Agreements

HALOPV / PROHALO 4.X
USER MANUAL

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

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1. HALOPV / PROHALO Agreements module user manual

User Manual - Release 4.X (4.0 first released MAY 2022)

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

3. Introduction

3.1. Purpose of this document

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

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

3.2. Modules of HALOPV

At the time of writing of this manual, the modules comprise of:

- Aggregate reporting module
- Agreements module
- Clinical studies module
- Complaints module
- Data collection programs module
- Devices module
- Entities (Organizations) module
- ICSRs module
- Labelling module
- Literature module
- Medical information and communications module
- 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, on Admin Guide (insife.com).

3.3. About HALOPV (incl. PROHALO)

HALOPV is a cloud-based system. Internet connectivity is required, but 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.

4. Navigating the Agreements module

It is assumed that you have logged in and have the module overview available in the left menu. Otherwise, please refer to our General Features user manual.

The Agreements module will appear if your user profile has access to the module.

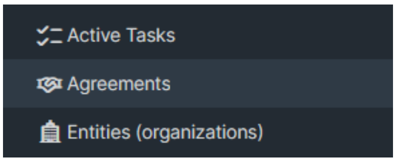


Figure 1 Left menu, Agreements is available for users with the appropriate access role

4.1. Module main screen

The main screen for the module lists all available *workflows* as well as *functionalities* (if any)

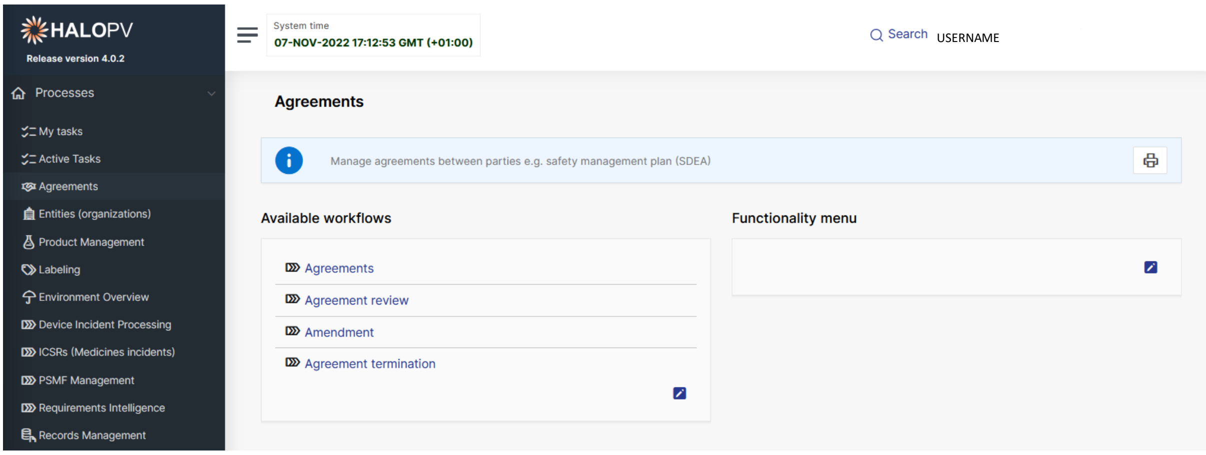


Figure 2 The standard list of Workflows and Functionality Menu items for Agreements module

Simply 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 be allowing access or editing rights for a record when it is in a specific workflow task step. Please consult the table below for standard user roles that are provided with the system. Other user roles may have been configured by your administrator. For a description on how to administer users and user roles, please refer to the Admin Guide (insife.com)

User role	Description
Generic Agreements processing	Provides access to the Agreements module in the navigation and all task roles

Table 1 User roles for the Agreements module

5. Standard Workflows

The module comes pre-configured with a number of standard workflows. These are described in the following sections, including tasks and actions associated.

> 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 to the standards.

Clicking on a workflow takes you to the worklist for the workflow, with all the records that are in workflow at the current time. See also Figure 2.

Clicking on the “Record ID” or “Agreement name” takes you to the individual record. See Figure 3 below.

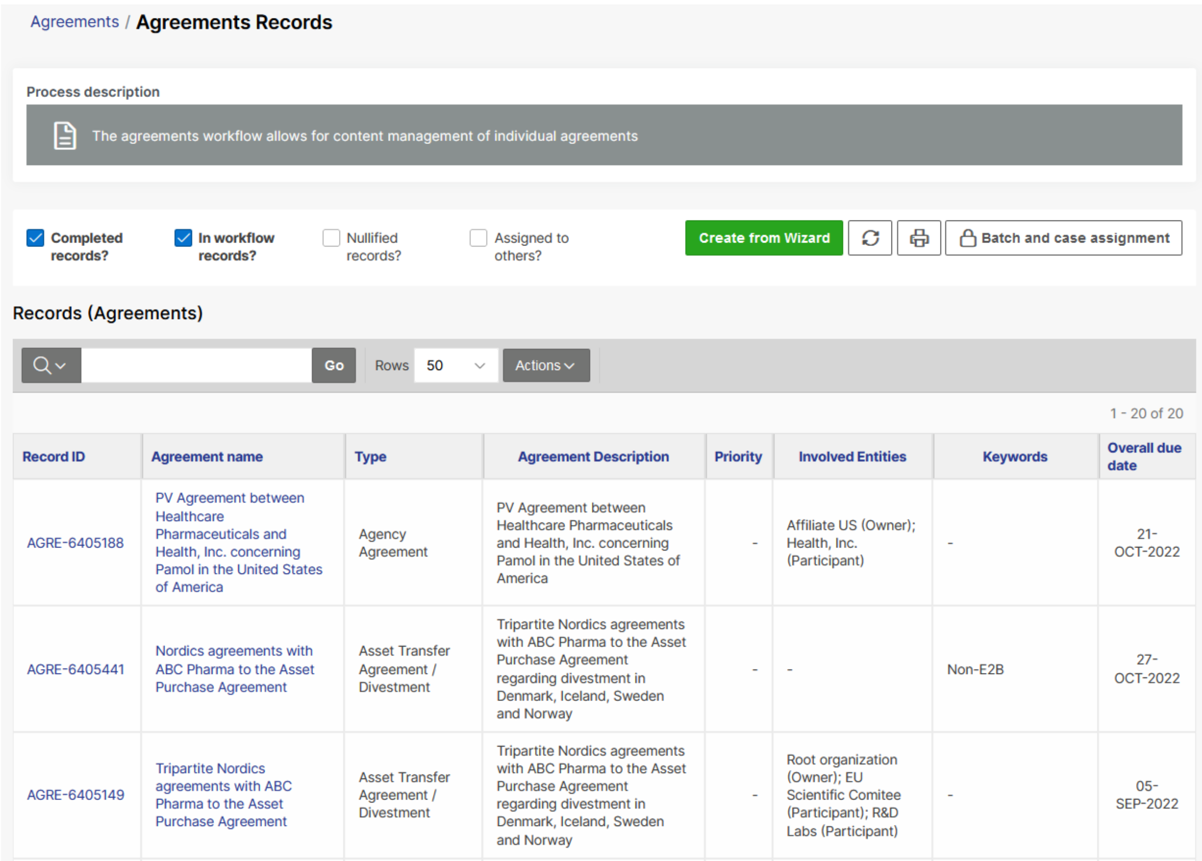


Figure 3 When clicking on a workflow, the following screen displays Process and workflow description (if configured) as well as a worklist of records, where the Record ID and title can be clicked to access the record.

5.1. Agreements workflow

The purpose of the workflow is to manage an agreement between your organization and a 3rd party (e.g. license partner, CRO, Service Provider) as a records with the ability to create agreement documents from templates, manage the activities for the agreement and to document the content of the agreement for further use in HALOPV / ProHALO.

The workflow consists of the following task steps:

The following sections will explain the tasks in further detail.

5.1.1. Create/update Agreement

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):

Initiate the agreement creation/update process and populate the agreement form.

The PV Agreement (SDEA) can be generated in this step. It will be stored in the attachments section for further distribution. Alternatively, an agreement ID can be added if the agreement is stored in another source system.

As with any other task in the application, you must have the corresponding role assigned to be able to process the record in the task step. The first task step contains the following activities (link to click to view/process information):

Data form action	Description
Agreements form (PVA)	This form allows for capturing information about the agreement, including agreement details, involved organizational entities, territories, products and/or studies covered by the agreements and the role of the agreement. Please see the Form reference section (14) for details about the form elements.
Generate document from template	Generate an Agreement document from a defined template. The template may contain placeholders to incorporate HALO information into the agreement itself, e.g. address details of the involved organizations.
Agreement responsibilities	This form allows for documenting the responsibilities of the 3rd party with regards to PV relevant activities such as Forwarding of case reports, regulatory reporting, reconciliation, etc.
Assign Partner to agreement	This form allows to link an agreement to a 3rd party (HALOPV / ProHALO external entity).
Copy previous attachment into current revision	In case an existing agreement needs to be updated, activity allows a user to copy the existing agreement from the previous record revision to the current revision.
Upload working file	In case the user manages the agreement documents outside of HALOPV / ProHALO, the user is able to upload the agreement to HALO.

5.1.2. Internal Review task step

The **Internal Review** task step allows for another member of the organization to perform a review of the proposed agreement.

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):
Check that the information in the record is correct and complete the task. If information is not ok, press “Send back task”

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 task step contains the following activity:

Data form action	**Description**
Agreements form (PVA)	This form allows for capturing information about the agreement, including agreement details, involved organizational entities, territories, products and/or studies covered by the agreements and the role of the agreement. Please see the Form reference section (14) for details about the form elements.

5.1.3. External Review task step

The **External Review** task step allows to document that a member of the 3rd party reviewed the proposed agreement.

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 by the 3rd party of the draft Agreement.

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 task step contains the following activity:

Data form action	**Description**
Agreements form (PVA)	This form allows for capturing information about the agreement, including agreement details, involved organizational entities, territories, products and/or studies covered by the agreements and the role of the agreement. Please see the Form reference section (14) for details about the form elements.

5.1.4. Agreement Signed task step

The **Agreement Signed** task step allows to document that the agreement was signed by all relevant company and 3rd party responsible person.

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):
All involved internal and external parties sign the agreement.

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 task step contains the following activity:

Data form action	Description
Agreements form (PVA)	This form allows for capturing information about the agreement, including agreement details, involved organizationeal entities, territories, products and/or studies covered by the agreements and the role of the agreement. Please see the Form reference section (14) for details about the form elements.
Agreement responsibilities	This form allows for documenting the responsibilities of the 3rd party with regards to PV relevant activities such as Forwarding of case reports, regulatory reporting, reconciliation, etc.

5.1.5. Agreement Completed task step

The **Agreement Completed** task step allows to document that the Agreement start (on the Agreements form) is defined.

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 Agreement Start Date is defined, and all Agreement activities are completed.

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 task step contains the following activity:

Data form action	Description
Agreements form (PVA)	This form allows for capturing information about the agreement, including agreement details, involved organizationeal entities, territories, products and/or studies covered by the agreements and the role of the agreement. Please see the Form reference section (14) for details about the form elements.
Agreement responsibilities	This form allows for documenting the responsibilities of the 3rd party with regards to PV relevant activities such as Forwarding of case reports, regulatory reporting, reconciliation, etc.

5.2. Agreement review workflow

The purpose of the workflow is to document the regular review of an existing agreement to determine whether an agreement is still valid, requires an update or should be terminated. While the reviewer performs the actual review, the review is approved by another person (e.g. supervisor).

An Agreement Review record should be linked to an agreement.

The workflow consists of the following task steps:

The following sections will explain the tasks in further detail.

5.2.1. Review agreement

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 an existing agreement and populate the review outcome form.

As with any other task in the application, you must have the corresponding role assigned to be able to process the record in the task step. The first task step contains the following activities (link to click to view/process information):

Data form action	Description
Agreements review outcome	This form allows for capturing the outcome of the review activity including the reason for review and the review outcome.

5.2.2. Approve 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): Approve the review of the Agreement.

As with any other task in the application, you must have the corresponding role assigned to be able to process the record in the task step. The first task step contains the following activities (link to click to view/process information):

Data form action	Description
Agreements review outcome	This form allows for capturing the outcome of the review activity including the reason for review and the review outcome.

5.3. Amendment workflow

The purpose of the workflow is to manage an amendment to an existing agreement between your organization and a 3rd party (e.g. license partner, CRO, Service Provider) as a record.

An Amendment record should always be linked to an Agreement record.

The workflow consists of the following task steps, which are closely related to the task steps in the Agreement workflow:

The following sections will explain the tasks in further detail.

5.3.1. Create/update amendment

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):

Create Amendment to an Agreement.

As with any other task in the application, you must have the corresponding role assigned to be able to process the record in the task step. The first task step contains the following activities (link to click to view/process information):

Data form action	Description
Agreements form (PVA)	This form allows for capturing information about the amendment, to capture the specific details, involved organizational entities, territories, products and/or studies covered by the agreements and the role of the agreement. Please see the Form reference section (14) for details about the form elements.

5.3.2. Internal Review task step

The **Internal Review** task step allows for another member of the organization to perform a review of the proposed amendment.

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):

Check that the information in the record is correct and complete the task. If information is not ok, press “Send back task”

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 task step contains the following activity:

Data form action	Description
Agreements form (PVA)	This form allows for capturing information about the amendment, to capture the specific details, involved organizational entities, territories, products and/or studies covered by the agreements and the role of the agreement. Please see the Form reference section (14) for details about the form elements.

5.3.3. External Review task step

The **External Review** task step allows to document that a member of the 3rd party reviewed the proposed amendment.

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 by the 3rd party of the draft Agreement.

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 task step contains the following activity:

Data form action	Description
Agreements form (PVA)	This form allows for capturing information about the amendment, to capture the specific details, involved organizational entities, territories, products and/or studies covered by the agreements and the role of the agreement. Please see the Form reference section (14) for details about the form elements.

5.3.4. Agreement Signed task step

The **Agreement Signed** task step allows to document that the amendment was signed by all relevant company and 3rd party responsible person.

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):
All involved internal and external parties sign the amendment.

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 task step contains the following activity:

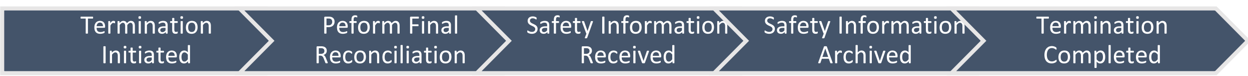
Data form action	Description
Agreements form (PVA)	This form allows for capturing information about the agreement, including agreement details, involved organizationeal entities, territories, products and/or studies covered by the agreements and the role of the agreement. Please see the Form reference section (14) for details about the form elements.

5.4. Agreement termination workflow

The purpose of the workflow is to manage the activities that need to be performed once a PV agreement expired or was terminated. These activities may include reconciliation activities, transfer of safety information source documentation for archiving purposes between your organization and the 3rd party.

An existing Agreement record should be moved to the Agreement termination workflow using the *Change* Workflow standard functionality.

The workflow consists of the following task steps, which are closely related to the task steps in the Agreement workflow:



The following sections will explain the tasks in further detail.

5.4.1. Termination Initiated

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):

Initiate the agreement termination process and populate the termination form.

As with any other task in the application, you must have the corresponding role assigned to be able to process the record in the task step. The first task step contains the following activities (link to click to view/process information):

Data form action	Description
Agreement termination form	This form allows for capturing information about the reason for termination and termination date, as well as documenting the activities required to collect relevant safety information (e.g. source documents) from the partner.

5.4.2. Perform Final Reconciliation

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 responsible person to perform a final reconciliation with the external partner to ensure all safety information is available.

As with any other task in the application, you must have the corresponding role assigned to be able to process the record in the task step. The first task step contains the following activities (link to click to view/process information):

Data form action	Description
Agreement termination form	This form allows for capturing information about the reason for termination and termination date, as well as documenting the activities required to collect relevant safety information (e.g. source documents) from the partner.

5.4.3. Safety Information Received

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

Task instructions (as shown in the application):

Safety Information from Partner has been requested for archiving and the partner has delivered the complete set of safety information.

As with any other task in the application, you must have the corresponding role assigned to be able to process the record in the task step. The first task step contains the following activities (link to click to view/process information):

Data form action	Description
Agreement termination form	This form allows for capturing information about the reason for termination and termination date, as well as documenting the activities required to collect relevant safety information (e.g. source documents) from the partner.

5.4.4. Safety Information Received

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 Safety Information received from the Partner/Vendor has been archived.

As with any other task in the application, you must have the corresponding role assigned to be able to process the record in the task step. The first task step contains the following activities (link to click to view/process information):

Data form action	Description
Agreement termination form	This form allows for capturing information about the reason for termination and termination date, as well as documenting the activities required to collect relevant safety information (e.g. source documents) from the partner.

5.4.5. Termination Completed

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):

Agreement responsible verifies that all agreement termination activities have been performed.

As with any other task in the application, you must have the corresponding role assigned to be able to process the record in the task step. The first task step contains the following activities (link to click to view/process information):

Data form action	Description
Agreement termination form	This form allows for capturing information about the reason for termination and termination date, as well as documenting the activities required to collect relevant safety information (e.g. source documents) from the partner.

6. Functionalities

Not applicable.

7. Forms reference

This section explains data elements for the various forms in use for the module as a reference.

7.1. Agreements form

The following information is required on the Agreements form:

Field Name	Field Type	Description
No SDEA required	Tick box	
Agreement owned by	Dropdown list	
Agreement owner / department	Dropdown list	
Agreement ID	Text	
Status of Business Relationship	Dropdown list	
Location of Contract	Text	
Internal Contract Owner	Text	
Agreement version	Dropdown list	
Agreement Effective date	Date	
Agreement Stop date (planned)	Date	
Agreement Stop date (actual)	Date	
Agreement Description	Text	
Appendix update	Text	
Agreement template	Dropdown list	
Agreement template version	Dropdown list	
Master Agreement ID	Text	
Master Agreement Start date	Date	
If the SDEA is late, then describe reason	Text	
EU Marketing Authorization	Yes / No	
Involved Organizational Entities	List	
Countries (Territories)	List	
Products	List	
Studies	List	
Party Roles	List	

7.2. Agreements Review form

The following information is required on the Agreements form:

Field Name	Field Type	Description
Reason for Review	Dropdown list	
Review Outcome	Dropdown list	
Review Comments	Text	

7.3. Agreement Termination form

The following information is required on the Agreements form:

Field Name	Field Type	Description
Reason for Termination	Dropdown list	
Termination Date	Date	
Termination Letter sent	Yes / No / NA	
Safety Information requested	Yes / No / NA	
Safety Information received	Yes / No / NA	
Safety Information archived	Yes / No / NA	
Safety Information Archive Location	Text	
Comments	Text	