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

Task instructions (as shown in the application):

Following Signal Confirmation create Safety Actions & Information Exchange for risks approved as "Confirmed Signals" together with Target Completion Dates for action tracking in the Risks and Labeling Module.

Some actions may not be applicable depending on markets and partnerships.

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step. There are no new preset actions defined for this step.

Once all activities are completed and documented, e.g. by attaching evidences or establishing further links to activities are created by adding new related records using this button 

or linking already established records to this Signal record, please click Complete task. The Signal is now completed.

5.4. Refuted signals

The purpose of the workflow is to maintain a log of any signal that did not get validated/prioritized or assessed with the conclusion that it should remain a Signal

The workflow consists of on task step:

- *Log refuted signal (5.4.1)*

The following sections will explain the task in further detail:

5.4.1. Log refuted signal (Step 1)

The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

Task instructions (as shown in the application):

Refuted signals do not require any additional actions

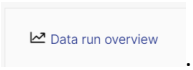
As with any other task in the application, you must have the corresponding role assigned in order to be able to process the record in the task step.

For the task, the only activity to perform is to click Complete task, provided you would like to complete the refuted signal record

6. Functionalities

The following functionalities are available for the Signals module:

6.1. Data run overview

On the Signals module front page, the Data run overview functionality action is available 

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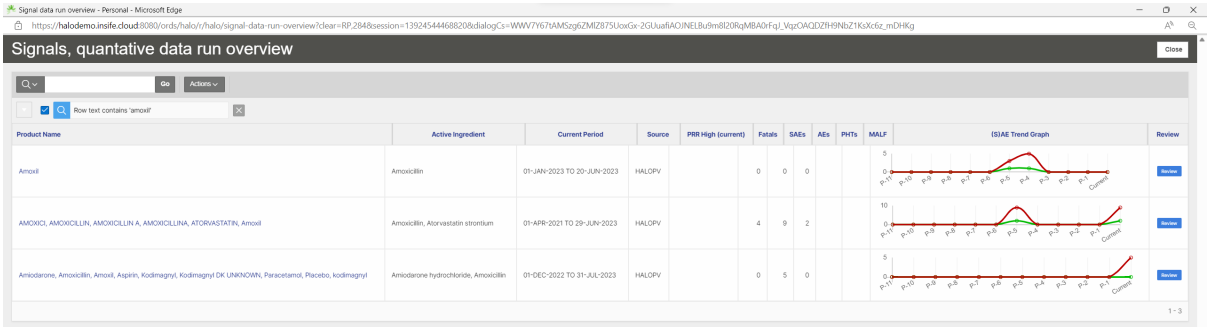
Clicking this opens a new window, where all conducted signal data runs are visualized with a number of columns and associated counts, as well as the worst-case statistical scores. The data on this screen is based on the dataset created by the automator described in 5.1.5. There is an associated graph that shows the current and up to 12 previous data runs (slices), and split by a red graph (SAE) and green graph (AE).



The exact columns shown on the screen can be modified by clicking the Actions button and adjusting the Columns.

Clicking Review will open the data run record that corresponds to the row on the screen.