HALOPV

Submissions

HALOPV 3.X USER GUIDE

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

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1. HALOPV

User Manual - Release 3.0 (JUNE 2021)

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2. Preface

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

https://www.halopv.com/

Insife Support

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

3. Introduction

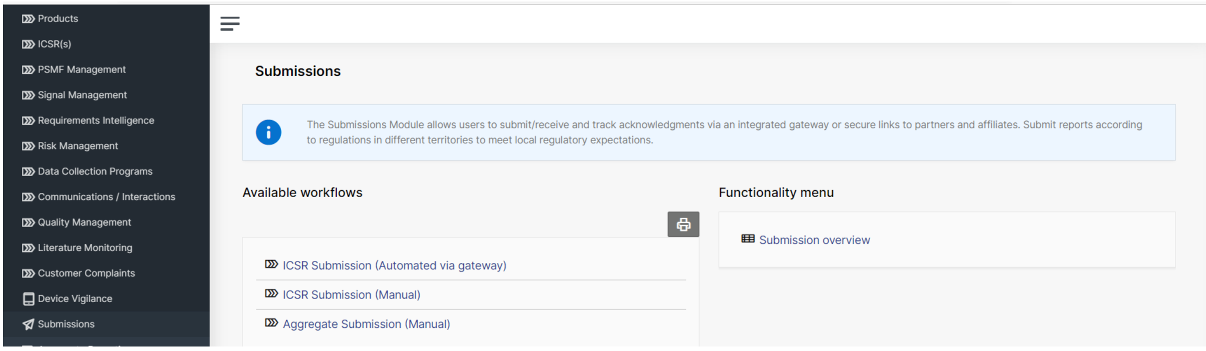
3.1. Purpose

This User Manual describes the process workflows for submissions in HALOPV.
Submissions is a module in the HALOPV application and is a toolbox for managing submissions of ICSRs and aggregate reports. The Submissions module allows users to submit/receive and track acknowledgments via an integrated gateway or secure links to partners and affiliates. Submit reports according to regulations in different territories to meet local regulatory expectations.

4. Access to the Submissions module

The **Submissions** module includes all available process workflows concerning creation and management of submissions records, including automated and manual workflows; The submissions records are typically setup as “child” records of the ICSR or aggregate report, as one ICSR or aggregate report may lead to multiple submissions. (See also separate manual on **ICSRs** and **Aggregate Reports**)

On the left menu, you will find a list of Processes available for your user profile. Please select **Submissions.** <u>If you do not see the menu item, please consult your User Administrator, as the access granting role is then not set up for you.</u>



There are two overall functionality sets for every module**, Workflows**, see section 5 and the **Functionality menu,** see section 6.

5. Submissions Workflows

Once clicking **Submissions**, you will find the **Available workflows** of the Submissions module (may vary based on configuration). This section will run through each of the workflows and associated forms and actions of the standard configuration.

N.B. As a general note, workflows in HALOPV are highly configurable, hence your HALOPV implementation may have other workflows and actions than portrayed in this manual.

5.1. ICSR Submissions (automated via gateway)

Purpose of the workflow: Automatic submission of a record. Generate and track ICSRs submitted by gateway route - including automatic acknowledgment receipts.

Let's select **ICSR Submission (automated via gateway).** By clicking, you will have an overview of all the ongoing records that are being processed through the workflow.
Click a **Record ID** to proceed. When clicking on a **Record ID**, a new window will open, showing the process workflow and the steps to follow.

5.1.1. Create a New Record for ICSR Submissions (automated via gateway)

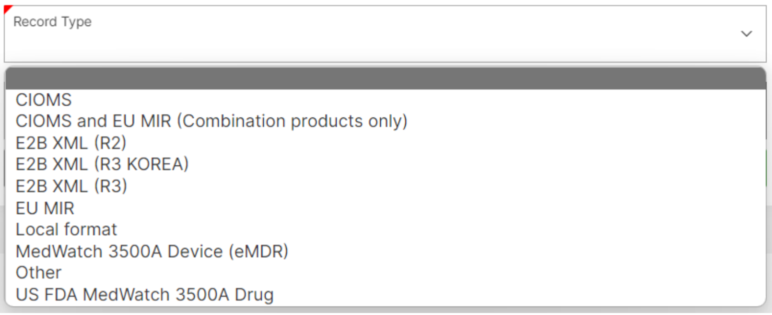
An ICSR Submissions record can be created from multiple routes.

- It can be created from the parent ICSR (using a "Create Submission record" action when in the Submission workflow state). The Submission record will automatically be a "child" to the "parent" ICSR record.
- HALOPV's Requirements Intelligence module also provides capabilities to automatically schedule (produce one or more records by automatic means) when the ICSR is in the Submission workflow step. The Submission record(s) will automatically be a "child" to the "parent" ICSR record.
- It can also be created from another system like Argus Safety or ARISg if you have these tools integrated with HALOPV.
  Or it can be directly created here: To create a new record, click **Create from wizard** (can also be called **Create new** depending on configuration).

N.B. you should consider if the submission reporting destination allows for automatic via gateway submissions (typically E2B / XML) or if the submission reporting destination only allows for manual submissions, like emails / CIOMS PDF report etc. If the latter is the case, please see. 5.2 (ICSR Submission (manual))

5.1.1.1. Set the record's basic data

The **Record Title** is the identifier of the submission record you are about to create. It will not be visible in the actual report, so it is for your internal reference.
The **Record Type** must also be set, default options include a long list of format options (actual list may vary from the screenshot)



You can in this screen also set the due date (**Master Duedate**). If you do not set a date, the system will set a default value based on the configuration.

*N.B. for submissions that have been auto-scheduled by HALOPV (or via Argus Safety / ARISg integration), the scheduler will calculate the proper due date. This calculation is based on latest case receipt date from the ICSR and the timelines entered in the **Requirement Intelligence** module, in a rule (record) that the system matched in the criteria with the ICSR with and hence decided to schedule the submission record on.*

*N.B. For a submission record, you will also want to set the **Reporting destination**. This is done after the record is created. Here, you can click the **More (…)** menu, select basic information and here you can set the Reporting to via a dropdown. The **Reporting destinations** listed are all the Entities where the **Reporting Destination?** Tick box has been set to "Yes". This is not necessary for submission records that have been auto-scheduled, or created from an integration to Argus Safety or ARISg (in those cases, the destination will already have been set).*

5.1.2. Working with the ICSR submissions (automated via gateway) records in the view/edit record screen

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

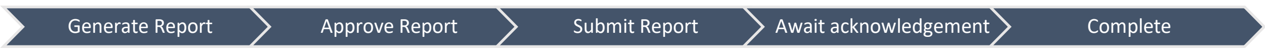
The **Record and task information** section of the view/edit record screen will indicate what is expected of the user, e.g. activities to be performed in the workflow task. The **Top workflow navigation bar** will indicate where in the workflow (which task step) your record is currently. If there is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

You can access the More (…) menu, marked with three dots in the top right section of the view / edit screen. By selecting **Print**, you can at any time generate a draft **CIOMS** of the ICSR or select from other print templates. For other options in the More (…) menu, please see the *General features of HALOPV* manual.

N.B. The automated workflow may not have any access for end-users to change anything, depending on configuration.

5.1.3. The ICSR Submission (automated via gateway) workflow

The default workflow for the ICSR Submission (automated via gateway) workflow is:



This also means that records will start in the **Generate** task step and the last step is **Complete.**
It should be noted that the configuration of the workflow may vary, as the tasks are configurable using the **Application management** part of HALOPV (requires Application admin roles).

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

5.1.4. Task activities for ICSR Submissions (automated via gateway) records

N.b. The workflow is typically automated, not leaving a lot of actions to the users. The ones that may be needed to know about are listed below:

Name of Activity	Type	Description
Re-run the current task step	Link	Re-runs the current task again, including automators that may be on the step. For the ICSR submissions (automated via

		gateway), when in the Generate report task step, this includes the automatic generation of the output file for submission (e.g. E2B XML). The re-run task is particularly useful if the generation has previously failed, e.g. due to missing information in the parent ICSR record. Or if created without a link to an ICSR. N.B. if a submission record is marked with an alert triangle in the Obs column, corrections are needed in order to progress the record. After making the corrections to the ICSR, go back to the Submission record and use the **Re-run the current task step** button.
Associate parent ICSR	Form	Allows the user to select the exact ICSR record that should be the **parent** of the Submission. This is important since the submission record will generate against the data / forms in the parent.
Manage Attachments	Link	Takes the user to the **Attachments screen.** This allows for reviewing the automatically created file for submission, or to upload you own submission file. If you upload your own file, you can afterwards complete the task in order to progress the workflow to next task.
Submissions details form	Form	Allows for viewing the status of the submission record, including data elements ordered in tabs: **Submissions details** (Submission task deadline, Actual Submission date, Authority confirmation date) **Scheduling details** (Submission version, case number, country of occurrence, event (LLT), seriousness, listedness, relatedness, nullification/amendment etc.) **Privacy and blinding** (Generate blinded, generate without Personal identifiable information) **Transmission details** (ID, acknowledgement date, submission status code, submission status message) For the automatic via gateway workflow, the transmissions details are automatically populated. N.B. The **scheduling details** tab must be filled out manually in case the submission is setup manually and also should be part of aggregate reports like the US PADER, as the PADER needs this tab to determine the submissions place in the PADER. N.B. The Submissions details tab can also be used for marking why a submission is not needed. In case you click the No submission tickbox, mandatory reason fields will appear. If the **No submission** tickbox is set, you can complete the task and the following steps will be omitted, i.e. no submission will occur, but the record will still be available.

5.1.5. Completing a Task and Sending it Forward

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

5.1.6. Re-initiating a Completed record

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

5.2. ICSR Submission (manual)

Purpose of the workflow: Manual tracking of a submission record. Generate and track ICSRs submitted by manual means and ensure users are entering submission dates etc.

Let’s select **ICSR Submission (manual).** By clicking, you will have an overview of all the ongoing records that are being processed through the workflow.
Click a **Record ID** to proceed. When clicking on a **Record ID**, a new window will open, showing the process workflow and the steps to follow.

5.2.1. Create a New Record for ICSR Submission (manual)

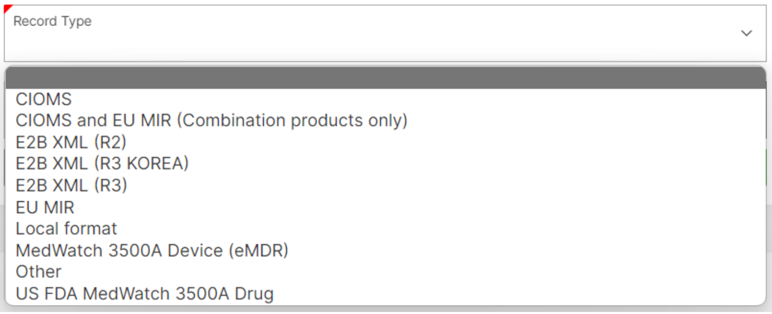
An ICSR Submissions record can be created from multiple routes.

- It can be created from the parent ICSR (using a “Create Submission record” action when in the Submission workflow state). The Submission record will automatically be a “child” to the “parent” ICSR record.
- HALOPV’s Requirements Intelligence module also provides capabilities to automatically schedule (produce one or more records by automatic means) when the ICSR is in the Submission workflow step. The Submission record(s) will automatically be a “child” to the “parent” ICSR record.
- It can also be created from another system like Argus Safety or ARISg if you have these tools integrated with HALOPV.
  Or it can be directly created here: To create a new record, click **Create from wizard** (can also be called **Create new** depending on configuration).

*N.B. It should be considered if your business process allows for creating an submissions record directly in the ICSR Submission (manual) workflow, or if it should be mandatory to take it through the ICSR Processing workflow first. It can be configured to only allow creation in the ICSR Processing workflow in the **Application management** part of HALOPV.*

5.2.1.1. Set the record’s basic data

The **Record Title** is the identifier of the submission record you are about to create. It will not be visible in the actual report, so it is for your internal reference.
The **Record Type** must also be set, default options include a long list of format options (actual list may vary from the screenshot)



You can in this screen also set the due date (**Master Duedate**). If you do not set a date, the system will set a default value based on the configuration.

*N.B. for submissions that have been auto-scheduled by HALOPV (or via Argus Safety / ARISg integration), the scheduler will calculate the proper due date. This calculation is based on latest case receipt date from the ICSR and the timelines entered in the **Requirement Intelligence** module, in a rule (record) that the system matched in the criteria with the ICSR with and hence decided to schedule the submission record on.*

*N.B. For a submission record, you will also want to set the **Reporting destination**. This is done after the record is created. Here, you can click the **More (…)** menu, select basic information and here you can set the Reporting to via a dropdown. The **Reporting destinations** listed are all the Entities where the **Reporting Destination?** Tick box has been set to "Yes". This is not necessary for submission records that have been auto-scheduled, or created from an integration to Argus Safety or ARISg (in those cases, the destination will already have been set).*

5.2.2. Working with the ICSR submissions (manual) records in the view/edit record screen

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

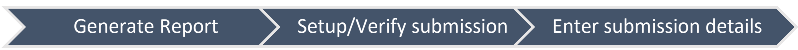
The **Record and task information** section of the view/edit record screen will indicate what is expected of the user, e.g. activities to be performed in the workflow task. The **Top workflow navigation bar** will indicate where in the workflow (which task step) your record is currently. If there is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

You can access the More (…) menu, marked with three dots in the top right section of the view / edit screen. By selecting **Print**, you can at any time generate a draft **CIOMS** of the ICSR or select from other print templates. For other options in the More (…) menu, please see the *General features of HALOPV* manual.

N.B. The automated workflow may not have any access for end-users to change anything, depending on configuration.

5.2.3. The ICSR Submission (manual) workflow

The default workflow for the ICSR Submission (manual) workflow is:



This also means that records will start in the **Generate** task step and the last step is **Enter submission details.** It should be noted that the configuration of the workflow may vary, as the tasks are configurable using the **Application management** part of HALOPV (requires Application admin roles).

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

5.2.4. Task activities for ICSR Submissions (manual) records

N.b. The first step in the workflow, **Generate report**, is typically automated, not leaving a lot of actions to the users. In case of generation failure, you can either use the Re-run the current task step action (see below table) The ones that may be needed to know about are listed below:

Name of Activity	Type	Description
Re-run the current task step	Link	Re-runs the current task again, including automators that may be on the step. For the ICSR submissions (automated via gateway), when in the Generate report task step, this includes the automatic generation of the output file for submission (e.g. E2B XML). The re-run task is particularly useful if the generation has previously failed, e.g. due to missing information in the parent ICSR record. Or if created without a link to an ICSR. N.B. if a submission record is marked with an alert triangle in the Obs column, corrections are needed in order to progress the record. After making the corrections to the ICSR, go back to the Submission record and use the **Re-run the current task step** button.
Associate parent ICSR	Form	Allows the user to select the exact ICSR record that should be the **parent** of the Submission. This is important since the submission record will generate against the data / forms in the parent.
Generate report	Link	Allows the user to select a template, e.g. CIOMS or E2B and also specify the output format (MS Word or PDF), as well as determine if the file should be placed in HALOPV or in a Working folder (associated folder in Sharepoint / Onedrive).
Manage Attachments	Link	Takes the user to the **Attachments screen.** This allows for reviewing the automatically created file for submission, or to upload you own submission file. If you upload your own file, you can afterwards complete the task in order to progress the workflow to next task.
Submissions details form	Form	Allows for adding/viewing the status of the submission record, including data elements ordered in tabs: **Submissions details** (Submission task deadline, Actual Submission date, Authority confirmation date) **Scheduling details** (Submission version, case number, country of occurrence, event (LLT), seriousness, listedness, relatedness, nullification/amendment etc.) **Privacy and blinding** (Generate blinded, generate without Personal identifiable information) **Transmission details** (ID, acknowledgement date, submission status code, submission status message) For the automatic via gateway workflow, the transmissions details are automatically populated.

N.B. The **scheduling details** tab must be filled out manually in case the submission is setup manually and also should be part of aggregate reports like the US PADER, as the PADER needs this tab to determine the submissions place in the PADER.

N.B. The Submissions details tab can also be used for marking why a submission is not needed. In case you click the No submission tickbox, mandatory reason fields will appear. If the **No submission** tickbox is set, you can complete the task and the following steps will be omitted, i.e. no submission will occur, but the record will still be available.

5.2.5. Completing a Task and Sending it Forward

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

5.2.6. Re-initiating a Completed record

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

5.3. Aggregate report submission (manual)

Purpose of the workflow: Manual tracking of a submission record. Generate and track aggregate reports submitted by manual means and ensure users are entering submission dates etc.

Let's select **Aggregate Report Submission (manual).** By clicking, you will have an overview of all the ongoing records that are being processed through the workflow.
Click a **Record ID** to proceed. When clicking on a **Record ID**, a new window will open, showing the process workflow and the steps to follow.

5.3.1. Create a New Record for Aggregate report Submission (manual)

An Aggregate report Submissions record can be created from multiple routes.

- It can be created from the parent Aggregate report (using a "Create Submission record" action when in the Submission workflow state). The Submission record will automatically be a "child" to the "parent" Aggregate report record.
- Or it can be directly created here: To create a new record, click **Create from wizard** (can also be called **Create new** depending on configuration).

N.B. It should be considered if your business process allows for creating a submissions record directly in the Aggregate report submissions workflow, or if it should be mandatory to take it through the Aggregate report *workflow. It can be configured to only allow creation in the Aggregate report submission (manual) workflow in the **Application management** part of HALOPV.*

5.3.1.1. Set the record's basic data

The **Record Title** is the identifier of the submission record you are about to create. It will not be visible in the actual report, so it is for your internal reference.
The **Record Type** must also be set, default options include a long list of format options (actual list may vary from the screenshot)

You can in this screen also set the due date (**Master Duedate**). If you do not set a date, the system will set a default value based on the configuration.

*N.B. For a submission record, you will also want to set the **Reporting destination**. This is done after the record is created. Here, you can click the **More (…)** menu, select basic information and here you can set the Reporting to via a dropdown. The **Reporting destinations** listed are all the Entities where the **Reporting Destination?** Tick box has been set to "Yes". This is not necessary for submission records that have been auto-scheduled, or created from an integration to Argus Safety or ARISg (in those cases, the destination will already have been set).*

5.3.2. Working with the Aggregate report submissions (manual) records in the view/edit record screen

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

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

5.3.3. The Aggregate report Submission (manual) workflow

The default workflow for the Aggregate report Submission (manual) workflow is:

This also means that records will start in the **Setup/Verify submission** task step and the last step is **Enter submission details.**
It should be noted that the configuration of the workflow may vary, as the tasks are configurable using the **Application management** part of HALOPV (requires Application admin roles).

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

5.3.4. Task activities for Aggregate report Submissions (manual) records

N.b. The first step in the workflow, **Generate report**, is typically automated, not leaving a lot of actions to the users. In case of generation failure, you can either use the Re-run the current task step action (see below table) The ones that may be needed to know about are listed below:

Name of Activity	Type	Description
Associate parent Aggregate report	Form	Allows the user to select the exact aggregate report record that should be the **parent** of the Submission. This is important since the submission record will generate against the data / forms in the parent.
Manage Attachments	Link	Takes the user to the **Attachments screen.** This allows for reviewing the automatically created file for submission, or to upload you own submission file. If you upload your own file, you can afterwards complete the task in order to progress the workflow to next task.
Submissions details form	Form	Allows for adding/viewing the status of the submission record, including data elements ordered in tabs: **Submissions details** (Submission task deadline, Actual Submission date, Authority confirmation date) **Scheduling details** (not used for aggregate reports) **Privacy and blinding** (Generate blinded, generate without Personal identifiable information) **Transmission details** (ID, acknowledgement date, submission status code, submission status message) For the automatic via gateway workflow, the transmissions details are automatically populated. N.B. The Submissions details tab can also be used for marking why a submission is not needed. In case you click the No submission tickbox, mandatory reason fields will appear. If the **No submission** tickbox is set, you can complete the task and the following steps will be omitted, i.e. no submission will occur, but the record will still be available.

5.3.5. Completing a Task and Sending it Forward

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

5.3.6. Re-initiating a Completed record

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

6. The Functionality Menu for Submissions

The Functionality menu is found on the main module page, as described in section 4. For ICSRs, the Functionality menu includes a number of links to features to make it easier to work with ICSRs. The items are described in the below table. To access a functionality, simply click on the link.

6.1. List of items in the Functionality Menu for Submissions

Link title	Type	Description
Submission overview	Dashboard	This functionality is a comprehensive submissions dashboard. There are a number of parameters to filter by on the page, including: Date range (from), Date range (to), Case criteria (relevant for ICSRs only), Type, Format, Destination type, Destination. The output is a number of elements: **Submission overview** (Compliance bar-chart), showing which tasks that were completely timely (green) v. late (red). **Submissions, tabular per destination** (tabulation), where the period is grouped into destination and by month. **Submissions, tabular per destination type** (tabulation), where the period is grouped into destination types per month **Submission, details** (listing), where all the submission records are listed in the period with a long list of data points.