

 ICSRs

HALOPV 3.X USER GUIDE

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

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1. HALOPV

User Manual - Release 3.0 (JUNE 2021)

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The information contained herein is subject to change without notice and is not warranted to be error-free. If you find any errors, please report them to us in writing.

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

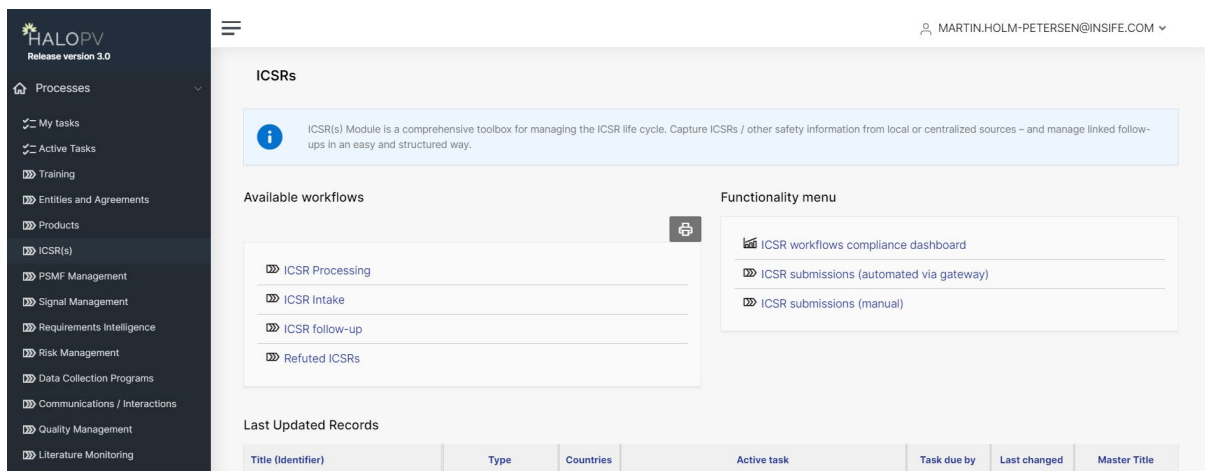
This User Manual describes the process workflows for ICSRs (adverse events / adverse drug reactions) in HALOPV.

ICSRs is a module in the HALOPV application and is a comprehensive toolbox for managing the ICSR life cycle. Capture ICSRs / other safety information from local or centralized sources – and manage linked follow-ups in an easy and structured way.

4. Access to the ICSRs module

ICSRs module includes all available process workflows concerning creation and management of adverse event reports, including intake, processing, follow-up, refuting and linking to the **Submissions** module for expedited reporting (See separate manual on Submissions)

On the left menu, you will find a list of Processes available for your user profile. Please select **ICSRs**. 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.



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

5. ICSR Workflows

Once clicking **ICSRs**, you will find the **Available workflows** of the ICSRs 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 intake

Purpose of the workflow: Intake safety information for triage and potential ICSR processing

Let's select **ICSRs intake**. 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 Intake

To create a new record, click **Create from wizard** (can also be called **Create new** depending on configuration).

5.1.1.1. Set the record

The **Record Title** is the identifier of the ICSR 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 **Spontaneous, Report from Study**

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.

5.1.2. Working with the ICSR intake 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.

5.1.3. ICSR Intake workflow

The default workflow for the ICSR intake workflow is:



This also means that records will start in the **Intake** task step and the last step is **Transfer record**. 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 Intake, the default list of actions is described in the following section:

5.1.4. Task Activities for ICSR Intake records

N.b. the forms are designed according to the [ICH E2B\(R3\) standard](#) and reference

Name of Activity	Type	Description
Sender(s) / Reporter(s)	Form	<p>Opens a form to fill in a series of tabs, for filling in information about the ICSR case and Reporter(s), namely:</p> <p>Case Safety Report (ICSR Category, Type of Report, Date of report, WWUI, etc.)</p> <p>Study Identification (Study name, Sponsor study number, etc.)</p> <p>Linked report(s) (List of linked reports)</p> <p>Source Identifier(s) (Source of the case identifier, Case identifier)</p> <p>Source(s) of information (Reporter title, Reporter name, Reporter qualification etc., Primary source for regulatory purposes, etc.)</p> <p>Literature Reference(s) (List of Literature reference(s) (documents))</p> <p>Additional Document(s) (List of Documents held by sender (documents))</p>
Patient / Parent	Form	<p>Opens a form to fill in a series of tabs, for filling in information about Patient and Parent information, namely:</p> <p>Patient (patient name, date of birth, age etc.)</p> <p>Patient Medical Records (Gestation, Medical record number(s), etc.)</p> <p>Parent (parent name, date of birth age etc.)</p> <p>Death (Date of death, autopsy details)</p> <p>Medical History (MedDRA code, Start date, End date etc.)</p> <p>Past Drug History (WhoDrug code, Start date, End date, etc.)</p> <p>Result of Test and Procedures (Test date, Test Name, Test result code etc.)</p> <p>Medical History of Parent (MedDRA code, Start date, End date, etc.)</p> <p>Relevant Past Drug History of Parent (WhoDrug code, Start date, End date, etc.)</p> <p>Causes of Death (Reported causes of Death MedDRA code, Autopsy determined causes of Death MedDRA code, etc.)</p>
Event(s)	Form	<p>Event(s) (Reaction/event as reported, MedDRA code, Seriousness criteria, Outcome, Medical Confirmation, etc.)</p>
Drug(s)	Form	<p>Drug(s) (Medicinal Product name as reported, WhoDrug code, Indication, Substance(s), Characterization of Drug role, Dose(s), etc.)</p>

Drug-event assessment(s)	Form	Drug(s)-reaction(s) matrix (Product, Event, Source of Assessment, Method of Assessment, Result of Assessment, Listedness, etc.)
Narrative / Summary	Form	Opens a form to fill in a series of tabs, for filling in information about Patient and Parent information, namely: Narrative Case Summary and Further Information (Case Narrative, Reporters Comments, Sender Comments) Diagnosis (Senders diagnosis / syndrome MedDRA) Reporters Comments (Case Summary and Reporters comments)
Manage attachments	Link	Opens the record attachment window, i.e. the link action it is a shortcut to managing attachments. The attachments functionality is generally available in all records types
Re-run the current task step	Link	Re-executes the step including automator actions, which can be used for adding source documents, XML case data etc. and get these analysed by HALOPV

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 Processing

ICSR processing allows you to register ICSRs and track progress of tasks in the case handling workflow. You are also able to link ICSRs to Submissions and ICSR Follow-up.

Let's select **ICSRs Processing**. 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 Processing

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 ICSR record directly in the ICSR Processing workflow, or if it should be mandatory to take it through the ICSR Intake workflow first. It can be configured to only allow creation in the ICSR Intake workflow in the **Application management** part of HALOPV.

5.2.1.1. Set the record title

The **Record Title** is the identifier of the ICSR you are about to create. It will not be visible in the actual report, so it is for your internal reference.

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.

5.2.2. Working with the ICSR Processing 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.

5.2.3. ICSR Processing workflow

The default workflow for the ICSR Processing workflow is:



This also means that records will start in the **Register ICSR Information** task step and the last step is **Submission**.

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 Processing, the default list of actions is described in the following section:

5.2.4. Task Activities for ICSR Processing records

N.b. the forms are designed according to the [ICH E2B\(R3\) standard](#) and reference

Name of Activity	Type	Description
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Sender(s) / Reporter(s)	Form	<p>Opens a form to fill in a series of tabs, for filling in information about the ICSR case and Reporter(s), namely:</p> <p>Case Safety Report (ICSR Category, Type of Report, Date of report, WWUI, etc.)</p> <p>Study Identification (Study name, Sponsor study number, etc.)</p> <p>Linked report(s) (List of linked reports)</p> <p>Source Identifier(s) (Source of the case identifier, Case identifier)</p> <p>Source(s) of information (Reporter title, Reporter name, Reporter qualification etc., Primary source for regulatory purposes, etc.)</p> <p>Literature Reference(s) (List of Literature reference(s) (documents))</p> <p>Additional Document(s) (List of Documents held by sender (documents))</p>
Patient / Parent	Form	<p>Opens a form to fill in a series of tabs, for filling in information about Patient and Parent information, namely:</p> <p>Patient (patient name, date of birth, age etc.)</p> <p>Patient Medical Records (Gestation, Medical record number(s), etc.)</p> <p>Parent (parent name, date of birth age etc.)</p> <p>Death (Date of death, autopsy details)</p> <p>Medical History (MedDRA code, Start date, End date etc.)</p> <p>Past Drug History (WhoDrug code, Start date, End date, etc.)</p> <p>Result of Test and Procedures (Test date, Test Name, Test result code etc.)</p> <p>Medical History of Parent (MedDRA code, Start date, End date, etc.)</p> <p>Relevant Past Drug History of Parent (WhoDrug code, Start date, End date, etc.)</p> <p>Causes of Death (Reported causes of Death MedDRA code, Autopsy determined causes of Death MedDRA code, etc.)</p>
Event(s)	Form	Event(s) (Reaction/event as reported, MedDRA code, Seriousness criteria, Outcome, Medical Confirmation, etc.)
Drug(s)	Form	Drug(s) (Medicinal Product name as reported, WhoDrug code, Indication, Substance(s), Characterization of Drug role, Dose(s), etc.)
Drug-event assessment(s)	Form	Drug(s)-reaction(s) matrix (Product, Event, Source of Assessment, Method of Assessment, Result of Assessment, Listedness, etc.)
Narrative / Summary	Form	<p>Opens a form to fill in a series of tabs, for filling in information about Patient and Parent information, namely:</p> <p>Narrative Case Summary and Further Information (Case Narrative, Reporters Comments, Sender Comments)</p> <p>Diagnosis (Senders diagnosis / syndrome MedDRA)</p> <p>Reporters Comments (Case Summary and Reporters comments)</p>
QC check	Form	QC Check (QC performed, Comments).

N.B. a validation has been applied to the QC Check form to only allow another user to complete it, in relation to who processed the previous task step.

Task Relocation (Refuted ICSR)	Link	The Task Relocation action allows for moving the record from the ICSR Processing workflow into the Refuted ICSR workflow, by this removing the ICSR record from the active processing and subsequent submission. When moving the record, a rationale must be provided, which will be recorded
Create Manual Submission	Link	The workflow submission step will assess if any submissions are to be created automatically. However, the Manual submissions are deemed necessary they can be setup with this action.
Create Follow-up	Link	A follow-up record can be created in order to pursue additional information. The record created will be in the ICSR Follow-up workflow, linking to the ICSR as a parent. Therefore, it is possible to proceed with the ICSR Processing record if desirable.

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. ICSR Follow-up

The ICSR follow-up workflow allows for sending inquiries / follow-ups to the source.

Let's select **ICSRs Follow-up**. 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 ICSR Follow-up

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 ICSR record directly in the ICSR Processing workflow, or if it should be mandatory to take it through the ICSR Intake workflow first. It can be configured to only allow creation in the ICSR Intake workflow in the **Application management** part of HALOPV.*

5.3.1.1. Set the record

The **Record Title** is the identifier of the ICSR you are about to create. It will not be visible in the actual report, so it is for your internal reference.

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.

5.3.2. Working with the ICSR Follow-up 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.

5.3.3. ICSR Follow-up workflow

The default workflow for the ICSR Processing workflow is:

Pursue ICSR follow-up questions and register information

This also means that records will start in the **Pursue ICSR follow-up questions and register information** task step and the first as well as last step.

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 Follow-ups, the default list of actions is described in the following section:

5.3.4. Task Activities for ICSR Follow-up records

Name of Activity	Type	Description
Associate parent ICSR	Link action	In case a follow-up record is created from the Create wizard button rather than from the ICSR Processing, it is necessary to link the follow-up to a parent ICSR record. Use this action.

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.

5.4. Refuted ICSRs

Refuted ICSRs are typically non-valid cases, or duplicates, or non-relevant products.

Let's select **Refuted ICSRs**. 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.

5.4.1. Create a New Record for Refuted ICSRs

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 Refuted ICSR as a new record, or if it should be mandatory to take it through the ICSR Intake workflow first. It can be configured to only allow creation in the ICSR Intake workflow in the **Application management** part of HALOPV.*

5.4.1.1. Set the record

The **Record Title** is the identifier of the Refuted ICSR you are about to create. It will not be visible in the actual report, so it is for your internal reference.

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. It should be noted that Refuted ICSRs typically do not have any fixed timeline, and the standard configuration does therefore not have any.

5.4.2. Working with the refuted ICSR 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.

5.4.3. Refuted ICSRs workflow

The default workflow for the Refuted ICSRs workflow is:



This also means that records will start in the **Manage refuted ICSR** task step and the first as well as last step.

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 Follow-ups, the default list of actions is described in the following section:

5.4.4. Task Activities for ICSR Follow-up records

N.b. the forms are designed according to the [ICH E2B\(R3\) standard](#) and reference

Name of Activity	Type	Description
Sender(s) / Reporter(s)	Form	<p>Opens a form to fill in a series of tabs, for filling in information about the ICSR case and Reporter(s), namely:</p> <ul style="list-style-type: none"> Case Safety Report (ICSR Category, Type of Report, Date of report, WWUI, etc.) Study Identification (Study name, Sponsor study number, etc.) Linked report(s) (List of linked reports) Source Identifier(s) (Source of the case identifier, Case identifier) Source(s) of information (Reporter title, Reporter name, Reporter qualification etc., Primary source for regulatory purposes, etc.) Literature Reference(s) (List of Literature reference(s) (documents)) Additional Document(s) (List of Documents held by sender (documents))
Patient / Parent	Form	<p>Opens a form to fill in a series of tabs, for filling in information about Patient and Parent information, namely:</p> <ul style="list-style-type: none"> Patient (patient name, date of birth, age etc.) Patient Medical Records (Gestation, Medical record number(s), etc.) Parent (parent name, date of birth age etc.) Death (Date of death, autopsy details) Medical History (MedDRA code, Start date, End date etc.) Past Drug History (WhoDrug code, Start date, End date, etc.)

		<p>Result of Test and Procedures (Test date, Test Name, Test result code etc.)</p> <p>Medical History of Parent (MedDRA code, Start date, End date, etc.)</p> <p>Relevant Past Drug History of Parent (WhoDrug code, Start date, End date, etc.)</p> <p>Causes of Death (Reported causes of Death MedDRA code, Autopsy determined causes of Death MedDRA code, etc.)</p>
Event(s)	Form	Event(s) (Reaction/event as reported, MedDRA code, Seriousness criteria, Outcome, Medical Confirmation, etc.)
Drug(s)	Form	Drug(s) (Medicinal Product name as reported, WhoDrug code, Indication, Substance(s), Characterization of Drug role, Dose(s), etc.)
Drug-event assessment(s)	Form	Drug(s)-reaction(s) matrix (Product, Event, Source of Assessment, Method of Assessment, Result of Assessment, Listedness, etc.)
Narrative / Summary	Form	<p>Opens a form to fill in a series of tabs, for filling in information about Patient and Parent information, namely:</p> <p>Narrative Case Summary and Further Information (Case Narrative, Reporters Comments, Sender Comments)</p> <p>Diagnosis (Senders diagnosis / syndrome MedDRA)</p> <p>Reporters Comments (Case Summary and Reporters comments)</p>
Task Relocation (Move to ICSR Processing)	Link	The Task Relocation action allows for moving the record from the Refuted ICSR workflow into the ICSR Processing workflow, and by this action re-activating the ICSR record to the active processing and subsequent submission. When moving the record, a rationale must be provided, which will be recorded
Create Follow-up	Link	A follow-up record can be created in order to pursue additional information. The record created will be in the ICSR Follow-up workflow, linking to the Refuted ICSR as a parent

5.4.5. 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.

5.4.6. 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 ICSRs

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 ICSRs

Link title	Type	Description
ICSR Workflows compliance dashboard	Dashboard	<p>This functionality is a shortcut to the dashboard section and sets the initial parameters to ICSR Intake (workflow) / Intake (task).</p> <p>There are a number of parameters to filter by on the page, and the output is a 12-month rolling bar-chart, showing which tasks that were completely timely (green) v. late (red). Also, the dashboard shows the KPIs that have been set for the task. Please refer to Application management to set KPIs for workflows and tasks.</p> <p>When done with the dashboard, click Back on the browser to return to the ICSRs module</p>
ICSR Submissions (Automated via gateway)	Link to another module	<p>This functionality is a shortcut to the ICSR Submission (Automated via gateway) workflow. By clicking this link, you will see a list of the ICSR submissions that was created for an automatic gateway route (i.e. normally does not require any human intervention). The items on the ICSR Submissions list are Submission records that have ICSRs as parent records</p> <p>Please note that this workflow is in the Submissions module and requires that you have a relevant role to access the records</p>
ICSR Submissions (Manual)	Link to another module	<p>This functionality is a shortcut to the ICSR Submission (Manual) workflow. By clicking this link, you will see a list of the ICSR submissions that was created for manual processing route. The items on the ICSR Submissions list are Submission records that have ICSRs as parent records</p> <p>Please note that this workflow is in the Submissions module and requires that you have a relevant role to access the records</p>