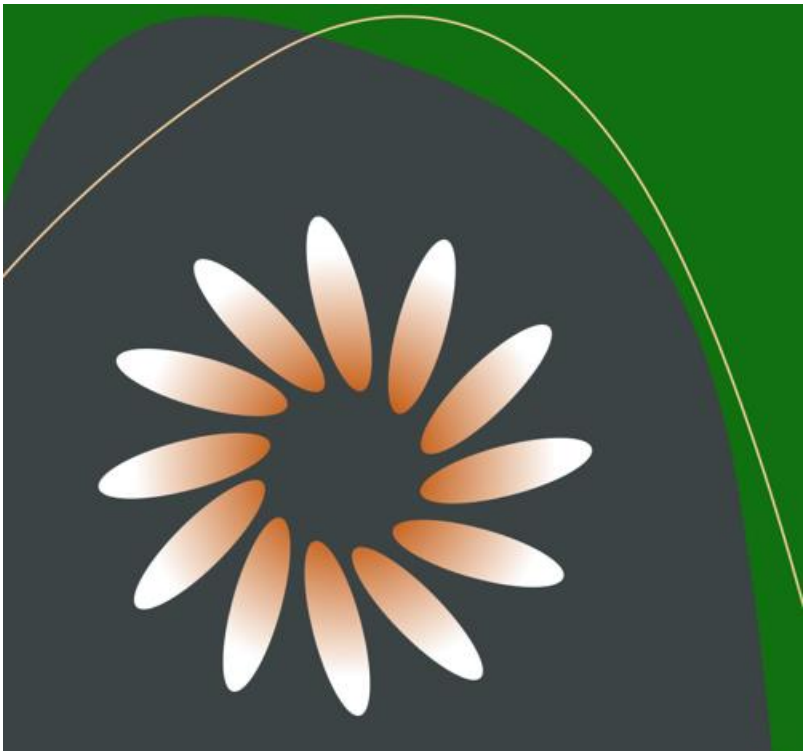
# ICSRs Module



## HALOPV/ PROHALO 4.X USER MANUAL

This is an end-user guide for the **Individual Case Serious Reports (ICSRs) Module** of the drug safety solution **HALOPV/PROHALO**.

# Contents

# 1. HALOPV / PROHALO ICSRs Module User Manual

User Manual - Release 4.X (4.2 first released March 2023)



# 2. Preface

The information in this user manual is based on the standard package of the Products Module and functionalities, which are subject to change. The latest product information, including release notes for HALOPV and multi-tenant HALOPV, is available at:

https://www.halopv.com or

https://insife.com/halopv

## 2.1. Insife Support

The Insife Support team can be reached at support@insife.com 24/7, depending on the agreed terms. Furthermore, the Insife Support team handles upgrades relat

ed to modules requiring MedDRA codes, EDQM codes, WHO Drug Dictionary, and more.

# 3. Introduction

## 3.1. Purpose of this document

This User Manual describes the Products 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 at 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 of this manual, the modules comprise of:

- 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 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 access your instance of HALOPV/PROHALO.

## 4. Navigating the ICSRs 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. To review HALOPV access and general features, please refer to our to our General Features user manual. If you can log in but cannot access the Module, please consult section 4.2.

The **ICSR(s) module** will appear if your user profile has access to the Module.

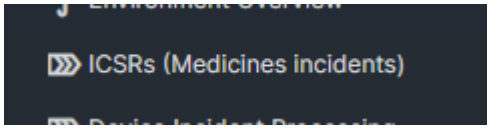



*Figure 1 Left menu, ICSR(s) is available for users with the appropriate access role*

## 4.1. Module main screen

The main screen for the Module lists all available *workflows* as well as *functionality menus*

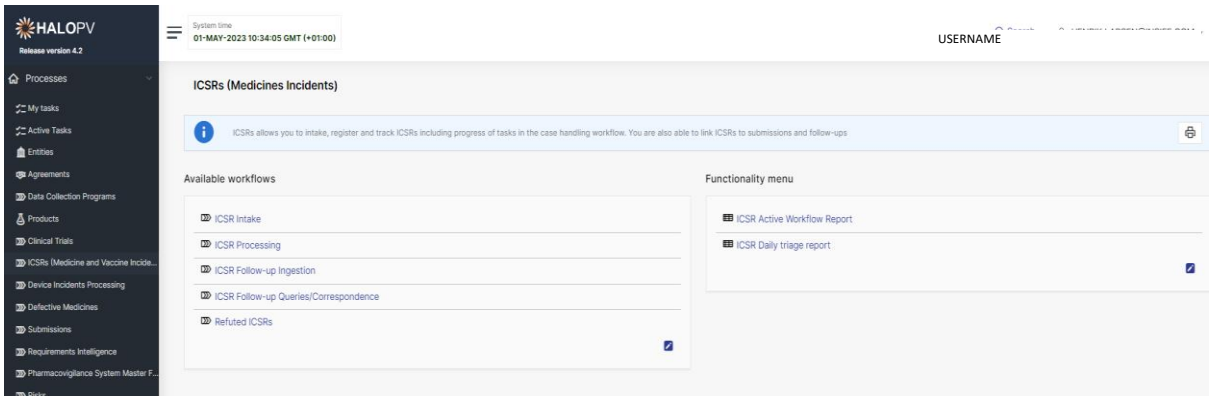



*Figure 2 The standard list of Workflows and Functionality Menu items for ICSRs module*

At the time of writing, the standard package of the ICSRs module consists of the following workflows and functionality menus.

- ICSR Processing
- ICSR Intake
- ICSR Follow-up Ingestion
- ICSR Queries/Correspondence
- Refuted ICSRs
- ICSR Active Workflow Report
- ICSR Daily Triage Report

Note: workflows in HALOPV are highly configurable. Hence your HALOPV implementation may have other workflows, names, and actions than portrayed in this manual.

Users can access the record worklist by clicking on one of the available workflows. **E.g., ICSR Intake**. The view will display the Record (s) created in the process workflow.

## 4.2. User roles relevant to the Module

Users must be assigned roles to access the relevant modules. Furthermore, user roles can allow access or editing rights for a record in a specific workflow task step. Please consult the table below for standard user roles provided by the system. Your administrator may have configured other user roles. For a description of how to administer users and user roles, please refer to the Admin Guide (insife.com)

| Defined Usergroup name (Role) | Description |
|---|---|
| **ICSR Module** | Required to access the Module |
| **ICSR Case Processing** | Main processing role for the Module. The role can create records and assign a due date. |

| | |
|---|---|
| **ICSR Quality Control** | Role needed to carry out QC Check of the data (if configuration is applied) |
| **ICSR Medical Review** | Role needed to carry out Medical Review of medical data (if configuration is applied) |
| **Triage** | Role can create records and assign due date. To access additional patient information, please suscribed to additional roles e.g. Privacy data access, Privacy flag edit |
| **Submission Manager** | Users with this role can submit ICSR records available in the ICSR Processing and process ICSR Submissions (Manual) |

*Table 1 User roles for the Requirements Intelligence module*

# 5. Standard Workflows

The Module comes pre-configured with several standard workflows. These are described in the following sections, including their individual workflow task steps and associated actions.

**Clicking on a workflow** takes you to the worklist for the workflow, with all the records in the workflow at the current time. See the below example of ICSR Intake Records in Figure 2 The standard list of Workflows and Functionality Menu items for ICSRs module.

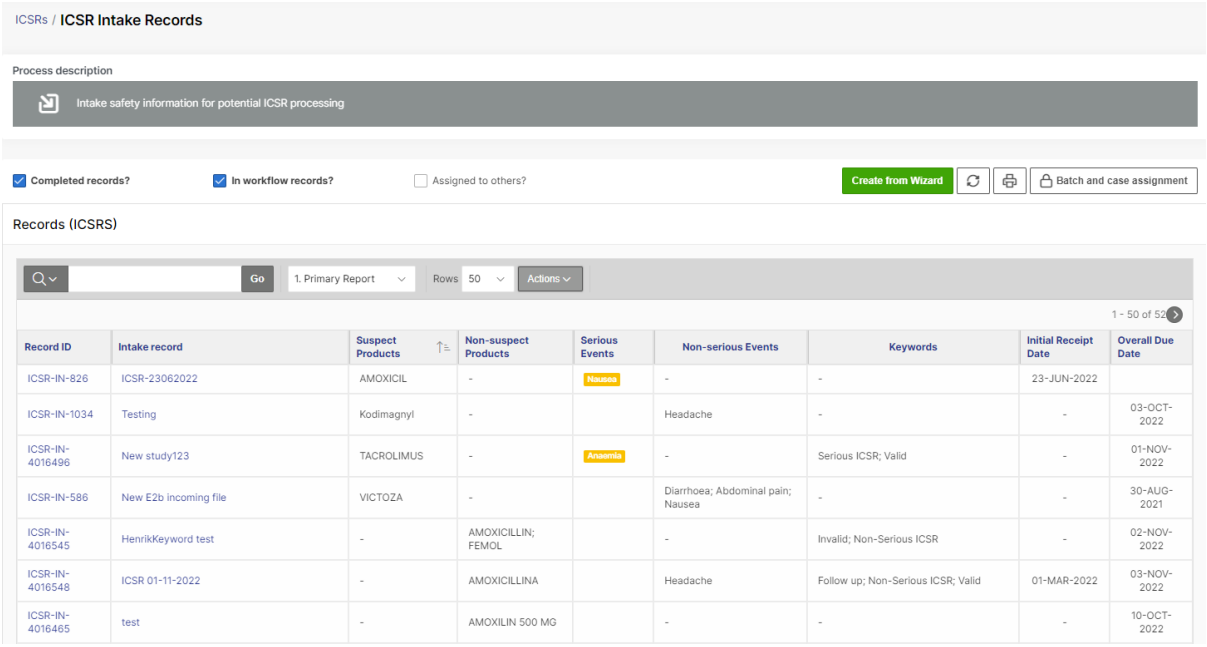



*Figure 3. When clicking on a workflow, the following screen displays a Process and workflow description (if configured) as well as a worklist of records, where the Record ID and title can be clicked to access the record.*

**Clicking on the Record ID** or **Record Title** takes you to the individual record. See Figure 3. When clicking on a workflow, the following screen displays a 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.below.

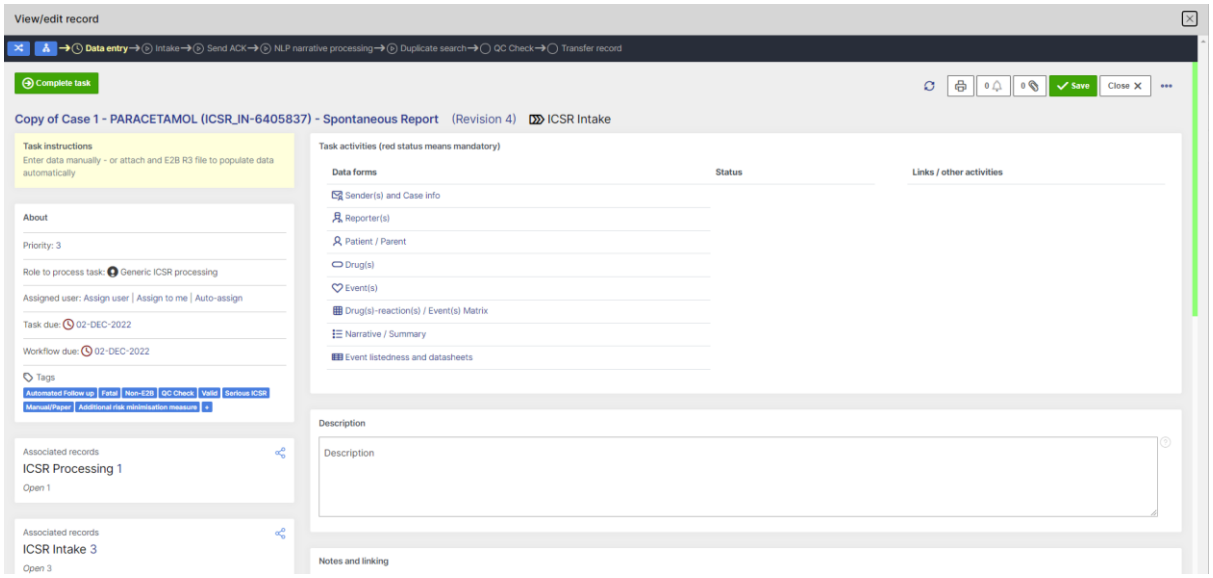



*Figure 4. When clicking on a Record ID, the following screen displays an overview and state of the record.*

The record overview shows general information such as the record title, record type, available task activities, and Link/Other activities (if any). The workflow step trail in the upper section of the screen highlights which workflow step the record currently resides in, and the 'Task instructions' boxed in yellow describes the expected tasks and actions for the specific workflow step. Lastly, the 'About' section provides a quick overview of priority, process owner, and due dates.

For more information about record management, please refer to the General features for users guide.

The following sections will describe the workflows and workflow steps related to the ICSR module.

## 5.1. ICSR Intake

Source Entry > E2B Intake > Auto Code > NLP Processing > Duplicate Search > Transfer Record

The purpose of the workflow is to manage the intake of safety information and decide whether the potential ICSR is to be processed in the system or refuted.

The workflow consists of 5 task steps:

- *Source Entry (**Error! Reference source not found.**)*
- *E2B Intake (**Error! Reference source not found.**)*
- *Auto Code (**Error! Reference source not found.**)*
- *NLP Processing (5.1.4)*
- *Duplicate Search (5.1.5)*
- *Transfer Record (5.1.6)*

The following sections will explain the tasks in further detail:

### 5.1.1. Source Entry

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):**

*Enter ICSR data manually from source information into the data forms or attach an E2B R3 file to populate source data automatically*.

This is the first and initial step for the intake of source data for processing ICSR data. The data can be entered manually using the individual data forms and sub-tabs or automatically populated by attaching an E2B XML file via the attachment icon or, if available, the 'Manage Attachments' link in the workflow step. Once the workflow step is completed, the E2B automation is initiated. See below section 5.1.2 for more information.

**Note:** Validation rules may be applied to the workflow task making one or more data fields in the forms mandatory before the task can be completed and routed to the next workflow step. These validation rules are reflected in red in the status bar, as illustrated in the below example.


*Figure 5. Example of one validation warning found in the Sender(s) and Case info form*

For more information on validation rules, please refer to General Overview and Main Features guide.

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 comprises of below activities:

| Name of Activity | Type | Description |
|---|---|---|
| | | |
| **Sender(s) / Reporter(s)** | Form | Opens a form to fill in a series of tabs for filling in information about the ICSR case and Reporter(s), namely:<br>**Case Safety Report** (ICSR Category, Type of Report, Date of report, WWUI, etc.)<br>**Study Identification** (Study name, Sponsor study number, etc.)<br>**Linked report(s)** (List of linked reports)<br>**Source Identifier(s)** (Source of the case identifier, Case identifier)<br>**Source(s) of information** (Reporter title, Reporter name, Reporter qualification, etc., Primary source for regulatory purposes, etc.)<br>**Literature Reference(s)** (List of Literature reference(s) (documents)) |
| **Patient / Parent** | Form | Opens a form to fill in a series of tabs for filling in information about the Patient and Parent information, namely:<br>**Patient** (Patient name, Date of Birth, Age, etc.)<br>**Medical History** (Patient Medical Records, Pregnancy, Medical record number(s), MedDRA code, Start date, End date etc.) |

| | | |
|---|---|---|
| | | **Past Drug History** (WhoDrug code, Start date, End date, etc.)<br>**Result of Test and Procedures** (Test date, Test Name, Test result code, etc.)<br>**Death** (Date of death, Reported causes of Death MedDRA code, Autopsy determined causes of Death MedDRA code, etc.)<br>**Parent** (parent name, date of birth, age etc.)<br>**Relevant Medical History of Parent** (MedDRA code, Start date, End date, etc.)<br>**Relevant Past Drug History of Parent** (WhoDrug code, Start date, End date, etc.) |
| **Reporter(s)** | Form | **Reporter(s)** (Source of information, Reporter name, Qualification, Country, Email address etc.) |
| **Event(s)** | Form | **Event(s)** (Reaction/event as reported, MedDRA code, Seriousness criteria, Outcome, Medical Confirmation, etc.) |
| **Drug(s)**[1] | Form | **Drug(s)** (Medicinal Product name as reported, WhoDrug code, Product type, Action(s) taken with Drug, etc.)<br>**Indication(s)** (Indication as reported, MedDRA code, etc.)<br>**Substance(s)** (Substance name, strength, MedDRA code, etc.)<br>**Dosage(s)** (Dose numbers, Start date, End Date, Batch Number, Pharmaceutical Dose Form, Route of Administration 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 | Opens a form to fill in a series of tabs for filling in information about the Patient and Parent information, namely:<br>**Narrative Case Summary and Further Information** (Case Narrative, Reporters Comments, Sender Comments)<br>**Diagnosis** (Senders diagnosis/syndrome MedDRA)<br>**Reporters Comments** (Case Summary and Reporters comments) |
| **Event listedness and datasheets** | Form | Opens a form in a tabular view to fill in listedness assessment details with information on Product, Event, Datasheet Name, and Assessment |
| **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 analyzed by HALOPV |

[1] *See section 5.1.4 for more information*

| | | |
|---|---|---|
| **Manage attachments** | Link | Opens the record attachment window, i.e., the link action is a shortcut to managing attachments. The attachments functionality is generally available in all records types |

*Table 2 Data Entry Form and Link activities*

### 5.1.2. E2B Intake

This automation imports R3 XML files from the attachment of the record in which the Automation runs (ICSR intake in this case). The system will then ingest identified E2B data elements to the matching data forms in the record. If any errors are found during intake, these errors are described in the Workflow history in the case.

This automation won't affect manual data entry without any E2B attachments.

### 5.1.3. Auto-code

This is an automation task in which the system auto-codes products based on the product dictionary. Direct matches will be auto-coded.

#### 5.1.3.1. (Manual coding)

Coding of products in the ICSRs module can also be done manually within the ***Drug(s***) tab using the Product Index and MedDRA browser. For instance, if you want to re-code existing products or events, add or even remove existing products or events.

The **Product Index** can be utilized in ***Drug(s)*** tab by typing in the ***Verbatim Medicinal Product Name*** *as* ***Reported (G.K.2.2)*** and clicking "**Code product**". This opens the product coding browser where you can apply different sets of filters to your query search, like product name, product type, and an array of coding levels such as filter substance, ingredient, authorization numbers, etc.

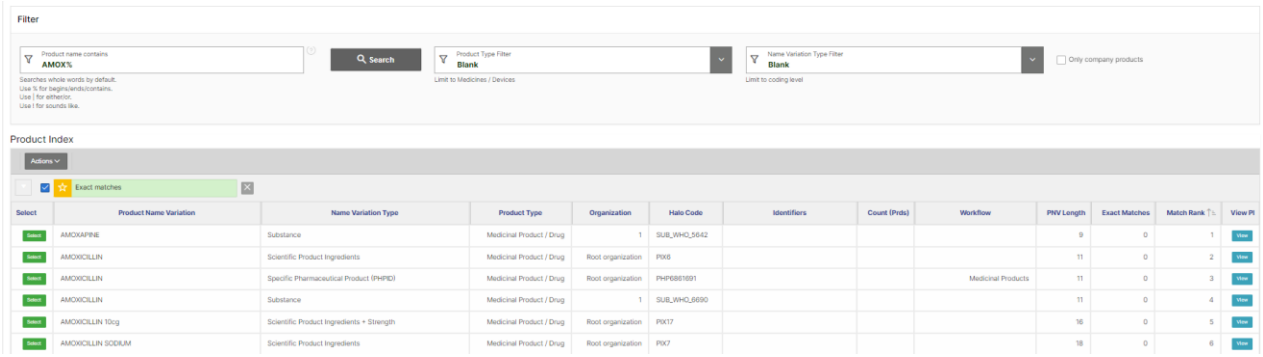



*Figure 6. Example of a search query in the Product Index browser*

After Product coding →

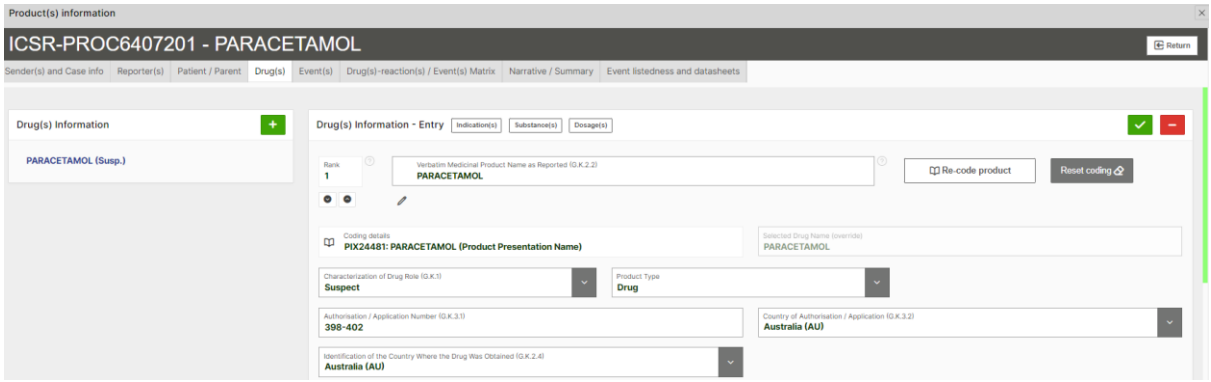



*Figure 7. The Drug(s) tab post coding of a drug*

You can opt to include only company products by using the tickmark box **Only company products**. This excludes products loaded from the WHO Drug dictionary and only filters on products configured in the **Products Module** of your HALOPV.

In the ***Drug(s)*** tab, you will also find the sub-sections ***Indication(s), Substance(s)*** and ***Dosage(s)*** (as seen in Figure 7) to allow the manual coding of these attributes:

- Coding of **Indication(s)** follows the same principle: you type the Indication as reported by the primary source and then click "Code event", which opens the **MedDRA browser**. Multiple sets of filters can be applied here, including searches on synonyms, collections, and language, as well as, SOC, HLGT, HLT, PT, and LLT.filters.

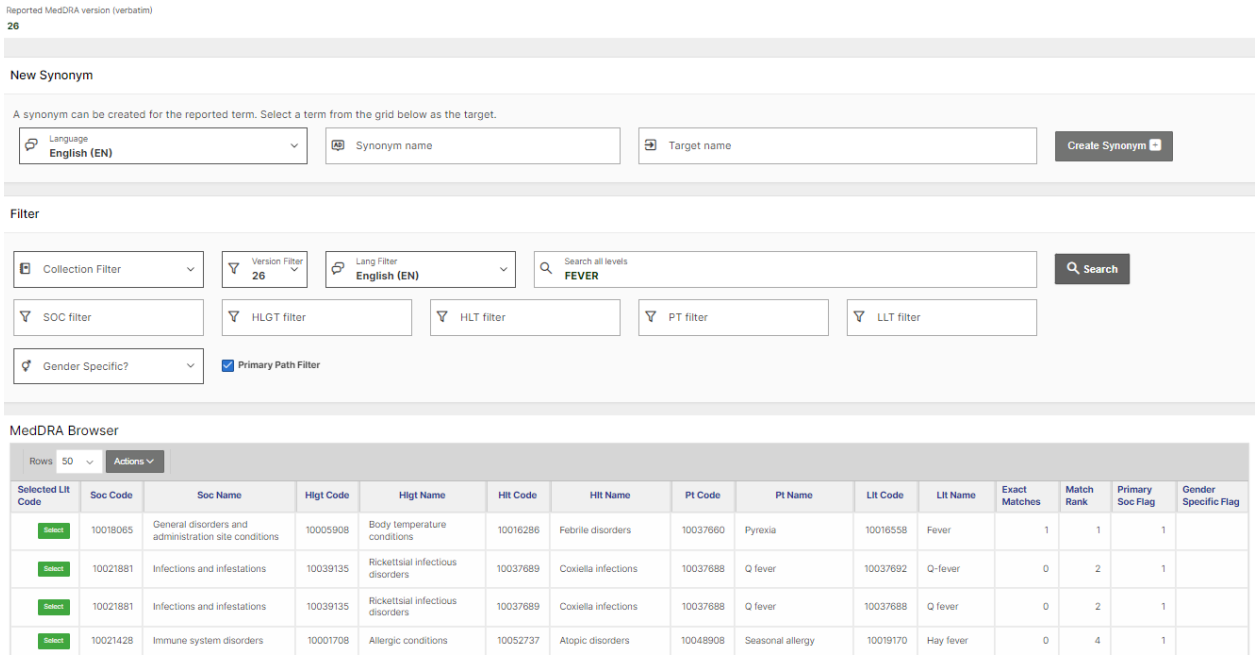



*Figure 8. Example of a search query in the MedDRA browser*

After Indication coding →

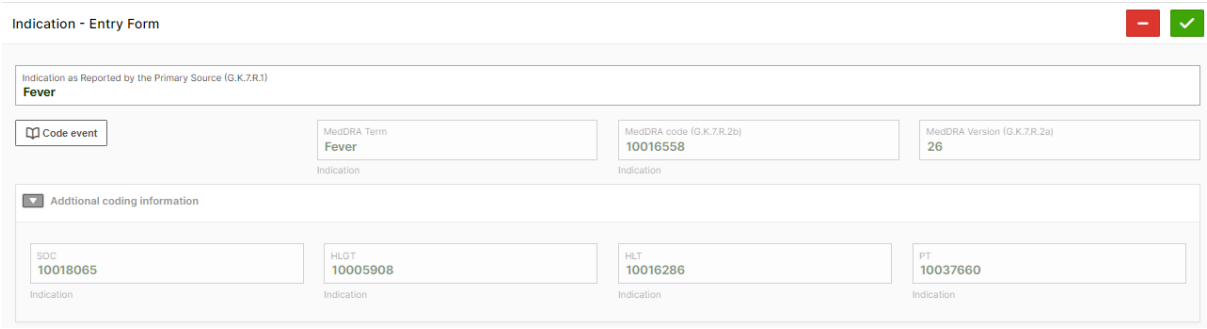



*Figure 9. The Indication(s) tab post coding of an indication*

- Coding of **Substance(s)** is managed via a drop-down list. The list contains all acknowledged substances listed in the WHO Drug Dictionary. In scenarios where the Substance is still in an investigational phase and not yet reflected in the WHO Drug dictionary, the Substance can be configured in your application by our technical team (Please contact support@insife.com to help set additional values in your application)

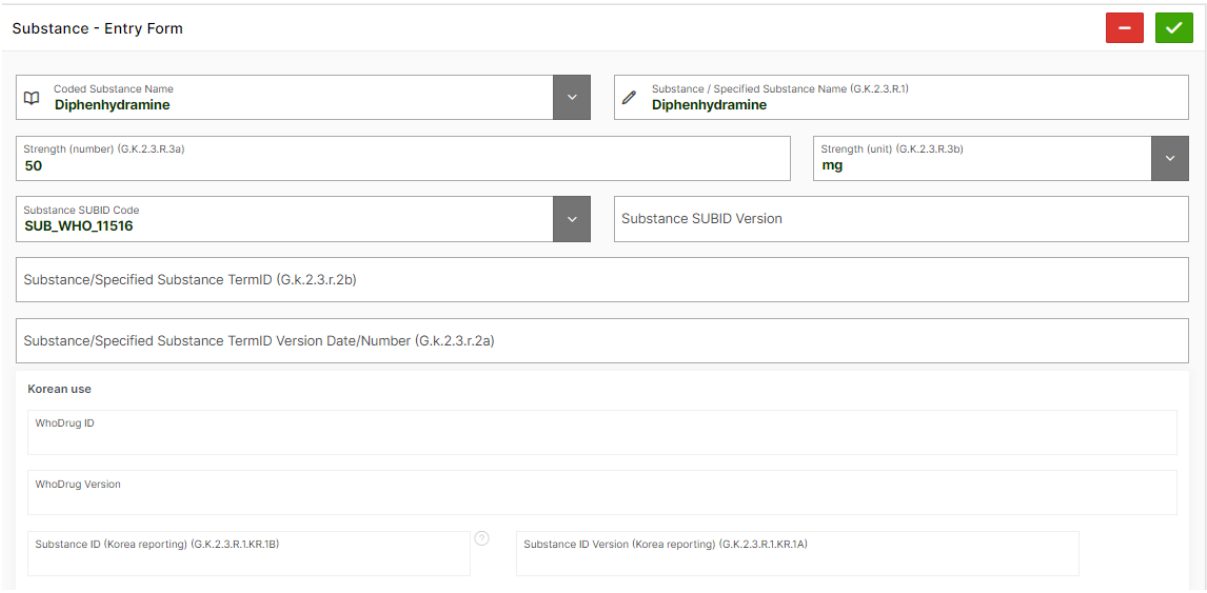



*Figure 10. Example of a Substance selection in the Substance(s) tab*

- The **Dosage(s)** section is where essential information related to Dosage, like dose/unit, date and time of Start of drug/Last time of administration and frequency, etc., is entered along with the coding of pharmaceutical dosage forms and routes of administration. These code selections are based on the EDQM codes list, uploaded and maintained in HALO.

**Note:** Please ensure your WHODrug dictionary, EDQM codes list, etc., are updated to the latest version. Otherwise contact support@insife.com

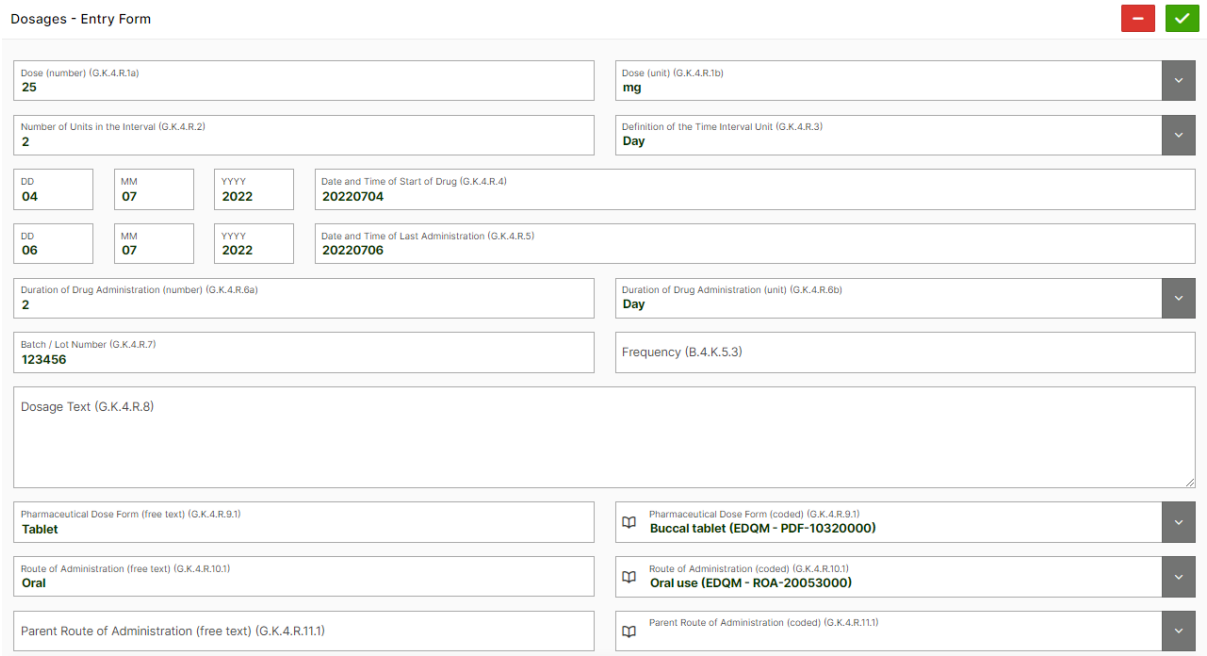



*Figure 11. Example of PDF and ROA selection in the Dosage(s) tab*

The EDQM dictionary is handled in the Product module, where you can search and manage the **Pharmaceutical Dosage Forms** and **Routes of Administration** using the functionality menus "**Manage Pharm Forms**" and **Manage Admin Routes**".

Please refer to the user manual for the **Products Module** for more information.

### 5.1.4. NLP Narrative Processing

Natural Language Processing (also known as AI processing) is an automation that checks if the record NLP Processing is applicable and will detect possible additional codes from the report narrative fields.

NLP processing may take minutes to complete from the previous work task. If the record stops at any of the NLP processing steps, the user should wait five minutes and refresh the page for the record to progress to the next work task automatically.

### 5.1.5. Duplicate Search

The Duplicate Search workflow is an automation workflow in which the system will perform the duplicate search automatically. The workflow step will only stop during the task if any other records are found in the system with≥70% matching information against a set criterion of fields. At this stage, you can manually decide to link the case as a record and then merge it or mark the record as a follow-up if this is more appropriate or ignore the suggestions if it is determined they are not duplicates.

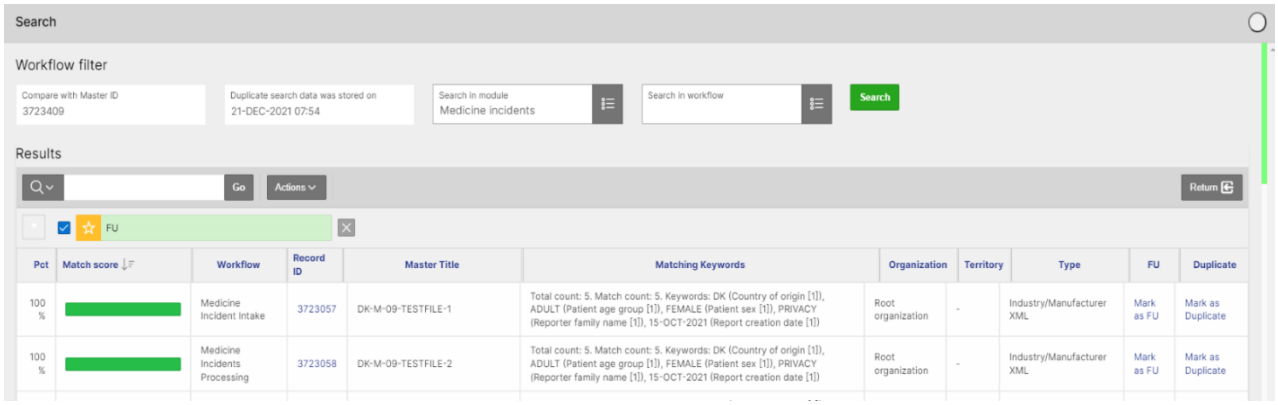



*Figure 5 - Duplicate search acceptance screen*

If a record is marked as a duplicate, it will be tagged as such, and a relation between the two records is created to show the duplicate relation. Routing rules are used to move the duplicate to a dedicated duplicate processing workflow.

**Duplicate search Algorithm**

The duplicate search is based on keywords from within the record. The search engine compares the keywords on the incoming record with the keywords of existing records in the target workflow (configurable) – the more matches (out of the total number of keywords in the target record), the higher the duplicate search score.

When a record having the same *DUP-SEARCH-ID* tag as an existing case is received, it is automatically tagged as an *Automatic duplicate* and linked as a duplicate record to the existing record.

**Note:** Rules (Keywords) that apply to your business requirements for duplicate search should be set up on your HALOPV application. Don't hesitate to contact your HALOPV system administrator or contact person for this update.

### 5.1.6. Transfer Record

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 system assesses the record to be transferred to ICSR Processing, ICSR Follow-up Ingestion or to Refuted ICSRs workflow based on the record's ICSR information. Click the appropriate action item to execute the relocation.*

Once the record has been processed through the prior automation workflows the record lands in the final step 'Transfer Record,' in which the system transfers the record to either **ICSR Processing** (5.2), **ICSR Follow-up Ingestion** (5.3), or to the **Refuted ICSRs** (5.4) workflow. This is based on data calculations of previous workflow steps. The system can also recommend what workflow the record is to be transferred to, which the user can either accepts or rejects.

The Transfer Record specific activities are described in the below table.

| Name of Activity | Type | Description |
|---|---|---|
| | | |
| **Task Relocation (Move to ICSR Processing)** | Link | Opens a dialog box to confirm task relocation (Move to ICSR Processing) and a comments section in which the user states a reason for the relocation.<br>The reason provided will be added to the record Notes field. |
| **Task Relocation (Move to ICSR Follow-up)** | Link | Opens a dialog box to confirm task relocation (Move to ICSR Follow-up) and a comments section in which the user states a reason for the relocation.<br>The reason provided will be added to the record Notes field. |
| **Task Relocation (Refuted ICSR)** | Link | Opens a dialog box to confirm task relocation (Refute ICSR) and a comments section in which the user states a reason for the refusion.<br>The reason provided will be added to the record Notes field. |

*Table 4 Data Entry Form and Link activities*

## 5.2. ICSR Processing


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

The workflow consists of 3 task steps:

- *Process ICSR Information* (***Error! Reference source not found.***)
- *Quality Control (5.2.2)*
- *Medical Review* (***Error! Reference source not found.***)[2]
- *Submission* (***Error! Reference source not found.***)

The following sections will explain the tasks in further detail:

### 5.2.1. Process ICSR Information

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):**

*Data entry and/or assessment of essential ICSR information. Use the link to the case forms to add/assess data entered in the case.*

Records transferred to this workflow from the ICSR Intake workflow are to be assessed in this task with the option to add additional information. If the record requires further follow-up information, the user can use the

[2] Conditional mandatory – Medical Review only applies to serious cases.

Create Follow-up link or move the record to Refuted ICSRs if the record is deemed invalid for further processing. Additional tasks might be available in the step.

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 10 possible actions:

| Name of Activity | Type | Description |
|---|---|---|
| | | |
| **Sender(s) / Reporter(s)** | Form | Opens a form to fill in a series of tabs for filling in information about the ICSR case and Reporter(s), namely:<br>**Case Safety Report** (ICSR Category, Type of Report, Date of report, WWUI, etc.)<br>**Study Identification** (Study name, Sponsor study number, etc.)<br>**Linked report(s)** (List of linked reports)<br>**Source Identifier(s)** (Source of the case identifier, Case identifier)<br>**Source(s) of information** (Reporter title, Reporter name, Reporter qualification, etc., Primary source for regulatory purposes, etc.)<br>**Literature Reference(s)** (List of Literature reference(s) (documents)) |
| **Patient / Parent** | Form | Opens a form to fill in a series of tabs for filling in information about the Patient and Parent information, namely:<br>**Patient** (Patient name, Date of Birth, Age, etc.)<br>**Medical History** (Patient Medical Records, Pregnancy, Medical record number(s), MedDRA code, Start date, End date, etc.)<br>**Past Drug History** (WhoDrug code, Start date, End date, etc.)<br>**Result of Test and Procedures** (Test date, Test Name, Test result code, etc.)<br>**Death** (Date of death, Reported causes of Death MedDRA code, Autopsy determined causes of Death MedDRA code, etc.)<br>**Parent** (parent name, date of birth, age etc.)<br>**Relevant Medical History of Parent** (MedDRA code, Start date, End date, etc.)<br>**Relevant Past Drug History of Parent** (WhoDrug code, Start date, End date, etc.) |
| **Reporter(s)** | Form | **Reporter(s)** (Source of information, Reporter name, Qualification, Country, Email address, etc.) |
| **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, Product type, Action(s) taken with Drug, etc.)<br>**Indication(s)** (Indication as reported, MedDRA code, etc.)<br>**Substance(s)** (Substance name, strength, MedDRA code, etc.) |

| | | |
|---|---|---|
| | | **Dosage(s)** (Dose numbers, Start date, End Date, Batch Number, Pharmaceutical Dose Form, Route of Administration, 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 | Opens a form to fill in a series of tabs for filling in information about the Patient and Parent information, namely:<br>**Narrative Case Summary and Further Information** (Case Narrative, Reporters Comments, Sender Comments)<br>**Diagnosis** (Senders diagnosis/syndrome MedDRA)<br>**Reporters Comments** (Case Summary and Reporters comments) |
| **Event listedness and datasheets** | Form | Opens a form in a tabular view to fill in listedness assessment details with information on Product, Event, Datasheet Name, and Assessment |
| **Task Relocation (Refuted ICSR)** | Link | Opens a dialog box to confirm task relocation (Refute ICSR) and a comments section in which the user states a reason for the refusion.<br>The reason provided will be added to the record Notes field. |
| **Create Follow-up** | Link | Allows the user to create a related/follow-up record to the existing record. |

*Table 5 Register ICSR Information Form and Link activities*

### 5.2.2. Quality Control

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):**

*Quality Control is to be performed according to procedures. Click on the data forms to review the case information. Fill in the QC form and Complete task if the record information and quality is satisfactory.*

*Send task back to previous workflow step if the quality of the ICSR information doesn't live up to the required standards.*

This workflow step ensures records are peer-reviewed and quality controlled. The record has a **Quality Control form** which needs to be checked and performed by another user who completed the record initially. Depending on the validation rules applied, this form must be completed before the task can be routed to the next step in the workflow. If the quality of the ICSR information does not meet the required standards, the record can be routed back to the previous step.

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step. The additional task steps for the Medical Review workflow (in addition to above mentioned in table 5) comprise two actions:

| Name of Activity | Type | Description |
|---|---|---|
| | | |
| **Quality Control** | Form | Opens a dialog box to confirm that Quality Control has been performed and a comments section in which the user states any quality comments.<br>Depending on the validation rules applied, this form is mandatory before the task can be routed to the next step in the workflow (note: A different user must complete Quality Control than the user completing the previous task). |
| **Create Submission Record** | Link | Allows the user to manually create a linked submission record to the record, which will appear in the Submission process Module. |

### 5.2.3. Medical Review

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):**

*Medical review is to be performed according to procedures. Click on actions to review case information and click Complete task once the review is completed.*

*Note: Medical Review is only mandatory for Serious cases.*

As with the Quality Control step, the Medical review step is introduced to ensure that serious cases are medically reviewed and controlled by a Medical Reviewer.

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step. The additional task steps for the Medical Review workflow (in addition to above mentioned in table 5) comprise two actions:

| Name of Activity | Type | Description |
|---|---|---|
| | | |
| **MR Review** | Form | Opens a dialog box to confirm that Medical Review has been performed and a comments section in which the user states any review comments.<br>Depending on the validation rules applied, this form is mandatory before the task can be routed to the next step in the workflow (note: MR review must be completed by a different user than the user completing the previous task). |

| | | |
|---|---|---|
| **Create Submission Record** | Link | Allows the user to manually create a linked submission record to the record, which will appear in the Submission process Module. |

### 5.2.4. Submission

The Submission workflow is an automatic step. The automator compares the ICSR record with the **ICSR Requirements** and the **Product configuration**. Suppose all mandatory ICSR information and applicable rules are matched. In that case, the Automator creates submission record(s) according to the rule(s) configured, which will show as child records in the **Related Records** section.

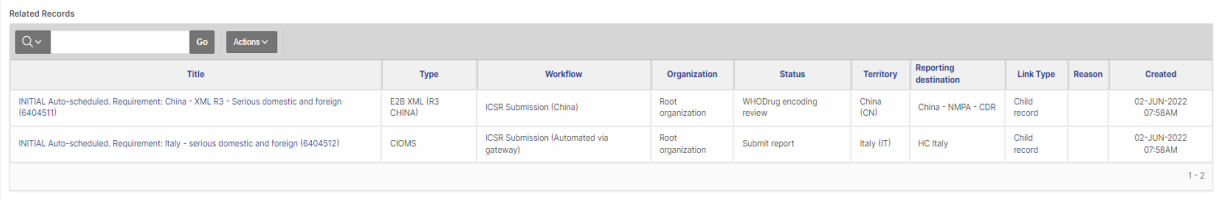



*Figure 6 – Auto-scheduled submission records*: *For more details on the actual submission record, see the Submissions Module Manual.*

After scheduling, the automation step is completed, and the next step in the workflow (if configured) is activated.

If auto-scheduling fails, the record **Workflow history** is updated with either a message indicating no applicable rules were found or an error message if any errors were found.

Submission records are available in the Submission Module and assigned to the different workflow processes depending on your system configuration.

## 5.3. ICSR Follow-up Ingestion

This workflow aims to add and process Follow-up information to existing ICSR records.


The workflow consists of 2 task steps:

- *Add Follow-up Information* (***Error! Reference source not found.***)
- *Completed Follow-up* (***Error! Reference source not found.***)

**Add Follow-up Information**

### 5.3.1. Add Follow-up Information

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):**

*Register and/or review new data points for follow-up information to existing records by using the 'Show and process follow-up data' link. Use the 'Associate parent ICSR' link to link the record to an existing parent record. Attach or link documented attempt to follow up with source if applicable.*

This workflow enables users to ingest follow-up information to existing ICSR records received either from a source or from the ICSR Intake workflow, deemed to be follow-up. Using the **'Show and process follow-up data**' link, users can review new data points and verify if the new data is applicable as new follow-up information to be merged into an existing ICSR record.

The' **Associate parent ICSR'** link can be used if the record is not already linked to a parent ICSR record. Remember to attach any source documents and/or link any ICSR Follow-up Queries/Correspondence records to the record.

### 5.3.2. Completed Follow-up

This is an automation in which the follow-up information is automatically merged into the master record upon completion.

If the case is not automatically transferred, then look up the workflow history for error investigation.

## 5.4. ICSR Follow-up Queries/Correspondence

The ICSR Follow-up Queries/Correspondence workflow aims to pursue inquiries for follow-ups from the source and process the information.


The workflow consists of 4 task steps:

- *Pursue ICSR follow-up questions and register information (**Error! Reference source not found.**)*
- *Send Correspondence (**Error! Reference source not found.**)*
- *Await Information (5.4.3)*
- *Receive/Process Information (5.4.4)*

### 5.4.1. Pursue ICSR Follow-up Questions and Register Information

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):**

*Register ICSR Correspondence e.g. Follow-up questions in the Contents field. Use the Generate from template to auto-populate the contents with a predefined template.*

*Any ICSR Correspondence record should be linked to either an ICSR Processing or ICSR Follow-up record. This is done by clicking the Associate parent ICSR button and choosing the associated ICSR or associate parent Follow-up button and choosing the associated Follow-up parent (Follow-up query record can also be created from parent ICSR record).*

This workflow allows the user to pursue follow-up information to any ICSR record from the source. The ICSR Follow-up Query/Correspondence record should be linked using either the '**Associate parent ICSR'** link or by creating the follow-up query from within the parent ICSR record.

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 3 actions:

| Name of Activity | Type | Description |
|---|---|---|
| | | |
| **Correspondence Recipient(s)** | Drop down / Text field | A tabular view where users can add desired recipient(s) email address on the source to pursue any inquiries/follow-up. The date when the inquiry is sent will be auto-populated once the task is completed. |
| **Generate Document From Template** | Form | Form in which document template is defined (if configured) as well as a template file, output format, and possibility to upload to the working folder |
| **Correspondence Contents** | Text field | Allows the user to formulate a follow-up inquiry and generate a document(s) from templates (if configured), which can also be downloaded locally. |
| **Manage Attachments** | Link | Opens the record attachment window, i.e., the link action is a shortcut to managing attachments. The attachments functionality is generally available in all records types. |
| **Letter Template** | Link | Directs the user to a specified Letter template (if configured) |
| **Associate Parent ICSR** | Link | Allows the user to Link the ICSR follow-up record to a parent ICSR record. |

### 5.4.2. Send Correspondence

The Send Correspondence workflow is an automation workflow. The Automator sends an email containing the correspondence contents to the configured recipient(s) from the previous step. The recipients will then be able to respond to correspondence directly from their mailbox.

### 5.4.3. Await Information

This automated step waits for any reply to the Follow-up correspondence sent in the previous step. Once any reply is received, the Automator transfers to the next workflow step, Receive/Process information with the new information.

Users can only go to the record and view the time stamp in the correspondence recipient box to check the date and time the correspondence was sent.

### 5.4.4. Receive/Process Information

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 information has been received from source and can be amended to the parent ICSR record either manually or via the Follow-up Ingestion workflow.*

The record with the acquired follow-up information in the ICSR Follow-up Queries/Correspondence workflow should be linked as a child record to the parent ICSR record if not already done in previous workflow steps.

All ICSR Follow-up Queries/Correspondence records will be stored in the workflow to document any follow-up inquiries made and distributed accordingly.

## 5.5. Refuted ICSRs


The Refuted ICSRs workflow aims to have an overview of all ICSRs deemed for non-processing and therefore refuted.

The workflow consists of one task step:

- *Manage Refuted ICSRs (**Error! Reference source not found.**)*

The following section will explain the task in further detail:

### 5.5.1. Manage Refuted ICSRs

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 ICSRs do not have a pre-defined set of activities. The task can be completed if no further action is deemed necessary.*

All Refuted ICSR records will be stored in the workflow in case they are found valid for later re-activation.

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step. The available task steps contain the below actions.

| Name of Activity | Type | Description |
|---|---|---|
| | | |
| **Sender(s) / Reporter(s)** | Form | Opens a form to fill in a series of tabs for filling in information about the ICSR case and Reporter(s), namely: |

| | | |
|---|---|---|
| | | **Case Safety Report** (ICSR Category, Type of Report, Date of Report, WWUI, etc.)<br>**Study Identification** (Study name, Sponsor study number, etc.)<br>**Linked report(s)** (List of linked reports)<br>**Source Identifier(s)** (Source of the case identifier, Case identifier)<br>**Source(s) of information** (Reporter title, Reporter name, Reporter qualification, etc., Primary source for regulatory purposes, etc.)<br>**Literature Reference(s)** (List of Literature reference(s) (documents)) |
| **Patient / Parent** | Form | Opens a form to fill in a series of tabs for filling in information about the Patient and Parent information, namely:<br>**Patient** (Patient name, Date of Birth, Age, etc.)<br>**Medical History** (Patient Medical Records, Pregnancy, Medical record number(s), MedDRA code, Start date, End date, etc.)<br>**Past Drug History** (WhoDrug code, Start date, End date, etc.)<br>**Result of Test and Procedures** (Test date, Test Name, Test result code, etc.)<br>**Death** (Date of death, Reported causes of Death MedDRA code, Autopsy determined causes of Death MedDRA code, etc.)<br>**Parent** (parent name, date of birth, age, etc.)<br>**Relevant Medical History of Parent** (MedDRA code, Start date, End date, etc.)<br>**Relevant Past Drug History of Parent** (WhoDrug code, Start date, End date, etc.) |
| **Reporter(s)** | Form | **Reporter(s)** (Source of information, Reporter name, Qualification, Country, Email address, etc.) |
| **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, Product type, Action(s) taken with Drug, etc.)<br>**Indication(s)** (Indication as reported, MedDRA code, etc.)<br>**Substance(s)** (Substance name, strength, MedDRA code, etc.)<br>**Dosage(s)** (Dose numbers, Start date, End Date, Batch Number, Pharmaceutical Dose Form, Route of Administration 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 | Opens a form to fill in a series of tabs for filling in information about the Patient and Parent information, namely: |

| | | |
|---|---|---|
| | | **Narrative Case Summary and Further Information** (Case Narrative, Reporters Comments, Sender Comments)<br>**Diagnosis** (Senders diagnosis/syndrome MedDRA)<br>**Reporters Comments** (Case Summary and Reporters comments) |
| **Event listedness and datasheets** | Form | Opens a form in a tabular view to fill in listedness assessment details with information on Product, Event, Datasheet Name, and Assessment |
| **Task Relocation (Move to ICSR Processing)** | Link | Opens a dialog box to confirm task relocation (Move to ICSR Processing) and a comments section in which the user states a reason for the relocation.<br>The reason provided will be added to the record Notes field. |

Note: these actions wouldn't usually be edited in the Refuted ICSRs workflow as the ICSR is refuted. Only the final Action would be applicable in case the record was refuted in error, and the ICSR record is needed to be relocated to ICSR processing workflow.

# 6. Functionalities

The functionalities of the Module are found on the Module's main screen. The following section(s) list the available functionalities and describe their use. Typically, the functionalities add value to the Module by providing dashboarding, reporting, or associated features. The standard functionalities for the ICSRs module are below:

- ICSR Active Workflow Report
- ICSR Daily Triage Report

Besides searching and filtering in the reports, the **Actions** button can perform advanced searches, add/remove columns, create charts, and much more. For further instructions on how to work with the interactive reports, please consult the separate Guide - Interactive Reports.

## 6.1. ICSR Active Workflow Report

The ICSR Active Workflow Report provides an overview of all ICSR records and which current workflow task they reside in by clicking the report. This allows users to quickly identify in which state any ICSR record of interest is currently in, and gives an idea of the workload for each of the different tasks associated with the ICSR processing.

Additionally, the report holds key ICSR information like Case Number, Case Seriousness, Country of origin, Initial Receipt date and Events, etc., which helps apply filtered searches in the report.

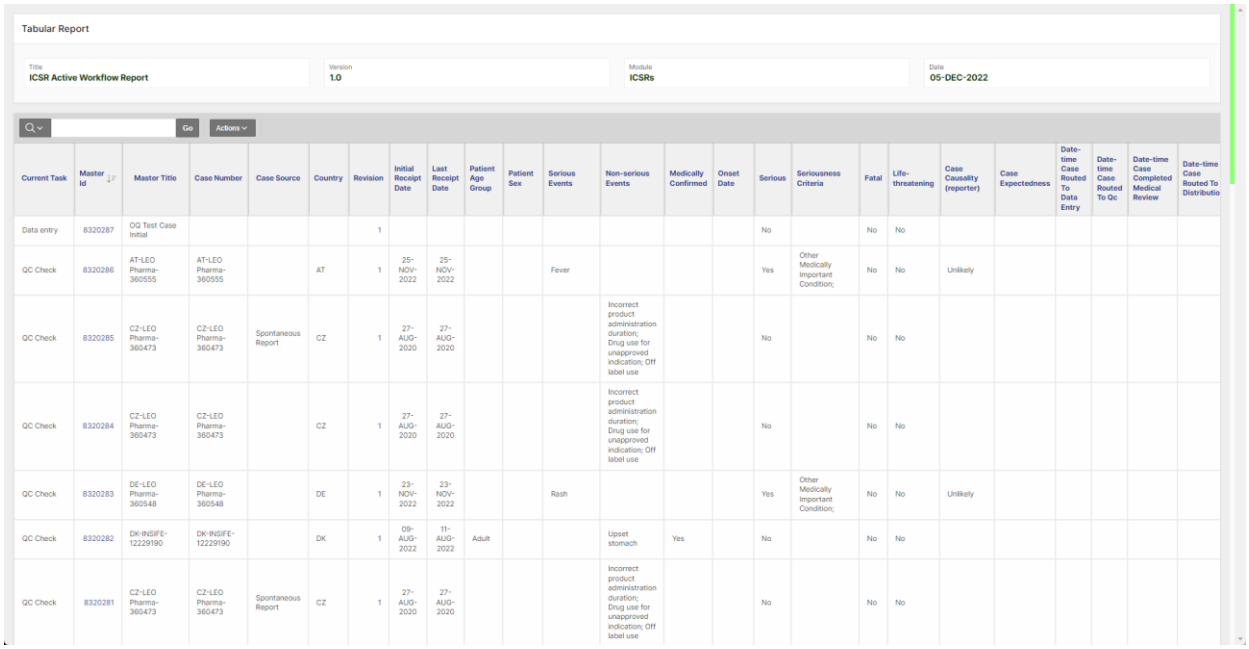



*Figure 7 – ICSR Active Workflow Report*

## 6.2. ICSR Daily Triage Report

The ICSR Daily Triage Report provides an overview of all ICSR records and their overall due date and next submission date. This allows users to quickly identify the number of cases closing in on their due dates and get a sense of the projected workload in the near future. This helps prioritize the right ICSR records daily and is a simple but effective tool for due diligence in terms of ICSR submissions and maintaining compliance.

Additionally, the report holds key ICSR information like Case Number, Case Seriousness and Country of Origin, etc., which is helpful for applying filtered searches in the report.

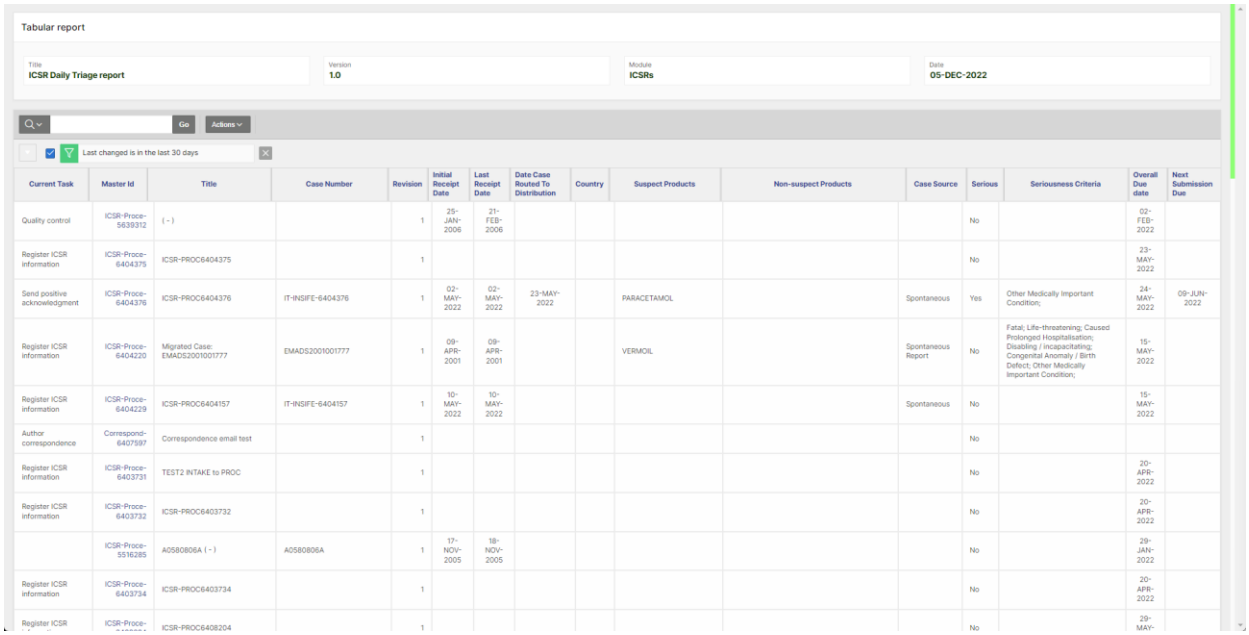



*Figure 8 – ICSR Daily Triage Report*

Note: A default filter is applied to the report ('Last changed is in the last 30 days') to minimize the data load time, as the report would otherwise load every ICSR record in the system.

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