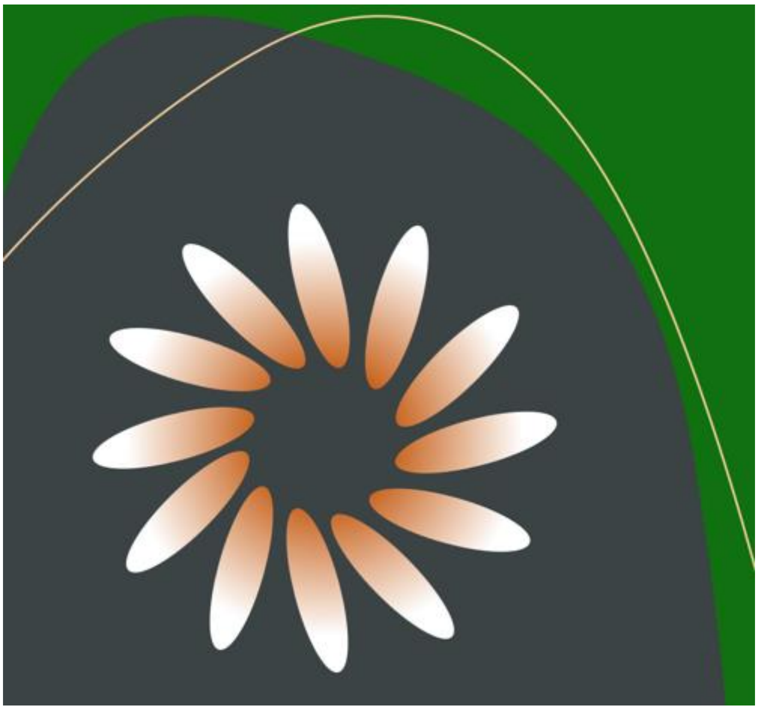
HALOPV

Entities Module



HALOPV
USER GUIDE

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

Contents

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)

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.

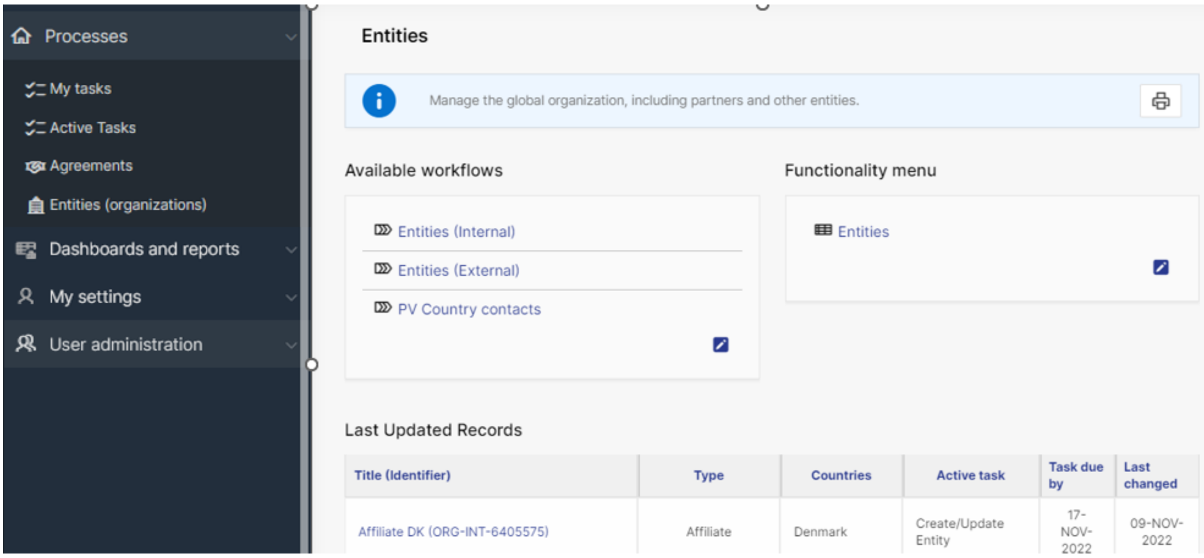


Figure 1 Left menu, Entities is available for users with the appropriate access role

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.

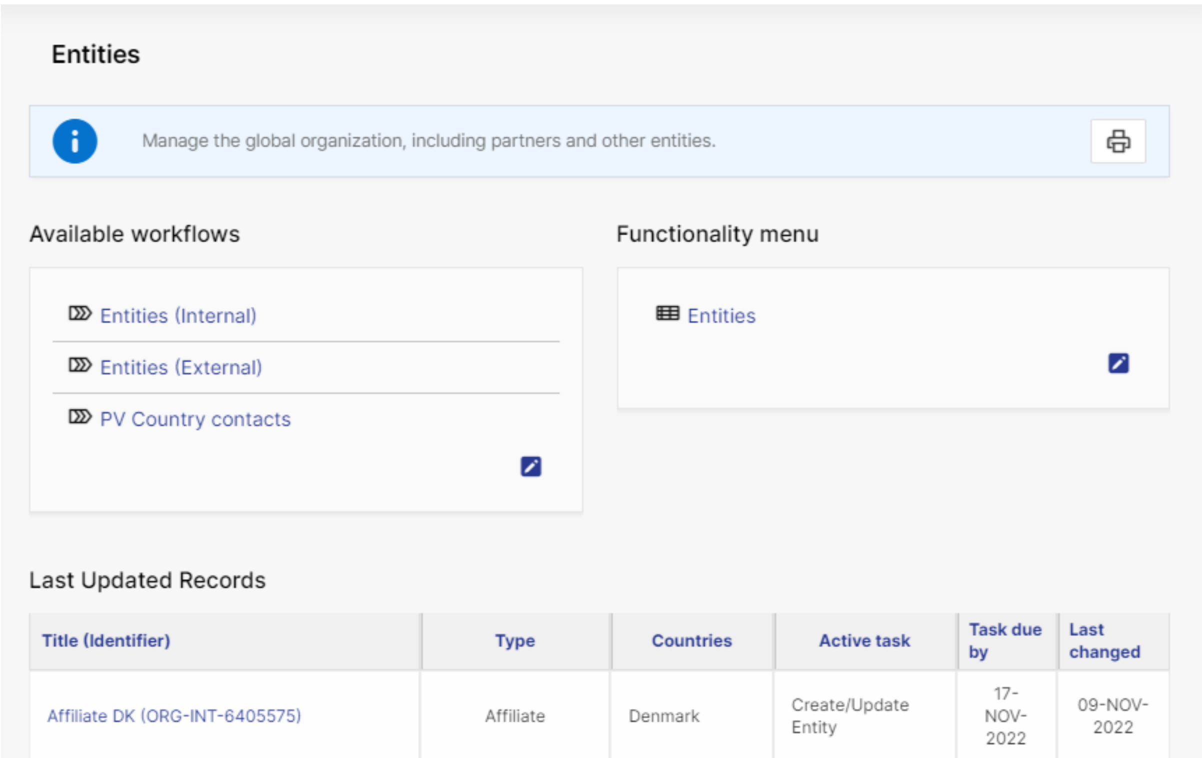


Figure 2 The standard list of Workflows and Functionality Menu items for the Entity Module

HALOPV

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.

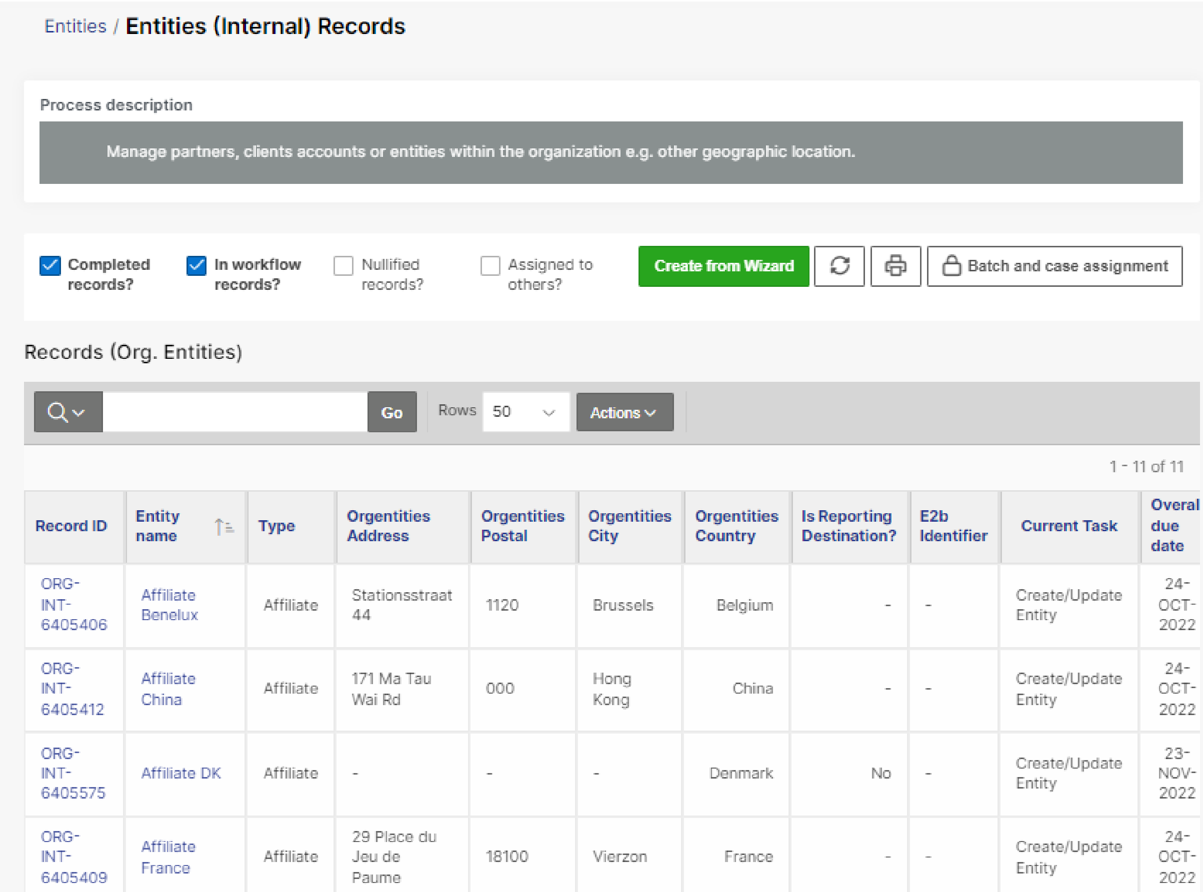


Figure 3 When clicking on a workflow, the following screen displays the Process workflow description (if configured) and a worklist of records, where the Record ID and title can be clicked to access the individual record.

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.

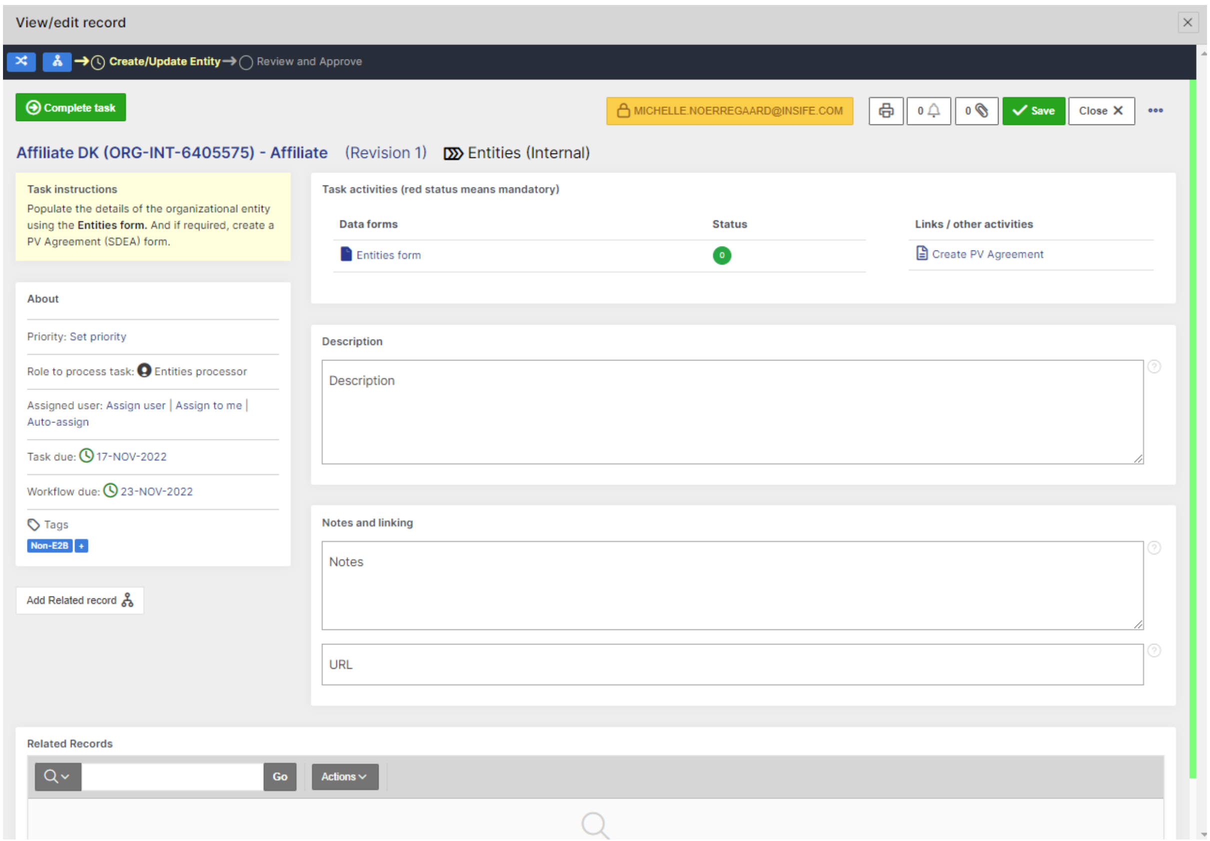
A Workflow shows a graphical representation of an active and inactive step, your role, the tasks assigned to that role, and the due date.

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.

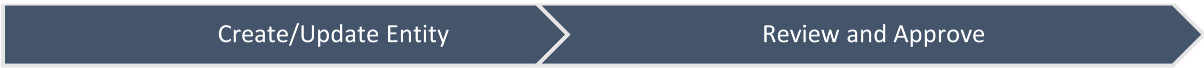


The purpose of the Entities workflow is to manage either **'Internal'** or **'External'** Entities in your organization. Users can update organizational information, create PV Agreements (SDEA)

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.



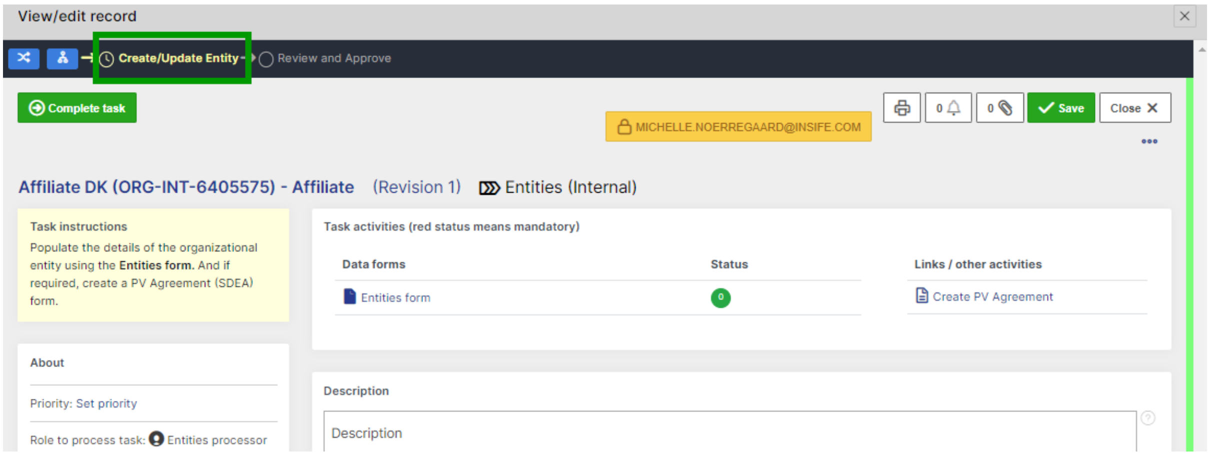
The following sections will explain the tasks in further detail for **Entities (Internal)** and **Entities (External.)**

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.



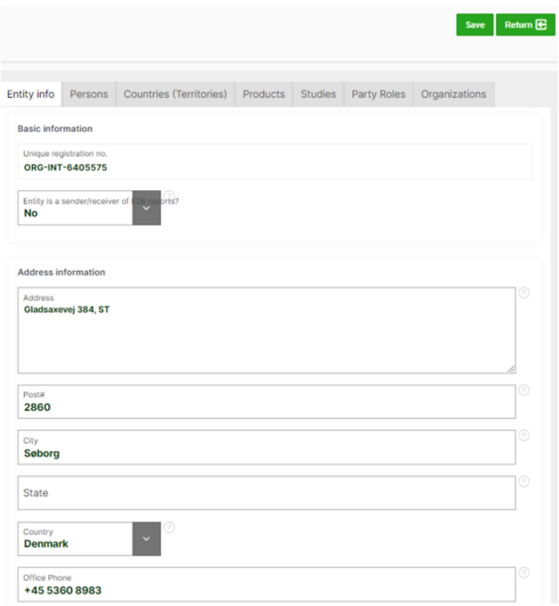
The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

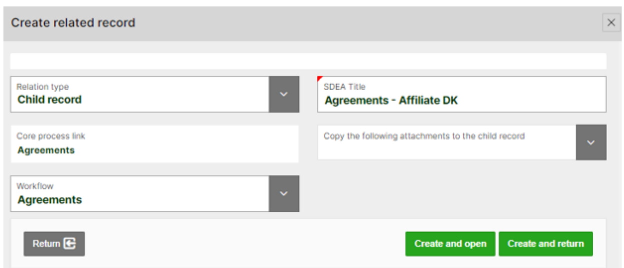
Role to process task: Entities processor

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:

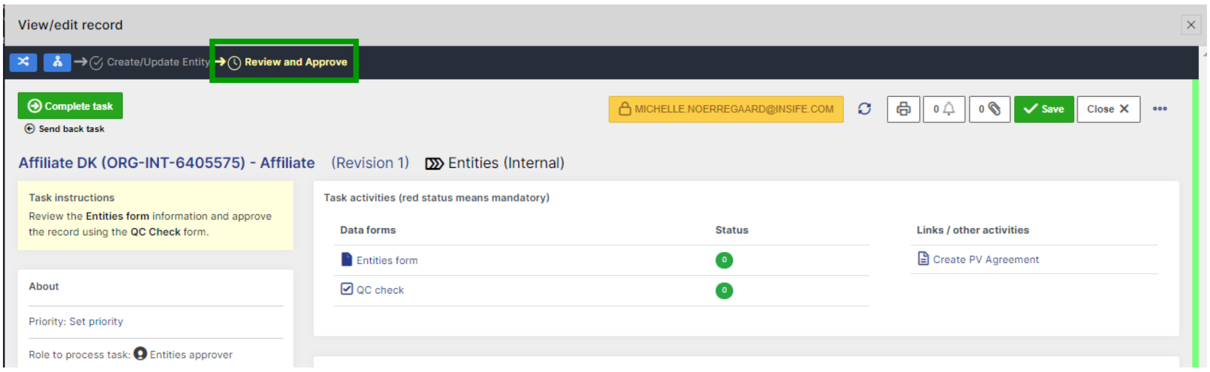
Data form action	Description
Entity form	This form allows registering organizational information – including **Entity information, Persons** *(list of users under the organizational entity, e.g., Official Main Contact Person, QPPV Deputy, QPPV Backup, Local Contact Person),* ***Other tabs included (some might be disabled in your system):*** **Reporting obligations:** The tab automatically updates when reporting rules are created in the 'Requirement Intelligence' Module. **Territories:** This can be manually adjusted. Territories listed in the record scope are also transferred to this tab. **Products:** This tab should not be filled with products records that are not created by HQ (Multinant solution available in HALOPV 5.0) **Studies:** This tab should not be filled with studies records that are not created by HQ (Multinant solution available in HALOPV 5.0) **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) **E2B info:** The tab enables when the user update 'Entity Info' > Entity is a sender/receiver of E2B reports?=Yes.'
Create PV Agreement	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.**





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.

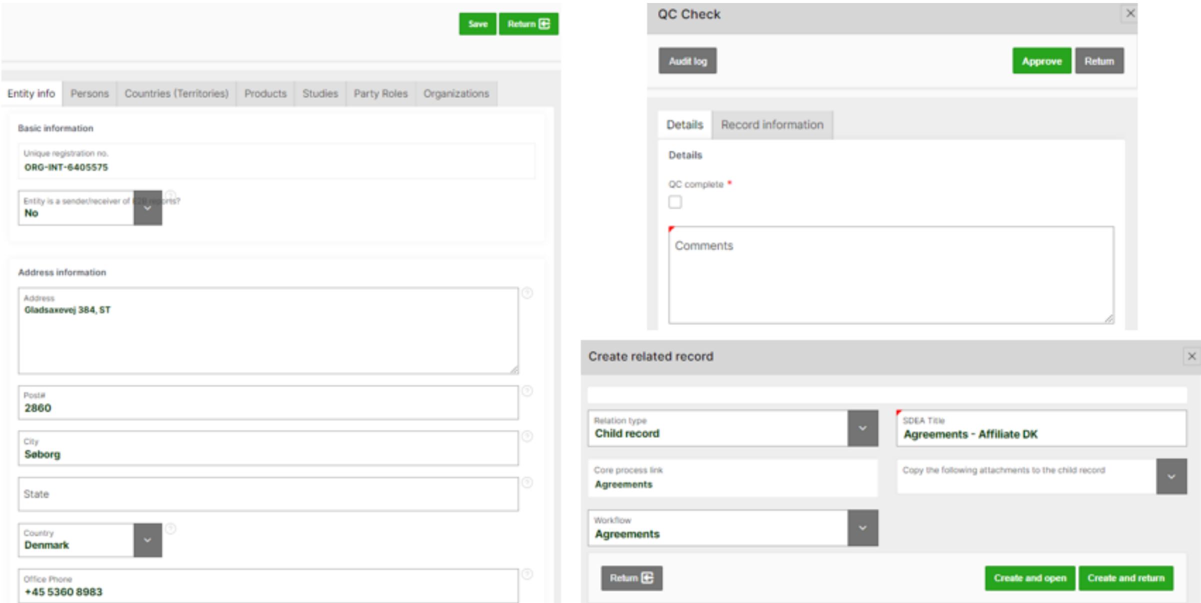
Role to process task: Entities approver.

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	This form allows registering organizational information – including **Entity information, Persons** *(list of users under the organizational entity, e.g., Official Main Contact Person, QPPV Deputy, QPPV Backup, Local Contact Person)* ***<u>Other tabs included (some might be disabled in your system):</u>*** **Reporting obligations:** The tab automatically updates when reporting rules are created in the 'Requirement Intelligence' Module. **Territories:** This can be manually adjusted. Territories listed in the record scope are also transferred to this tab. **Products:** This tab should not be filled with products records that are not created by HQ (Multinant solution available in HALOPV 5.0) **Studies:** This tab should not be filled with studies records that are not created by HQ (Multinant solution available in HALOPV 5.0) **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) **E2B info:** The tab enables when the user update ‘Entity Info’ > Entity is a sender/receiver of E2B reports?=Yes.’
Create PV Agreement	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.**

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

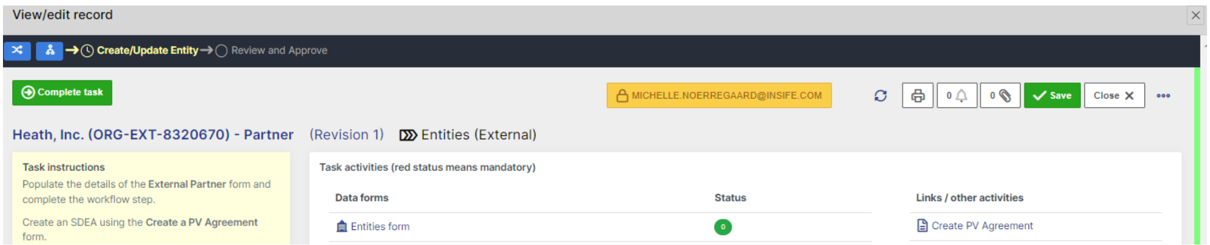


5.1.2. Workflow: Entities (External)

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 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	This form allows registering organizational information – including **Entity information, Persons** *(list of users under the organizational entity, e.g., Official Main Contact Person, QPPV Deputy, QPPV Backup, Local Contact Person.)* ***<u>Other tabs included (some might be disabled in your system):</u>*** **Reporting obligations:** The tab automatically updates when reporting rules are created in the 'Requirement Intelligence' Module. **Territories:** This can be manually adjusted. Territories listed in the record scope are also transferred to this tab. **Products:** This tab should not be filled with products records that are not created by HQ (Multinant solution available in HALOPV 5.0) **Studies:** This tab should not be filled with studies records that are not created by HQ (Multinant solution available in HALOPV 5.0) **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) **E2B info:** The tab enables when the user update ‘Entity Info’ > Entity is a sender/receiver of E2B reports?=Yes.’
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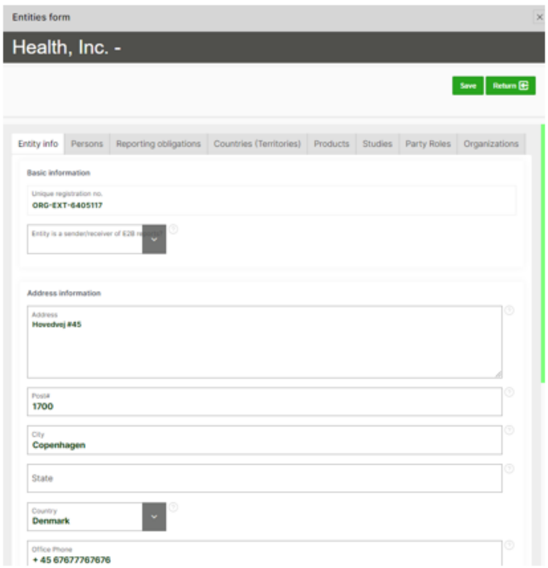

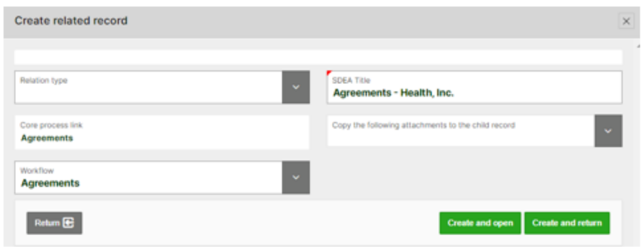

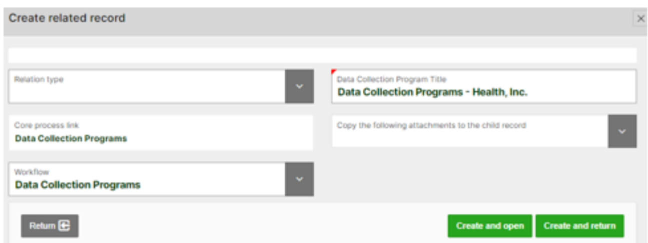

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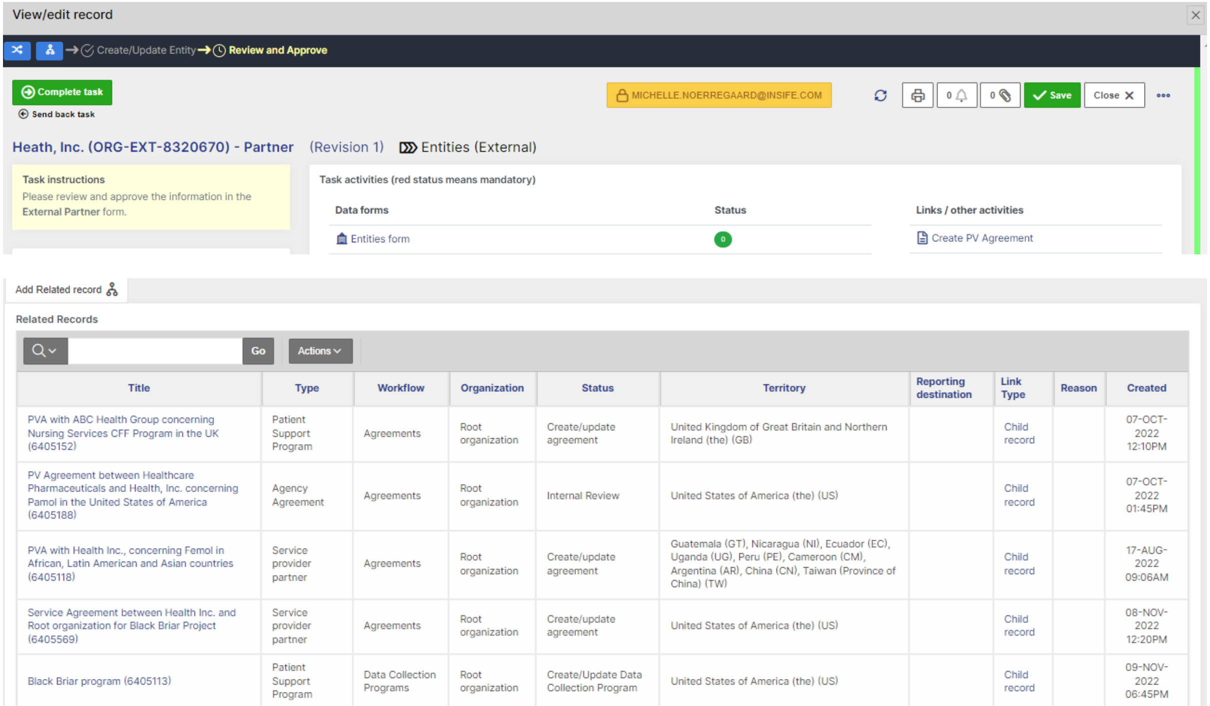

The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

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	This form allows registering organizational information – including **Entity information, Persons** *(list of users under the organizational entity, e.g., Official Main Contact Person, QPPV Deputy, QPPV Backup, Local Contact Person.)* ***<u>Other tabs included (some might be disabled in your system):</u>*** **Reporting obligations:** The tab automatically updates when reporting rules are created in the 'Requirement Intelligence' Module. **Territories:** This can be manually adjusted. Territories listed in the record scope are also transferred to this tab. **Products:** This tab should not be filled with products records that are not created by HQ (Multinant solution available in HALOPV 5.0) **Studies:** This tab should not be filled with studies records that are not created by HQ (Multinant solution available in HALOPV 5.0) **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) **E2B info:** The tab enables when the user update 'Entity Info' > Entity is a sender/receiver of E2B reports?=Yes.'
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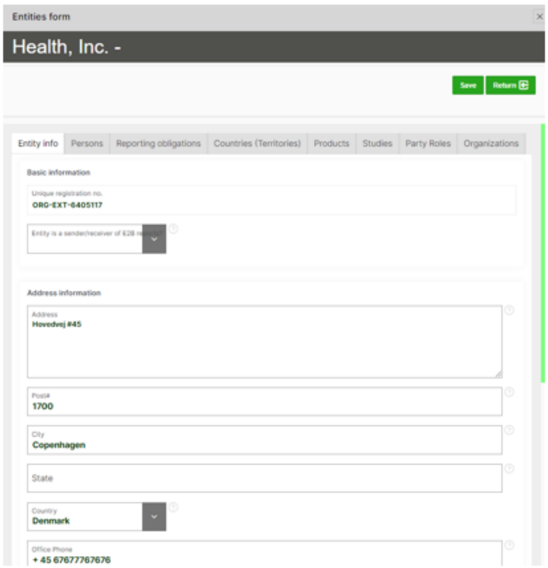

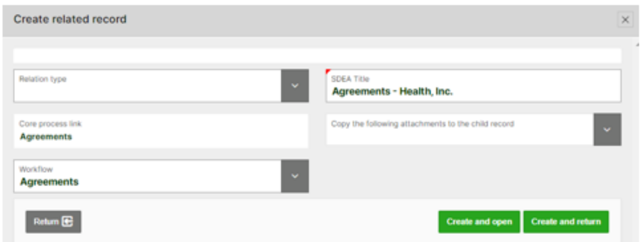

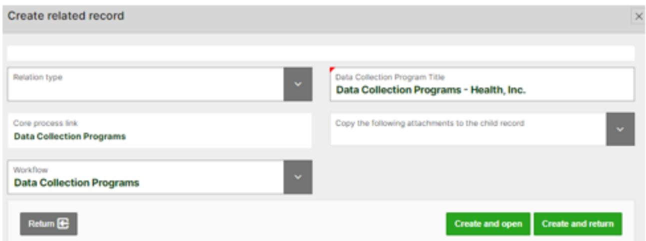

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