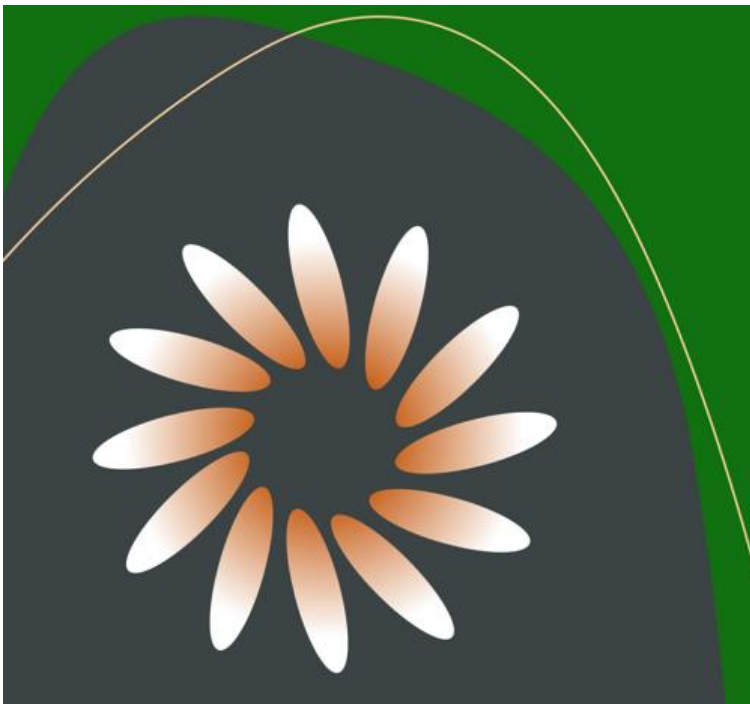


Entities Module



HALOPV USER GUIDE

This is an end-user guide for the **Entities Module** of the drug safety solution HALOPV.

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1. HALOPV Entities Module User Manual

User Manual - Release 4.X (4.1 first released 30 NOV 2022)

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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

The insife Support team can be reached at Support@insife.com

3. Introduction

3.1. Modules of HALOPV

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 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 \(insife.com\)](https://insife.com/general-features)

3.2. Modules of HALOPV

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

- Aggregate Reporting



- Agreements
- Clinical Trials
- Complaints
- Data Collection Programs
- Device Incidents Processing
- Entities
- ICSRs (Medicine and Vaccine Incidents)
- Literature Monitoring
- Labelling
- Medical Information and Communications
- Pharmacovigilance System Master File (PSMF)
- Products
- Quality
- Requirements Intelligence
- Risks
- Signals
- Submissions
- Training

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.

4. Navigating the Entities 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 **General Features User Manual** and **User Guide Introduction and Main Features**.

The **Entities Module** will show if your user has the role to access the Module.

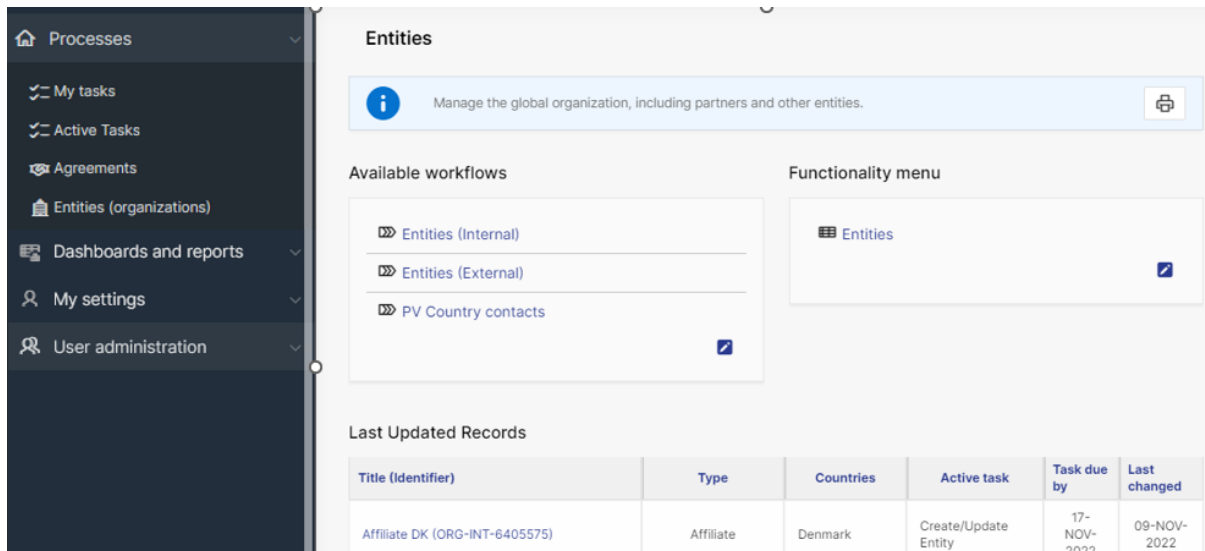


Figure 1 Left menu, Entities is available for users with the appropriate access role

4.1. Module Main Screen

The Main Screen displays the list of workflows available in the Module Entities – including the Functionality Menu.

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.

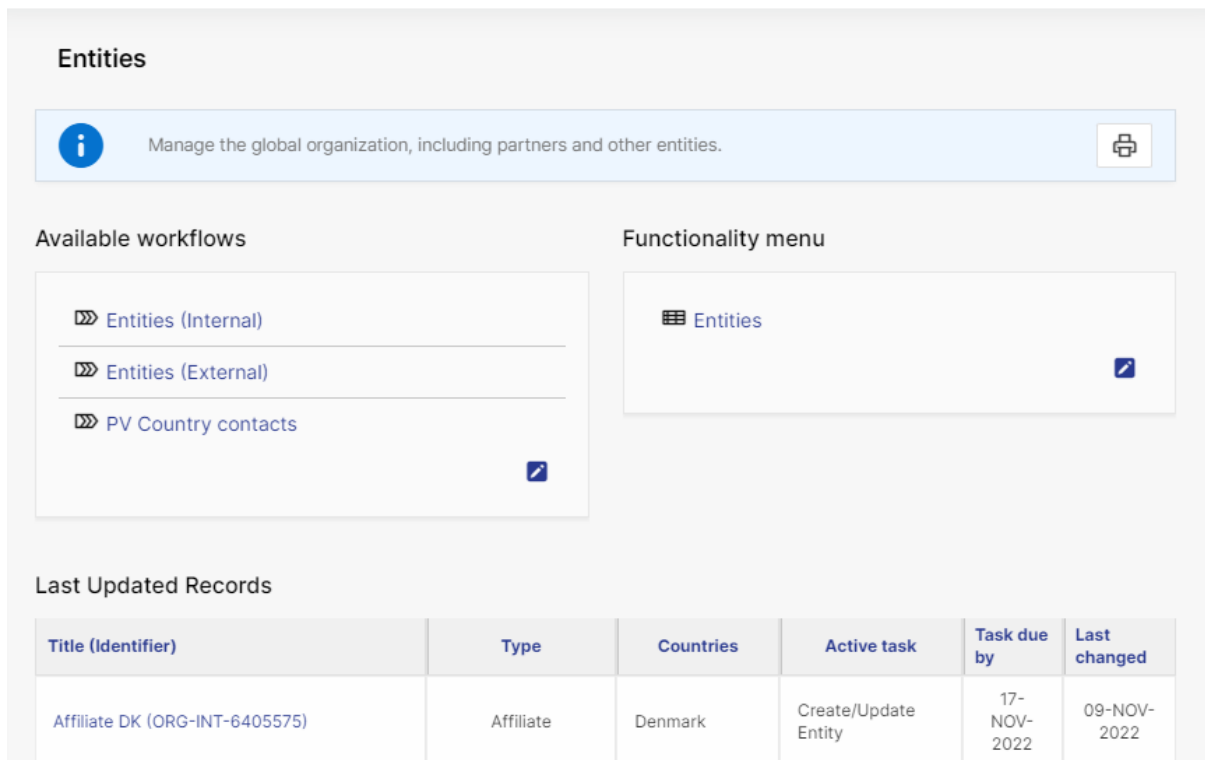


Figure 2 The standard list of Workflows and Functionality Menu items for the Entity Module

5. Standard Workflows

You can access a record worklist by clicking on one of the available workflows. **E.g., Entities (Internal)**. The view will display the Entities created in the process workflow.

The Records worklist may have different columns, depending on the selected workflow. However, the principle is the same for all workflows. You will have a **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.

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.

[Entities](#) / **Entities (Internal) Records**

Process description

Manage partners, clients accounts or entities within the organization e.g. other geographic location.

Completed records?
 In workflow records?
 Nullified records?
 Assigned to others?
 [Create from Wizard](#)

Records (Org. Entities)

Go
Rows 50
Actions

1 - 11 of 11

Record ID	Entity name ↑	Type	Orgentities Address	Orgentities Postal	Orgentities City	Orgentities Country	Is Reporting Destination?	E2b Identifier	Current Task	Overall due date
ORG-INT-6405406	Affiliate Benelux	Affiliate	Stationsstraat 44	1120	Brussels	Belgium	-	-	Create/Update Entity	24-OCT-2022
ORG-INT-6405412	Affiliate China	Affiliate	171 Ma Tau Wai Rd	000	Hong Kong	China	-	-	Create/Update Entity	24-OCT-2022
ORG-INT-6405575	Affiliate DK	Affiliate	-	-	-	Denmark	No	-	Create/Update Entity	23-NOV-2022
ORG-INT-6405409	Affiliate France	Affiliate	29 Place du Jeu de Paume	18100	Vierzon	France	-	-	Create/Update Entity	24-OCT-2022

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

Note: Columns name may vary depending on your system configuration.

5.1. Entities Workflows

Clicking on the "Record ID" or "Entity name" takes you to the individual record, as shown below.


Please note that access to Records is restricted to the user role assigned to you, e.g., 'Read-only access to the current workflow' means that the user cannot create or delete a record but can execute the task(s) assigned within the record.

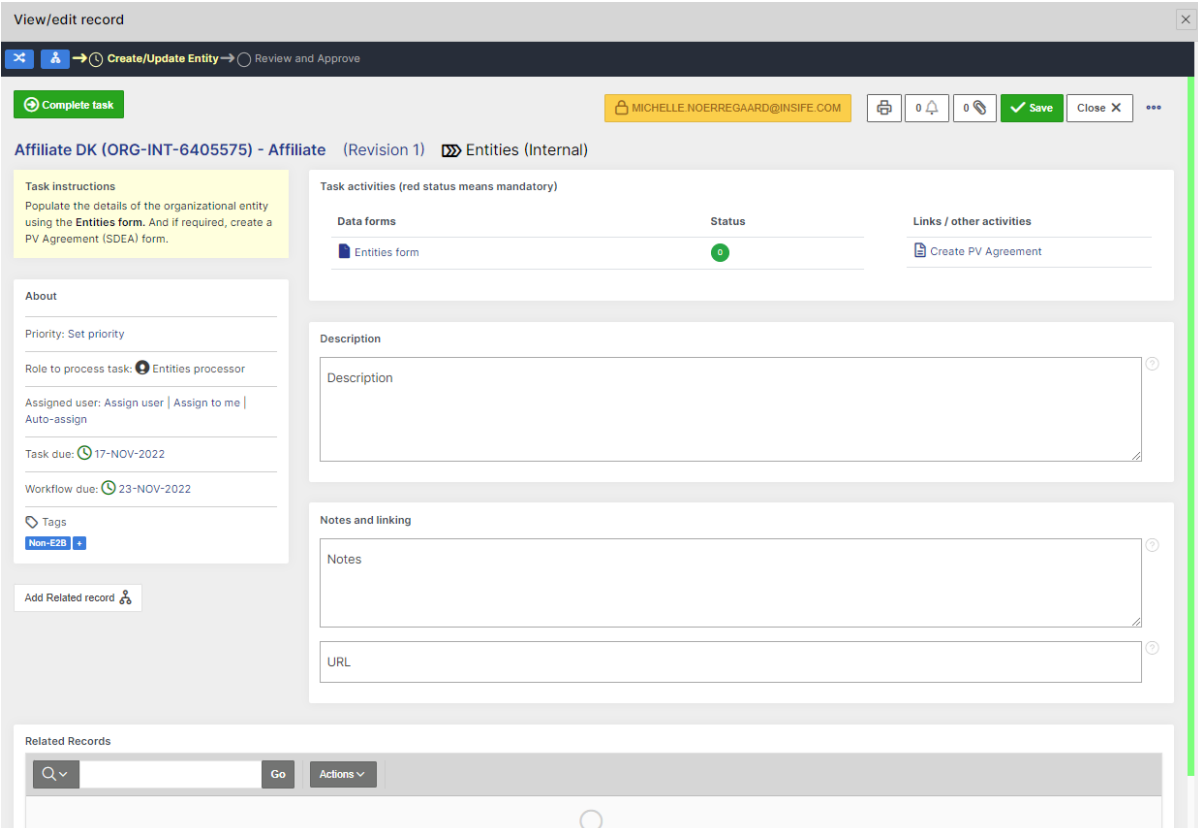
A Workflow shows a graphical representation of an active and inactive step, your role, the tasks assigned to that role, and the due date.

When a user has a record open, no other user can perform activities in the record.

A workflow step may have task actions. The status is marked with colors:

- **Green mark:** the task is not mandatory.
- **Red mark:** the task action is mandatory, and the task cannot be completed before it is done.
- **Pending actions:** a validation rule is active. This is usually linked to a mandatory task (red mark) that requires your attention.

If an existing record should be moved to a new workflow, e.g., from **Entities (Internal)** to **Entities (External)** user can use the *change Workflow*  standard functionality located on the left corner of the record view.



The screenshot displays the 'View/edit record' interface for 'Affiliate DK (ORG-INT-6405575) - Affiliate (Revision 1) Entities (Internal)'. The interface is divided into several sections:

- Task instructions:** A yellow box containing the text: 'Populate the details of the organizational entity using the **Entities form**. And if required, create a PV Agreement (SDEA) form.'
- Task activities (red status means mandatory):** A table with three columns: 'Data forms', 'Status', and 'Links / other activities'. The 'Entities form' is listed under 'Data forms' with a green status indicator. A 'Create PV Agreement' link is shown under 'Links / other activities'.
- About:** A section with fields for 'Priority: Set priority', 'Role to process task: Entities processor', 'Assigned user: Assign user | Assign to me | Auto-assign', 'Task due: 17-NOV-2022', and 'Workflow due: 23-NOV-2022'. It also includes a 'Tags' section with a 'Non-E2B' tag.
- Description:** A large text area for entering the description of the record.
- Notes and linking:** A section for adding notes and a 'URL' field.
- Related Records:** A section at the bottom with a search bar and 'Go' and 'Actions' buttons.

The purpose of the Entities workflow is to manage either 'Internal' or 'External' Entities in your organization. Users can update organizational information, create PV Agreements (SDEA)

Entities (Internal) help users manage Affiliates or entities within the organization, *e.g.*, other geographic locations.

Entities (External) help users manage Partners, Regulators, Sub-contractors, Committees, Authorities, and Customers.

The workflow usually consists of a **create/update** step, a **review** step, and an **approval step**. It might be that your local requirement might have only two steps, 'Create/Update' and a 'Review and Approve,' as shown in the example above.



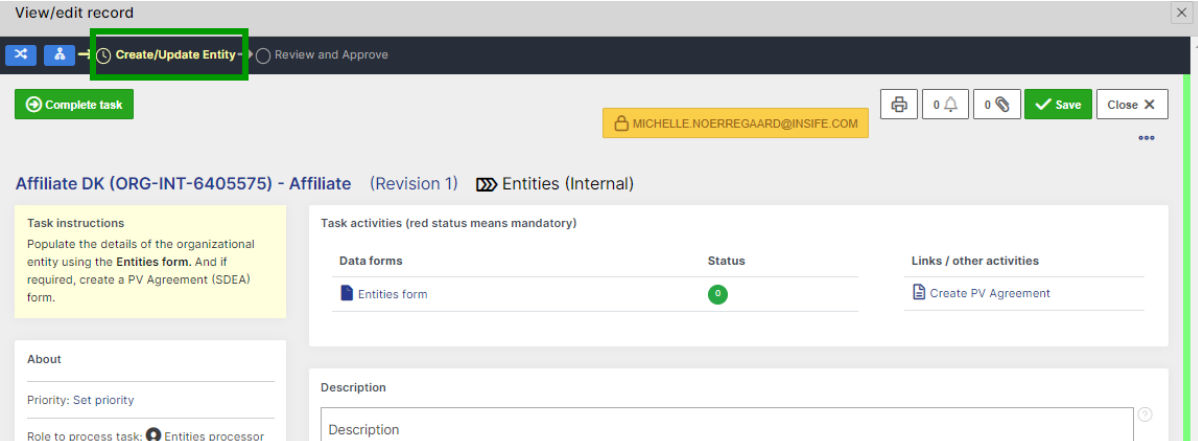
The following sections will explain the tasks in further detail for **Entities (Internal)** and **Entities (External)**.

5.1.1. Workflow: Entities (Internal)

Entities (Internal)

Create/Update Entity (Step 1)

The **Create/Update Entity** task allows users to fill in the **Entities form** or update the information when required.



Data forms	Status	Links / other activities
Entities form	0	Create PV Agreement

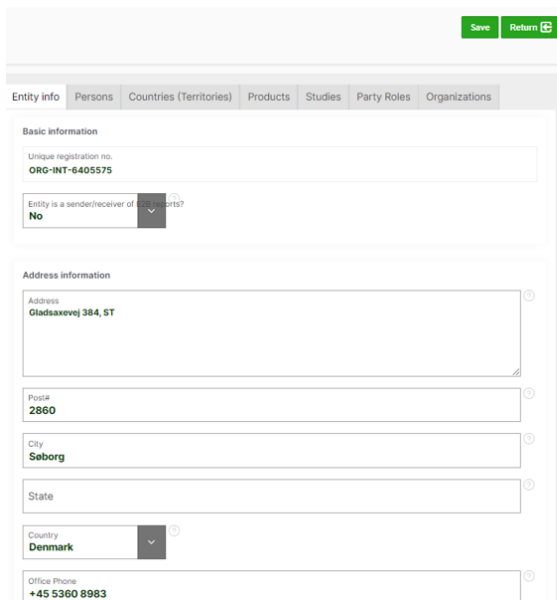
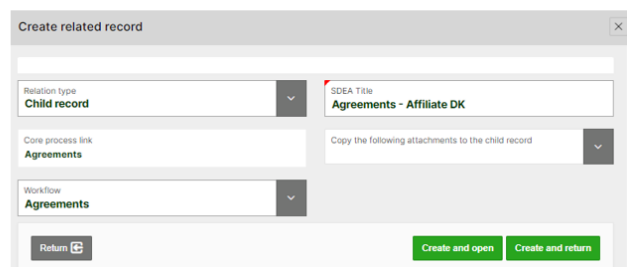
The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

Role to process task: Entities processor

Task instructions (as shown in the application): Populate the details of the organizational entity using the Entities form. And if required, create a PV Agreement (SDEA) form.

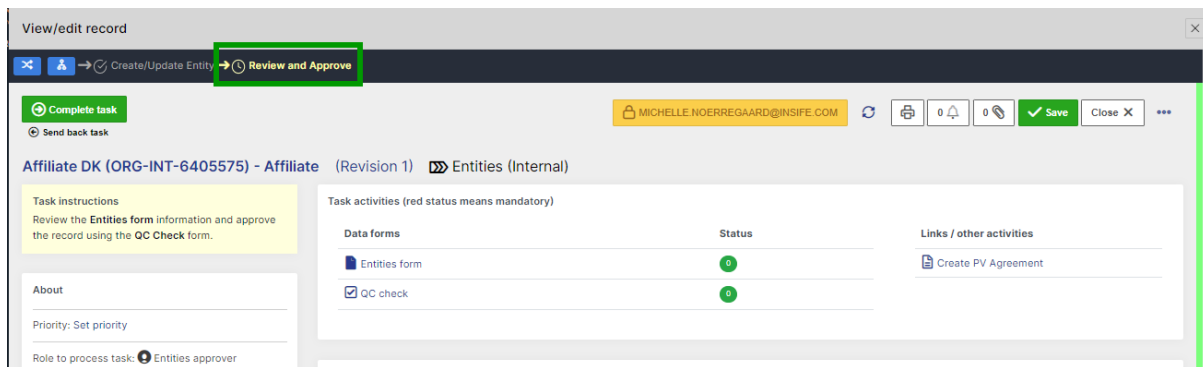
As with any other task in the application, you must have the corresponding role assigned to be able to process the record in the task step. The task step contains the following activities:

Data form action	Description
Entity form	<p>This form allows registering organizational information – including Entity information, Persons (<i>list of users under the organizational entity, e.g., Official Main Contact Person, QPPV Deputy, QPPV Backup, Local Contact Person</i>),</p> <p><u>Other tabs included (some might be disabled in your system):</u></p> <p>Reporting obligations: The tab automatically updates when reporting rules are created in the 'Requirement Intelligence' Module.</p> <p>Territories: This can be manually adjusted. Territories listed in the record scope are also transferred to this tab.</p> <p>Products: This tab should not be filled with products records that are not created by HQ (Multinant solution available in HALOPV 5.0)</p> <p>Studies: This tab should not be filled with studies records that are not created by HQ (Multinant solution available in HALOPV 5.0)</p> <p>Organizations: Affiliates/Partners should belong to HQ. When creating a new affiliate, please add HQ to the organization tab (Multinant solution available in HALOPV 5.0)</p> <p>E2B info: The tab enables when the user update 'Entity Info' > Entity is a sender/receiver of E2B reports?=Yes.'</p>
Create PV Agreement	<p>This form allows users to create new SDEA records. The agreement records will be stored in the Agreements Module. The record will show as a child record/linked record in the record view, section Related Records.</p>

Review and Approve (Step 2)

The **Review and Approve** step allows documenting that a different user role reviewed the record information. Depending on your configuration, a **QC Check** form might be available.



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.

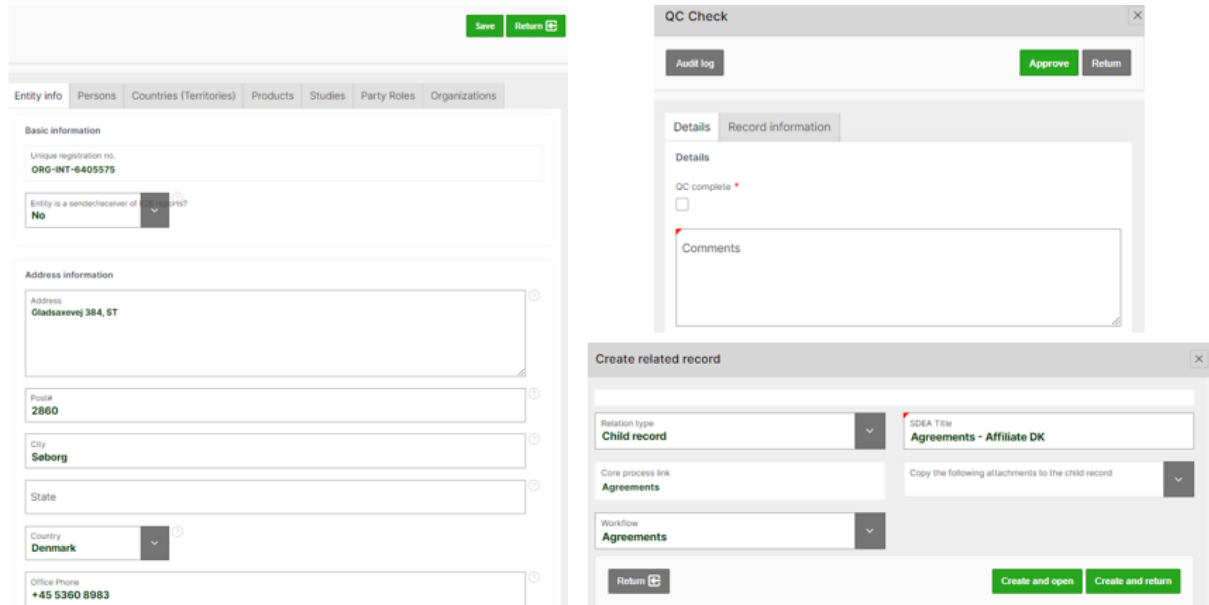
Role to process task: Entities approver.

Task instructions (as shown in the application): Review the Entities form information and approve the record using the QC Check 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 task step contains the following activities:

Data form action	Description
Entity form	<p>This form allows registering organizational information – including Entity information, Persons (<i>list of users under the organizational entity, e.g., Official Main Contact Person, QPPV Deputy, QPPV Backup, Local Contact Person</i>)</p> <p><u>Other tabs included (some might be disabled in your system):</u></p> <p>Reporting obligations: The tab automatically updates when reporting rules are created in the 'Requirement Intelligence' Module.</p> <p>Territories: This can be manually adjusted. Territories listed in the record scope are also transferred to this tab.</p> <p>Products: This tab should not be filled with products records that are not created by HQ (Multinant solution available in HALOPV 5.0)</p> <p>Studies: This tab should not be filled with studies records that are not created by HQ (Multinant solution available in HALOPV 5.0)</p> <p>Organizations: Affiliates/Partners should belong to HQ. When creating a new affiliate, please add HQ to the organization tab (Multinant solution available in HALOPV 5.0)</p> <p>E2B info: The tab enables when the user update 'Entity Info' > Entity is a sender/receiver of E2B reports?=Yes.'</p>
Create PV Agreement	<p>This form allows users to create new SDEA records. The agreement records will be stored in the Agreements Module. The record will show as a child record/linked record in the record view, section Related Records.</p>

Data form action	Description
QC Check	<p>The page allows the QC reviewer to acknowledge the review and enter review comments.</p> <p>Note: The user completing the QC form cannot be the same user who completed the workflow's first step.</p> <p>Please, note that once the user clicks on 'Approve,' the workflow automatically completes.</p>



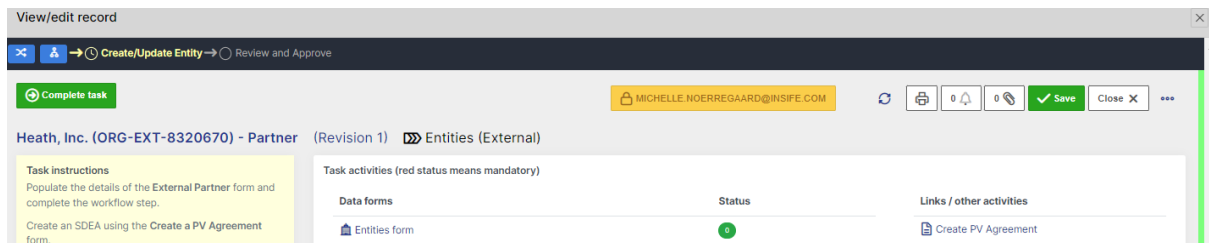
The image shows two overlapping screenshots from the application. The background screenshot displays the 'Entity info' page with tabs for 'Persons', 'Countries (Territories)', 'Products', 'Studies', 'Party Roles', and 'Organizations'. The 'Basic information' section includes 'Unique registration no.' (ORG-INT-6405575) and a dropdown for 'Entity is a sender/receiver of [SDEA]?' set to 'No'. The 'Address information' section includes 'Address' (Gladsaxevej 384, ST), 'Post#', 'City' (Seborg), 'State', 'Country' (Denmark), and 'Office Phone' (+45 5360 8983). The foreground screenshot shows the 'QC Check' form with an 'Audit log' button, 'Approve' and 'Return' buttons, and a 'Details' section with a 'QC complete' checkbox and a 'Comments' text area. Below it is the 'Create related record' form with fields for 'Relation type' (Child record), 'SDEA Title' (Agreements - Affiliate DK), 'Core process link' (Agreements), and 'Workflow' (Agreements), along with 'Create and open' and 'Create and return' buttons.

5.1.2. Workflow: Entities (External)

Entities (External)

Create/Update Entity (Step 1)

The **Create/Update Entity** task allows users to fill in the **Entities External form** or update the information when required.



The image shows a 'View/edit record' page for 'Heath, Inc. (ORG-EXT-8320670) - Partner' (Revision 1) under 'Entities (External)'. The page has a navigation bar with 'Create/Update Entity' and 'Review and Approve' buttons. A 'Complete task' button is visible. The main content area is divided into 'Task instructions' (highlighted in yellow) and 'Task activities'. The 'Task instructions' section states: 'Populate the details of the External Partner form and complete the workflow step. Create an SDEA using the Create a PV Agreement form.' The 'Task activities' section shows a table with columns for 'Data forms', 'Status', and 'Links / other activities'. The 'Entities form' activity is listed with a green status indicator and a link to 'Create PV 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.

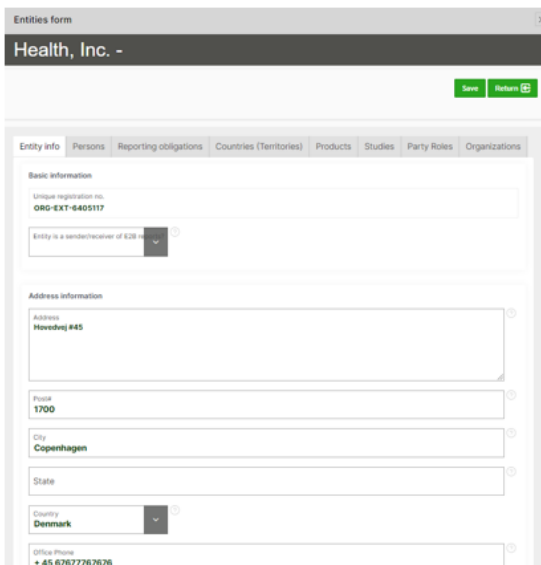
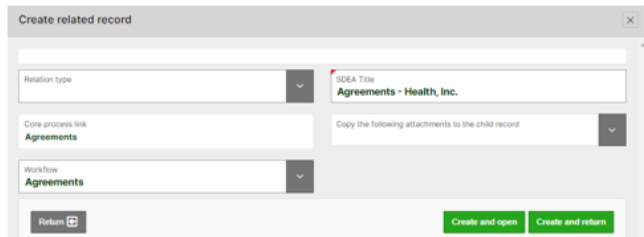
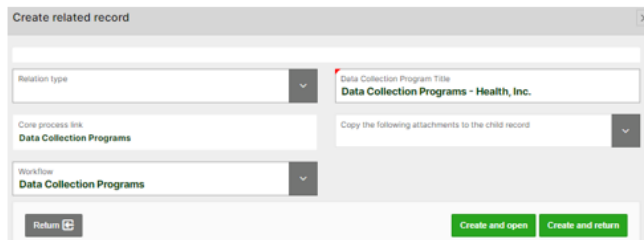
Role to process task: Entities processor

Task instructions (as shown in the application): Populate the details of the External Partner form and complete the workflow step.

Create an SDEA using the Create a PV Agreement form or a Data Collection Program record if required.

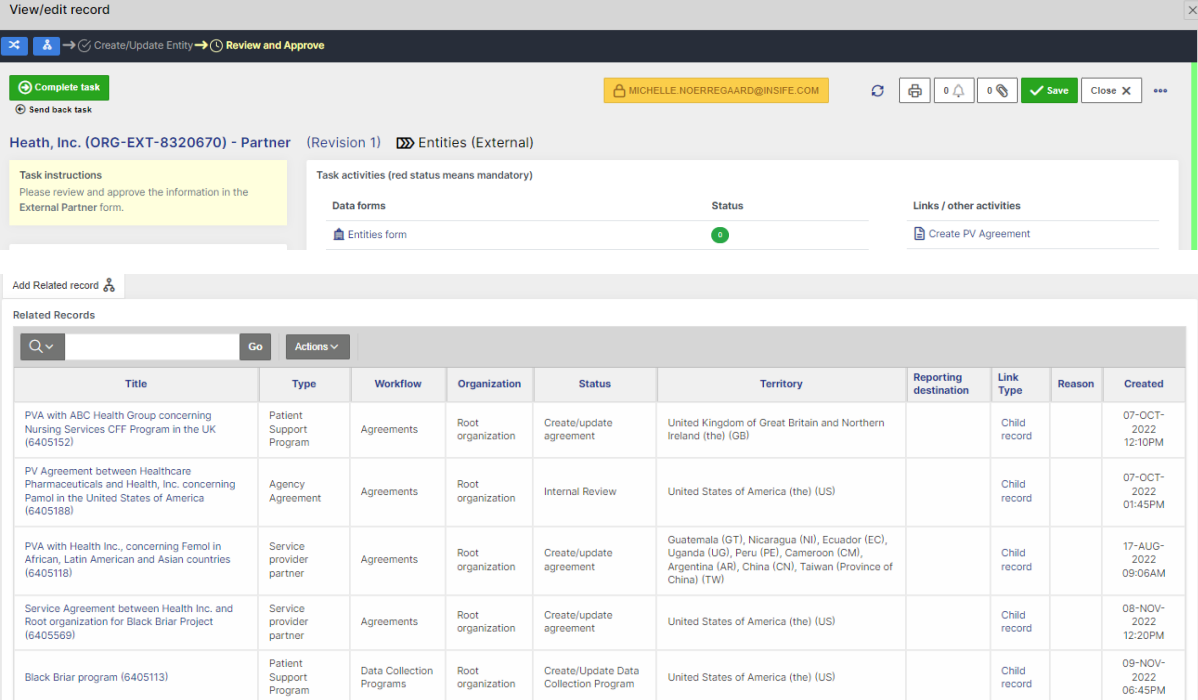
As with any other task in the application, you must have the corresponding role assigned to be able to process the record in the task step. The task step contains the following activities:

Data form action	Description
External Partner form	<p>This form allows registering organizational information – including Entity information, Persons (<i>list of users under the organizational entity, e.g., Official Main Contact Person, QPPV Deputy, QPPV Backup, Local Contact Person.</i>)</p> <p><u>Other tabs included (some might be disabled in your system):</u></p> <p>Reporting obligations: The tab automatically updates when reporting rules are created in the 'Requirement Intelligence' Module.</p> <p>Territories: This can be manually adjusted. Territories listed in the record scope are also transferred to this tab.</p> <p>Products: This tab should not be filled with products records that are not created by HQ (Multinant solution available in HALOPV 5.0)</p> <p>Studies: This tab should not be filled with studies records that are not created by HQ (Multinant solution available in HALOPV 5.0)</p> <p>Organizations: Affiliates/Partners should belong to HQ. When creating a new affiliate, please add HQ to the organization tab (Multinant solution available in HALOPV 5.0)</p> <p>E2B info: The tab enables when the user update 'Entity Info' > Entity is a sender/receiver of E2B reports?=Yes.'</p>
Create PV Agreement	<p>This form allows users to create new SDEA records. The agreement records will be stored in the Agreements Module. The record will show as a child record/linked record in the record view, section Related Records.</p>

Review and Approve (Step 2)

The **Review and Approve** step allows documenting that a different user role reviewed the record information. Depending on your configuration, a **QC Check** form might be available.



The screenshot shows the 'View/edit record' interface for a record titled 'Heath, Inc. (ORG-EXT-8320670) - Partner (Revision 1) Entities (External)'. A yellow highlight on the left contains the task instruction: 'Please review and approve the information in the External Partner form.' Below this, a table lists related records.

Title	Type	Workflow	Organization	Status	Territory	Reporting destination	Link Type	Reason	Created
PVA with ABC Health Group concerning Nursing Services CFF Program in the UK (6405152)	Patient Support Program	Agreements	Root organization	Create/update agreement	United Kingdom of Great Britain and Northern Ireland (the) (GB)		Child record		07-OCT-2022 12:10PM
PV Agreement between Healthcare Pharmaceuticals and Health, Inc. concerning Pamol in the United States of America (6405188)	Agency Agreement	Agreements	Root organization	Internal Review	United States of America (the) (US)		Child record		07-OCT-2022 01:45PM
PVA with Health Inc., concerning Femol in African, Latin American and Asian countries (6405118)	Service provider partner	Agreements	Root organization	Create/update agreement	Guatemala (GT), Nicaragua (NI), Ecuador (EC), Uganda (UG), Peru (PE), Cameroon (CM), Argentina (AR), China (CN), Taiwan (Province of China) (TW)		Child record		17-AUG-2022 09:06AM
Service Agreement between Health Inc. and Root organization for Black Briar Project (6405568)	Service provider partner	Agreements	Root organization	Create/update agreement	United States of America (the) (US)		Child record		08-NOV-2022 12:20PM
Black Briar program (6405113)	Patient Support Program	Data Collection Programs	Root organization	Create/Update Data Collection Program	United States of America (the) (US)		Child record		09-NOV-2022 06:45PM

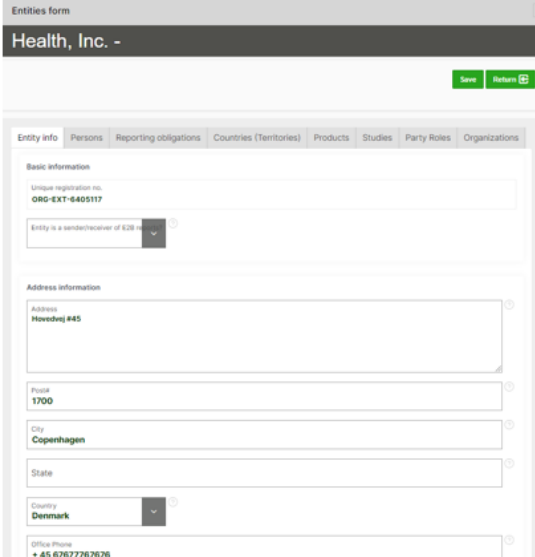
The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

Role to process task: Entities approver.

Task instructions (as shown in the application): Please review and approve the information in the External Partner 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:

Data form action	Description
External Partner form	<p>This form allows registering organizational information – including Entity information, Persons (<i>list of users under the organizational entity, e.g., Official Main Contact Person, QPPV Deputy, QPPV Backup, Local Contact Person.</i>)</p> <p><u>Other tabs included (some might be disabled in your system):</u></p> <p>Reporting obligations: The tab automatically updates when reporting rules are created in the 'Requirement Intelligence' Module.</p> <p>Territories: This can be manually adjusted. Territories listed in the record scope are also transferred to this tab.</p> <p>Products: This tab should not be filled with products records that are not created by HQ (Multinant solution available in HALOPV 5.0)</p> <p>Studies: This tab should not be filled with studies records that are not created by HQ (Multinant solution available in HALOPV 5.0)</p> <p>Organizations: Affiliates/Partners should belong to HQ. When creating a new affiliate, please add HQ to the organization tab (Multinant solution available in HALOPV 5.0)</p> <p>E2B info: The tab enables when the user update 'Entity Info' > Entity is a sender/receiver of E2B reports?=Yes.'</p>
Create PV Agreement	<p>This form allows users to create new SDEA records. The agreement records will be stored in the Agreements Module. The record will show as a child record/linked record in the record view, section Related Records.</p>



Entities form
Health, Inc. -

Save Return

Entity info | Persons | Reporting obligations | Countries (Territories) | Products | Studies | Party Roles | Organizations

Basic information

Unique registration no.
ORG-EXT-6405117

Entity is a sender/receiver of E2B no.

Address information

Address
Hovedvej #45

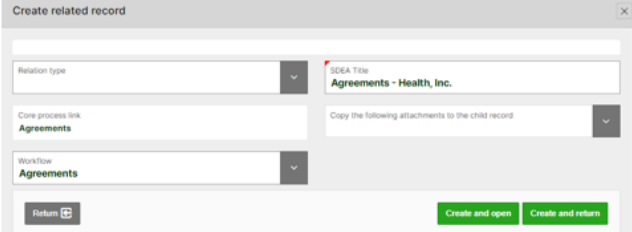
Post
1700

City
Copenhagen

State

Country
Denmark

Office phone
+45 67677767676



Create related record

Relation type

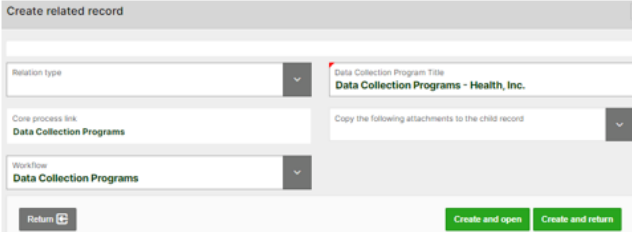
SDEA Title
Agreements - Health, Inc.

Core process link
Agreements

Copy the following attachments to the child record

Workflow
Agreements

Return Create and open Create and return



Create related record

Relation type

Data Collection Program Title
Data Collection Programs - Health, Inc.

Core process link
Data Collection Programs

Copy the following attachments to the child record

Workflow
Data Collection Programs

Return Create and open Create and return



To review additional HALOPV **User Guides** and **User Manuals** please visit our website <https://insife.com/halopv-user-guides-tutorials> or contact your system administrator.