

# Labelling (Dictionaries and Terms)



## HALOPV / PROHALO 4.X USER GUIDE

This is an end-user guide for  
Labelling (Dictionaries and  
Terms) module of the drug safety  
solution HALOPV / PROHALO.

# Contents

1.	HALOPV / PROHALO Labelling (Dictionary and Terms) module user manual .....	2
2.	Preface.....	2
3.	Introduction.....	3
3.1.	Purpose of this document.....	3
3.2.	Modules of HALOPV.....	3
3.3.	About HALOPV (incl. PROHALO) .....	3
4.	Navigating the Labelling (Dictionaries and Terms) module.....	4
4.1.	Module Main Screen.....	4
4.2.	User roles relevant for the Module .....	5
5.	Standard Workflows.....	6
5.1.	GMDN term collections workflow .....	6
5.2.	IMDRF term collections workflow .....	8
5.3.	MedDRA term collections workflow .....	10
5.4.	Summary of Product Characteristics workflow .....	12
6.	Functionalities .....	14
7.	Forms reference .....	14

# 1. HALOPV / PROHALO Labelling (Dictionary and Terms) module user manual

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

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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 and multi-tenant HALOPV (branded as PROHALO) is available at

<https://www.halopv.com> or

<https://insife.com/halopv>

Insife Support:

Insife Support team can be reached out at [Support@insife.com](mailto:Support@insife.com)

## 3. Introduction

### 3.1. Purpose of this document

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

The overall guide for using general features is available online on [General features \(insife.com\)](https://insife.com)

### 3.2. Modules of HALOPV

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

- Aggregate Reporting Module
- Agreements Module
- Clinical Trials Module
- Complaints Module
- Data Collection Programs Module
- Device Incidents Processing Module
- Entities Module
- ICSRs (Medicine and Vaccine Incidents) Module
- Literature Monitoring Module
- Labelling 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 \(insife.com\)](https://insife.com)

### 3.3. About HALOPV (incl. PROHALO)

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

## 4. Navigating the Labelling (Dictionaries and Terms) module

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

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

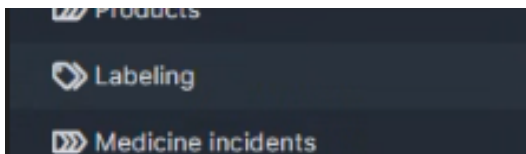
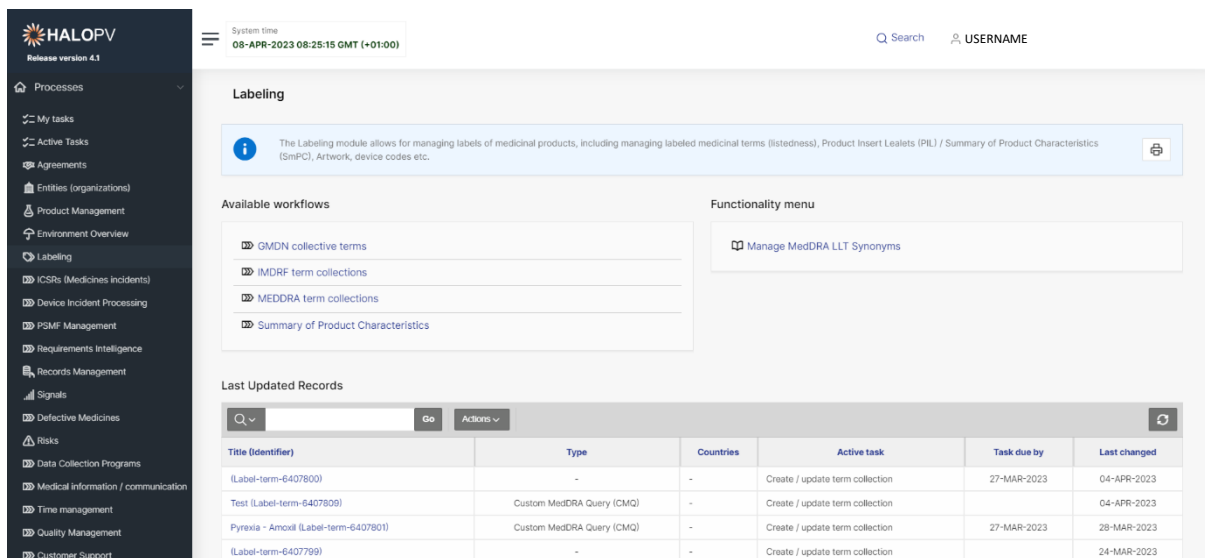


Figure 1 Left menu, Labelling is available for users with the appropriate access role

N.B. the Labelling module has changed name to Dictionaries and Terms. This is the official module name from HALOPV 5.0 onwards.

### 4.1. Module Main Screen

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

A screenshot of the HALOPV application's main screen for the 'Labeling' module. The interface includes a dark sidebar with the HALOPV logo and a list of navigation items. The main content area is titled 'Labeling' and contains a blue information banner, a section for 'Available workflows' with four items, a 'Functionality menu' with one item, and a 'Last Updated Records' table. The table has columns for Title (Identifier), Type, Countries, Active task, Task due by, and Last changed. The table contains four rows of data.

Title (Identifier)	Type	Countries	Active task	Task due by	Last changed
(Label-term-6407800)	-	-	Create / update term collection	27-MAR-2023	04-APR-2023
Test (Label-term-6407809)	Custom MedDRA Query (CMQ)	-	Create / update term collection		04-APR-2023
Pyrexia - Amoxicil (Label-term-6407801)	Custom MedDRA Query (CMQ)	-	Create / update term collection	27-MAR-2023	28-MAR-2023
(Label-term-6407799)	-	-	Create / update term collection		24-MAR-2023

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

Click on a workflow or functionality to access it.

## 4.2. User roles relevant for the Module

Users must be assigned roles to access the relevant modules. Furthermore, user roles can allow access or editing rights for a record when it is in a specific workflow task step. Please consult the table below for standard user roles that are provided with the system. Other user roles may have been configured by your administrator. For a description on how to administer users and user roles, please refer to the [Admin Guide \(insife.com\)](https://insife.com)

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

*Table 1 User roles for the Labelling module*

# 5. Standard Workflows

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

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

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

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

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

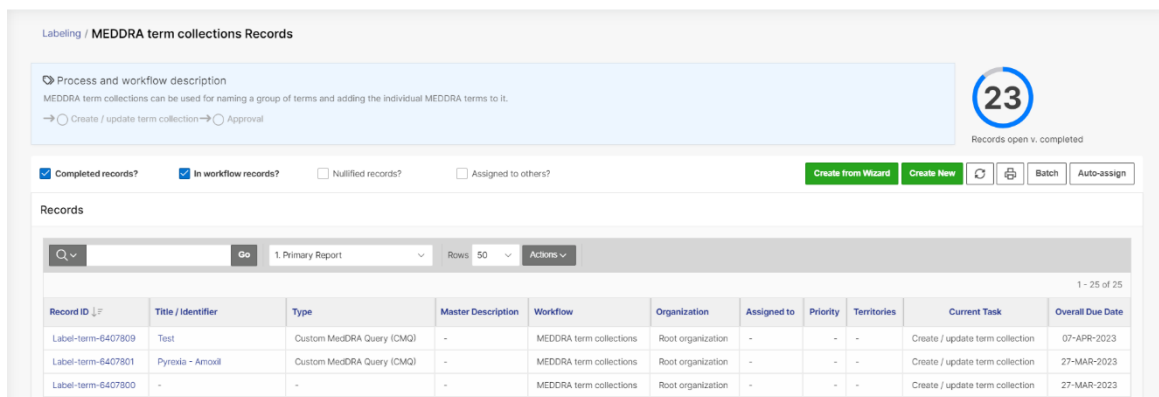


Figure 3 When clicking on a workflow, the following screen displays the Process and workflow description (if configured) as well as a worklist of records, where the Record ID and title can be clicked to access the record.

End users can update reports using the **Actions** button. Please consult the **User Guide - Interactive Reports**.

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

## 5.1. GMDN term collections workflow



The purpose of the workflow is to manage term collections based on the Global Medical Device Nomenclature (GMDN) dictionary from the [GMDN Agency](#). Users in HALOPV can decide contents in collections, i.e. with GMDN terms and GMDN “Collective terms” (CT) are included in the collection.

The workflow consists of two task steps:

- Create / update term collection (5.1.1)

- Review and approve term collection 5.1.2)

The following sections will explain the tasks in further detail:

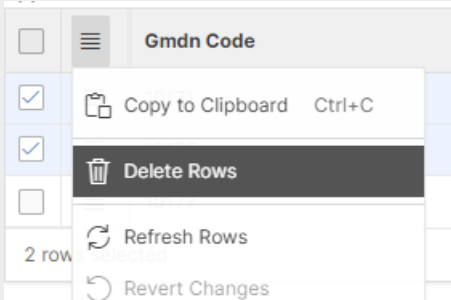
### 5.1.1. Create / update term collection (Step 1)

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

**Task instructions (as shown in the application):**

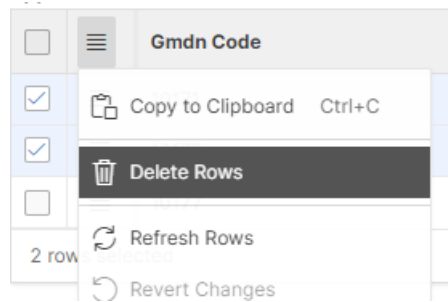
*The associated term collection form will allow you to manage the list of terms for the collection. You should provide a meaningful title of the record, i.e. the code of the CT (collective term), e.g. CT1234. Open the GMDN Collection form to add/edit GMDN codes to the CT. Open the GMDN Collective term group to add/remove already existing CTs into the CT*

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 two actions:

Data form action	Description
<b>GMDN Collection Selector</b>	<p>This form selector allows for selecting GMDN terms from the GMDN dictionary. Click the action to open the form. The top grid contains the terms already selected into the collection. To add a term, go to the bottom, interactive reports called "Add terms from GMDN", and click the "plus" icon on a GMDN term to add it to the collection. To remove one or more GMDN terms from the collection, use the tickmarks in the top grid. Once selected the items for deletion, click the icon with three lines and choose "Delete Rows"</p> 
<b>GMDN Collective term group</b>	<p>This form selector allows for selecting GMDN CTs from the list of existing GMDN collection (CTs) records. The top grid contains the terms already selected for the collection. To add a term, go to the bottom, interactive report called "Add GMDN Collective term to collection", and click the "plus" icon on a GMDN CT to add it to the collection. In order to remove one or more GMDN CTs from the collection,</p>



use the tickmarks in the top grid. Once selected the items for deletion, click the icon with three lines and choose “delete rows”



### 5.1.2. Review collection (Step 2)

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

#### Task instructions (as shown in the application):

*Review and approve the Collective term selections by clicking on the forms and reviewing the selected GMDN codes and CTs respectively. Click “Complete task” to complete the record revision.*

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

Data form action	Description
<b>GMDN Collection Selector</b>	The form used for review is the same as for editing, as described in the above section.
<b>GMDN Collective term group</b>	The form used for review is the same as for editing, as described in the above section.

## 5.2. IMDRF term collections workflow



The purpose of the workflow is to maintain a list of term collections for [the International Medical Device Regulators Forum \(IMDRF\)](#) codes, including terms from IMDRF annexes A-G

The workflow consists of two task steps:

- *Creates / update term collection (5.2.1)*
- *Review and approve term collection (5.2.2)*

The following sections will explain the tasks in further detail:

### 5.2.1. Create / update term collection (Step 1)

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

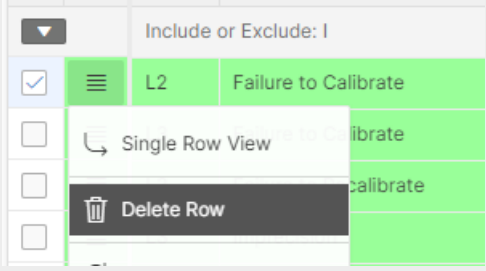
#### **Task instructions (as shown in the application):**

*The associated term collection will allow you to manage the list of terms for the collection. Click on the “Advanced IMDRF Query Builder” to create or update the collection of terms.*

*Remember to give the collection a meaningful title. Click on the link above to change title.*

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

<b>Data form action</b>	<b>Description</b>
<b>Advanced IMDRF Query Builder</b>	<p>This form selector allows for selecting IMDRF codes from various levels and from all IMDRF annexes, A-G</p> <p>Click the action to open the form.</p> <p>At the top, you will find the Dictionary selector. If kept blank, all annexes will be available in the selector. Selecting an annex in the dropdown will limit the selection options to that annex only.</p> <p>The collection builder is based on two sections:</p> <ul style="list-style-type: none"><li>- on the left side, you can in a grid search and select codes on various levels. (These may be color coded depending on the level, in a later version of HALOPV.) The search field on the top allows for a cross-search in all available columns. When identifying one or more terms to add to the collection, select them by clicking the tickbox(es) to the far left. Then click the “Add selected to included / preferred” (green button). You can also use the “Add selected to excluded” (red button) instead, if you want to mark the terms as terms that should subtract when using the collection in a query.</li><li>- on the right side, in another grid, you can see all the terms included in the collection in green color (if any). Below, you can see the terms (if any) that have been added to the excluded list in red. You can remove terms from both the included and excluded list by using the tickmarks to the left of the term(s) you want to remove, then clicking the icon with three lines and selecting “Delete Row”.</li></ul>



If you want to save the include/exclude list to an Excel sheet attached to the record, click the “Save report to Excel attachment” button. You can then find the sheet in the attachments section of the record.

### 5.2.2. Review and Approve term collection (Step 2)

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

**Task instructions (as shown in the application):**

*Review and approve the term collection selections by clicking on the forms and reviewing the selected include and exclude list. Click “Complete task” to complete the record revision.*

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

Data form action	Description
Advanced IMDRF Query Builder	The form used for review is the same as for editing, as described in the above section.

## 5.3. MedDRA term collections workflow



The purpose of the workflow is to maintain a list of term collections for [the Medical Dictionary for Regulatory Activities \(MedDRA\)](#) codes, from SOC to LLT levels

The workflow consists of two task steps:

- Create / update term collection (5.3.1)
- Review and Approve term collection (5.3.2)

The following sections will explain the tasks in further detail:

### 5.3.1. Create / update term collection (Step 1)

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

**Task instructions (as shown in the application):**

*The MedDRA term collection record allows associating any number of terms to the record as a “collection”. The associated term collection will allow you to manage the list of terms for the collection. Click on the “Advanced MedDRA Query Builder” to create or update the collection of terms. Remember to give the collection a meaningful title as well as a type, e.g., “CMQ”. Click on the link above to change the title and type.*

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 two actions:

Data form action	Description
<p><b>Advanced MEDDRA Query Builder</b></p>	<p>This form selector allows for selecting MedDRA codes from various levels.</p> <p>Click the action to open the form.</p> <p>The collection builder is based on two sections:</p> <ul style="list-style-type: none"> <li>- on the left side, you can, in a grid, search and select codes on various levels. (These may be color coded depending on the level in a later version of HALOPV.) The search field on the top allows for a cross-search in all available columns. When identifying one or more terms to add to the collection, select them by clicking the tickbox(es) to the far left. Then click the “Add selected to included / preferred” (green button). You can also use the “Add selected to excluded” (red button) instead, if you want to specifically mark the terms as terms that should subtract when using the collection in a query.</li> <li>- on the right side, you can in another grid see all the terms that have been included in the collection in green color (if any). Below, you can see the terms (if any) that have been added to the excluded list in red. You can remove terms from both the included and excluded list by using the tickmarks to the left of the term(s) you want to remove, then clicking the icon with three lines and selecting “Delete Row.”</li> </ul>  <p>If you would like to save the include/exclude list to an Excel sheet that is attached to the record, click the “Save report to Excel attachment” button. You can then find the sheet in the attachments section of the record.</p>

### 5.3.2. Review and Approve collection (Step 2)

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

**Task instructions (as shown in the application):**

*Review and approve the provided requirements information. Once the Task Activities are completed, please click the Complete Task button to finalize the registration.*

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

Data form action	Description
Advanced MEDDRA Query Builder	The form used for review is the same as for editing, as described in the above section.

## 5.4. Summary of Product Characteristics workflow



The purpose of the workflow is to maintain documentation, which contains a list of term collections for [the Medical Dictionary for Regulatory Activities \(MedDRA\)](#) codes, from SOC to LLT levels, specific to Summary of Product Characteristics (SmPC), which is used for assessing case listedness against the label of the product. The workflow also enables the user to print a full SmPC out based on a template.

The workflow consists of two task steps:

- *Create / update documentation incl. term collection (5.4.1)*
- *Review and approve documentation (5.4.2)*

The following sections will explain the tasks in further detail:

### 5.4.1. Create / update documentation incl. term collection (Step 1)

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

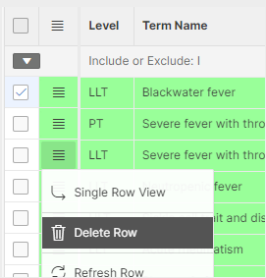
**Task instructions (as shown in the application):**

*Manage the attached document(s), and if relevant, use the MedDRA collection form to maintain a list of terms that are to be considered listed, i.e., in section 4.8 Undesirable effects. Click on the "Advanced MedDRA Query Builder" to create or update the collection of terms.*

*Remember to give the collection a meaningful title. Click on the link above to change the title.*

Click on the “Generate document from template” to apply the MedDRA collection into a template document. Click on the attachments icon to add or modify the list of documents

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

Data form action	Description
<p><b>Advanced MEDDRA Query Builder</b></p>	<p>This form selector allows for selecting MedDRA codes from various levels.</p> <p>Click the action to open the form.</p> <p>The collection builder is based on two sections:</p> <ul style="list-style-type: none"> <li>- on the left side, you can, in a grid, search and select codes on various levels. (These may be color coded depending on the level in a later version of HALOPV.) The search field on the top allows for a cross search in all available columns. When identifying one or more terms to add to the collection, select them by clicking the tickbox(es) to the far left. Then click the “Add selected to included / preferred” (green button). You can also use the “Add selected to excluded” (red button) instead, if you want to specifically mark the terms as terms that should subtract when using the collection in a query.</li> <li>- on the right side, in another grid, you can see all the terms included in the collection in green color (if any). Below, you can see the terms (if any) that have been added to the excluded list in red. You can remove terms from both the included and excluded list by using the tickmarks to the left of the term(s) you want to remove, then clicking the icon with three lines and selecting “Delete Row”.</li> </ul>  <p>If you want to save the include/exclude list to an Excel sheet attached to the record, click the “Save report to Excel attachment” button. You can then find the sheet in the attachments section of the record.</p>
<p><b>Generate document from template</b></p>	<p>This form can generate a document from a template and either download it directly or add it to the attachments section of the record. Documents will be generated in Word or PDF as per user choice. Once the template and format is selected, you can generate the document by clicking the “Generate” button.</p> <p>Options:</p> <p><b>Interactive report (Optional)</b></p>

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This option allows the selection of the interactive report for generation instead of the pre-defined interactive report configured in the Document generation template. This option requires that only one Interactive report placeholder is configured in the template

**Template file (Optional)**

This option allows the selection of the WORD template file to use for generation instead of the pre-defined template configured in the Document generation template

**Template file from work (Optional)**

This option allows the selection of the WORD template file to use for generation instead of the pre-defined template configured in the Document generation template

**Upload to working folder**

This option allows upload to the “Working folder” attachment area instead of the default attachment storage. This option is only available if a Working folder is configured (System configuration > OneDrive integration). Working folder is another word for a Sharepoint / Onedrive folder.

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## 5.4.2. Review and approve documentation (Step 2)

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

**Task instructions (as shown in the application):**

*Review the documents in the record and/or its attachments. Once the Task Activities are completed, please click the Complete Task button to conclude the record registration.*

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 no additional actions.

## 6. Functionalities

There are no functionalities configured in the standard Labelling module.

## 7. Forms reference

There are no specific form references for the Labelling module.