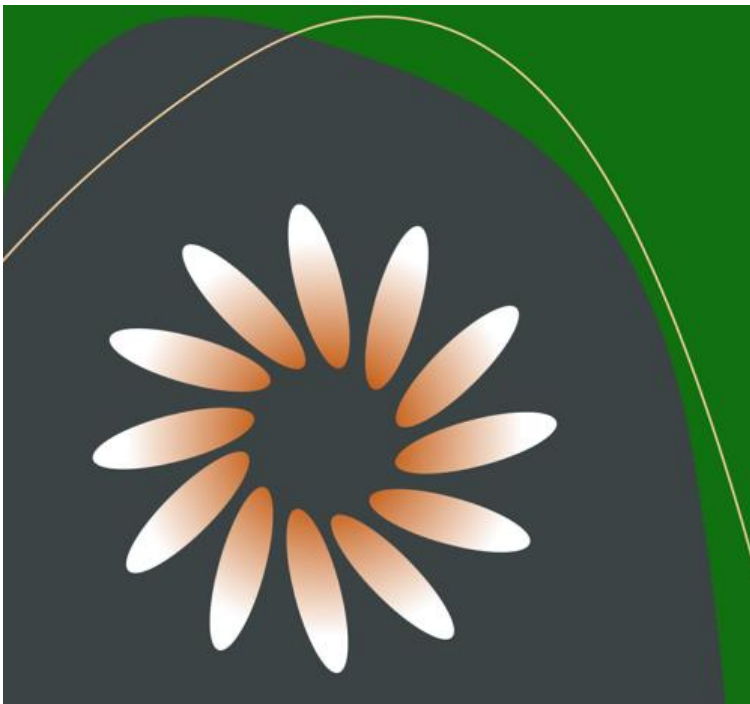# Clinical Trials Module

HALOPV
USER GUIDE

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

Contents

1. HALOPV Clinical Trials Module User Manual

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

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2. Preface

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

https://insife.com/halopv

2.1 Insife Support
The Insife Support team can be reached at support@insife.com 24/7, depending on the agreed terms. Furthermore, the Insife Support team handles upgrades related to Modules that require MedDRA codes, EDQM codes, WHO Drug dictionary, etc.

3. Introduction

3.1 Purpose of this document

This User Manual describes the Clinical Trials 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, HALOPV 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)](insife.com).
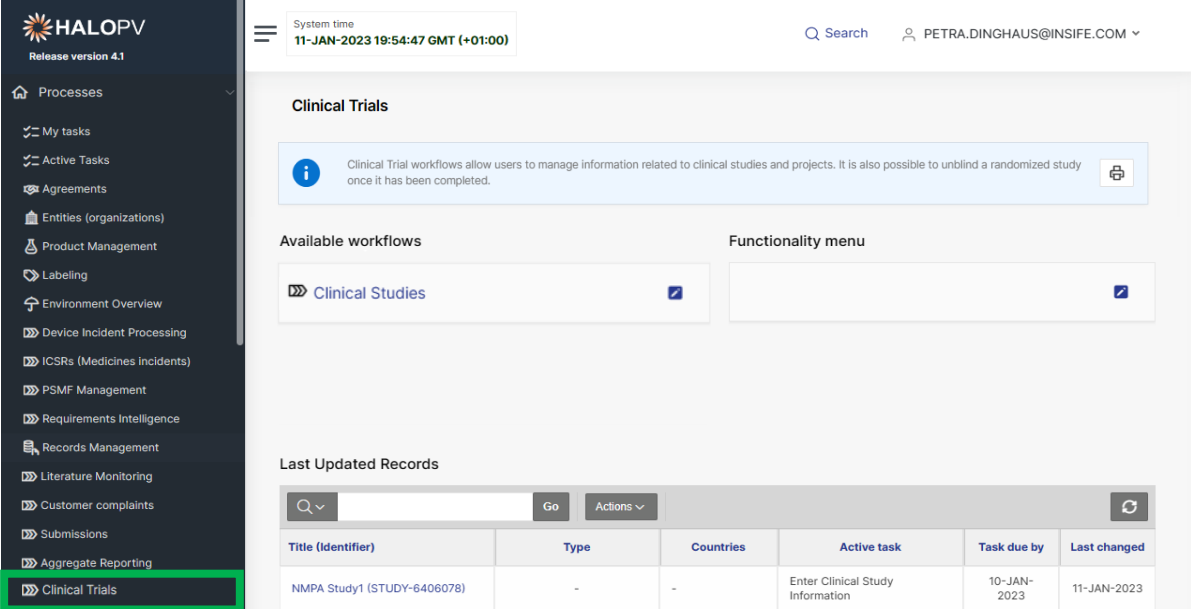
3.3 About HALOPV

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 Clinical Trials 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 **Clinical Trials Module** will show if your user has the role to access the Module.

Figure 1 Left menu, Clinical Trials 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 Clinical Trials – including the Functionality Menu.

> It is important to note that the workflows may be configured to local requirements in your HALOPV 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 Clinical Trials Module
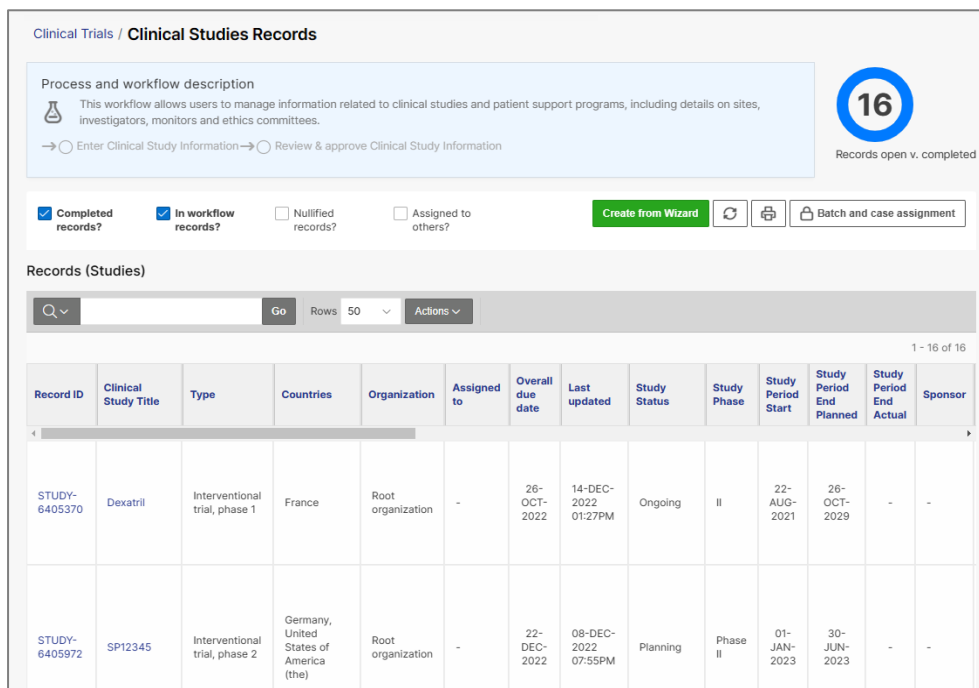
4.2   Standard Workflows

You can access a Records worklist by clicking on one of the available workflows. **E.g., Clinical Studies**. The view will display the record(s) 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.

The columns' names may vary depending on your system configuration.

It is important to note that the workflows may be configured to local requirements in your HALOPV setup. Hence the workflows may look different from the standard.

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

End users can manage the Records worklist and utilize it as a report by using the **Actions** button**.** Please consult the **User Guide on Interactive Reports**.

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

Figure 4 The screen displays the user's restriction to create new records.

Figure 5 The screen displays an example of a record where the user has 'Read-only' access. The record is locked, and the 'Complete Task' button is missing.

Figure 6 The screen displays an example of a user missing the role to access the workflow's step.

4.3 Workflow Structure

Clicking on the **"Record ID"** or **"Title/Identifier"** takes you to the individual record, as shown below.
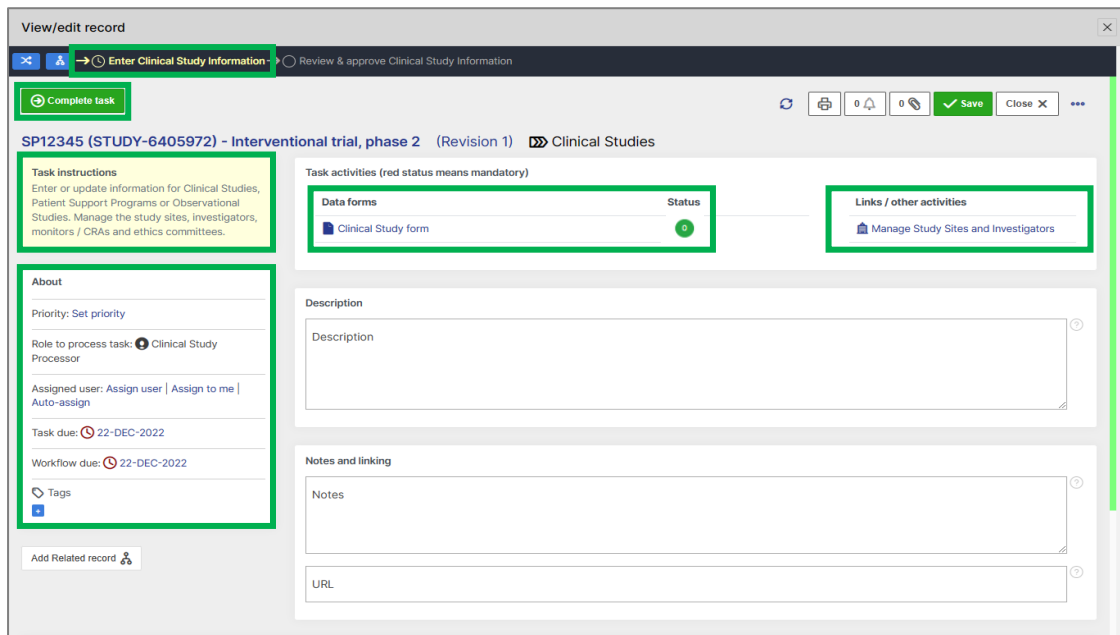

Figure 7 The screen displays an example of a user with the role to access the first step.

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.

The **Task instructions** are shown in the application on the left side of the screen, highlighted in yellow. Follow the task instruction for further information about the step.

The **About** section shows the role requires to access the step, the due task date, and the overall due date of the workflow.

The record view also displays the current **User** in the step. This means no other user can perform any task in the current step.

The **Task activities** and **Link/other activities** sections contain all required tasks buttons to execute in the step.

The **current process step** is highlighted in bold yellow. Clicking the **Complete Task** button moves the record to the next step.

A workflow step may have task actions. Their **Status** is marked with colors if validations have been configured:

- **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:** the task has activated validation rule(s). This is usually linked to a mandatory task (red mark) that requires your attention.

If an existing record should be moved to a different or even workflow step, the user can use the **Change Workflow** standard functionality located in the left corner of the record view.

A workflow consists of one or multiple Workflow Steps or Tasks, e. g. a **create/enter** step, a **review** step and an **approve** step. It might be that your local business requirement only requires two steps, **'Enter Clinical Study Information'** and **'Review & Approve Clinical Study Information'**, as shown in the example below.

Figure 8 Example of a workflow with two steps

4.3.1 User Roles Relevant to the Clinical Trials Module

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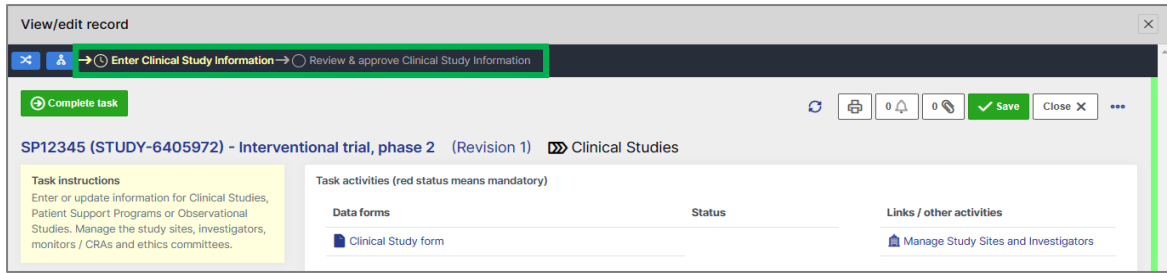our administrator may have configured other user roles. For a description of how to administer users and user roles, please refer to the Admin Guide (insife.com).

Defined User Group name (Role)	Description
Clinical Study Processor	User Group to enter and update Clinical Studies
Clinical Study Approval	User Group to approve Clinical Studies

4.4 Workflow: Clinical Studies

Clinical Study records can be created by a user, using the **Create from Wizard** button ![Create from Wizard], or they can be automatically created via an API, e. g. based on information in your Clinical Trials System.

> **Role to create record:** Clinical Study Processor
>
> **Task instructions (as shown in the application):** This workflow allows users to manage information related to clinical studies and patient support programs, including details on sites, investigators, monitors and ethics committees.

When creating a Clinical Study record manually, the user has to fill in the **Record Title** and select a **Record Type** from the drop-down list. If the **Master Duedate** is left blank, HALOPV calculates the due date for the record automatically based on the configurations.

> It is important to note that the drop-down lists may be configured to local requirements in your HALOPV setup. Hence the selections might look different from the standard.
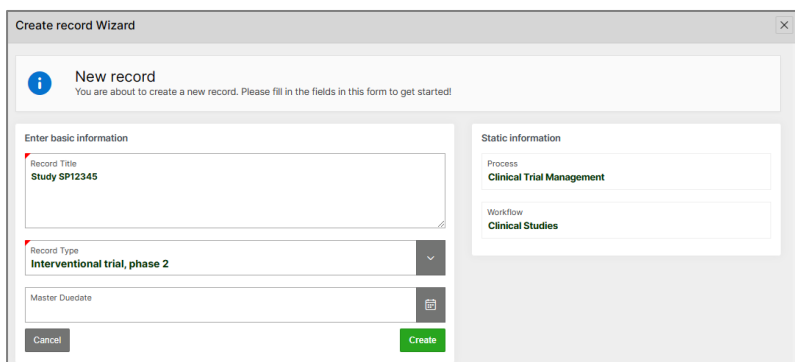

Figure 9 Manual creation of a new Clinical Studies record using the Wizard

After the Clinical Studies record is created it is displayed in step 1 of the Clinical Studies workflow:

| Enter Clinical Study Information | Review & approve Clinical Study Information |

The **Clinical Studies** workflow is composed of two steps. In the first step, users enter information regarding the clinical study and optionally upload a document (e. g. a study configuration form) into the attachment area.

The second step is the review & approve step, where the study record is reviewed and updated, if needed. If the information has been entered correctly, the record is approved, and the workflow completed.

4.4.1   Enter Clinical Study Information (Step 1)

The **Enter Clinical Study Information** step in the workflow allows users to enter information related to the clinical study.

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.
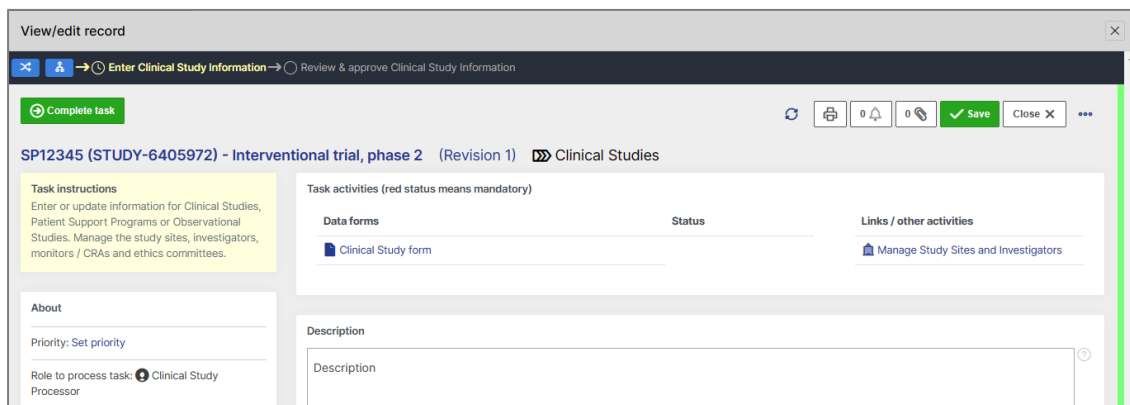

Figure 10 Clinical Studies, step 1

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.
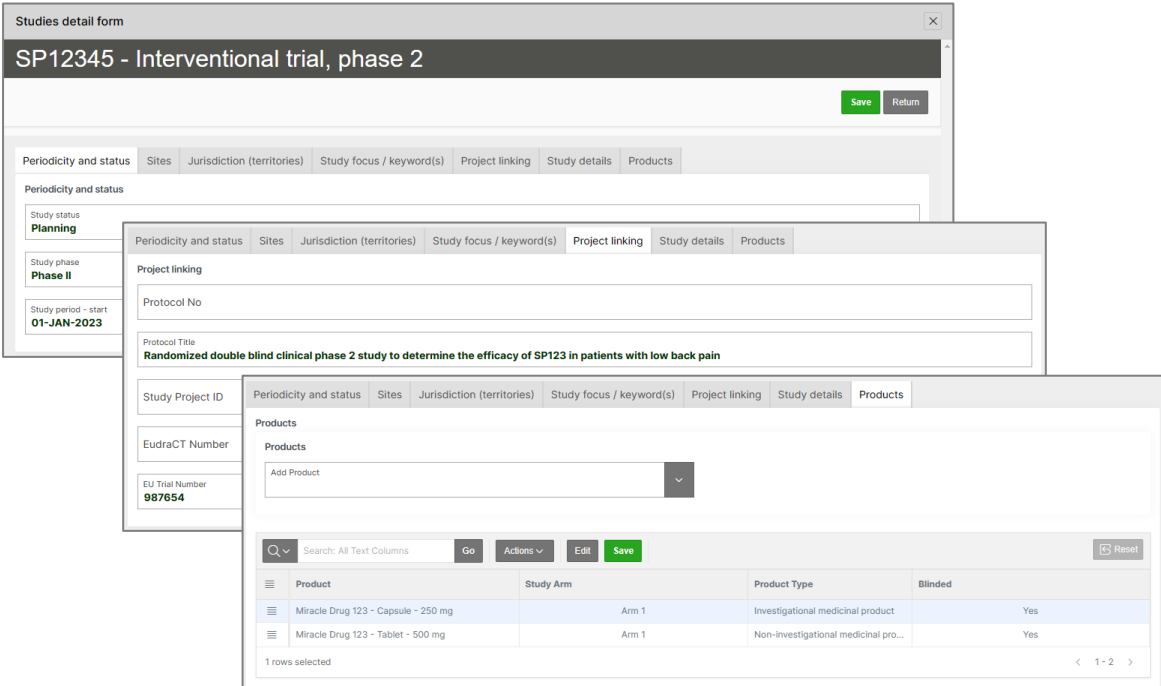
> **Role to process task:** Clinical Study Processor
>
> **Task instructions (as shown in the application):** Enter or update information for Clinical Studies, Patient Support Programs or Observational Studies. Manage the study sites, investigators, monitors / CRAs and ethics committees.

The task step contains the following data forms:

Data form	Description
Clinical Study form	This form allows entering, updating and viewing the required information captured for a clinical study, patient support program or observational study. The form is divided into several tabs, e. g. **Periodicity and status, Sites or Study Details**. Each tab contains a variety of data fields, e. g. Study status, Study period – start, Product, Blinding Status.

Key Fields	Instructions
Study Status	Enter the current status of the study, e. g. planned, ongoing or completed
Study Phase	Enter the phase of the study, e. g. II
Study Period – start, Study Period – end (planned), Study Period – end (actual)	Enter the start and end dates of the study
Add Country	Select the country(ies) that the study is conducted in
Protocol No	Enter the Protocol Number or ID
Protocol Title	Enter the Protocol Title
Study Project ID	Enter the Project ID that the study belongs to
EudraCT Number	Enter the EudraCT Number
EU Trial Number	Enter the EU Trial Number
Blinding Type	Select the blinding type of the study, e. g. double-blinded
Study has been unblinded	Check if the study has been unblinded
Add Product	Select the Product(s) that are used in the study per Protocol
Study Arm	Select the Study Arm for the Product, e. g. Arm 1, Arm 2 or n/a
Product Type	Select the type of the Product, Investigational Medicinal Product, Placebo, Comparator or Non-Investigational Medicinal Product
Blinded	Select Yes/No to indicate if the Product is blinded

Figure 11 Clinical Study form

The task step contains the following activities:

Links / other Activities	Description
Manage Study Sites and Investigators	This screen allows the user to add **Study Sites, Ethics Committees, and Investigators** to the study. Records entered in this screen will be available in the **Entities** module. Press the **'Add site', 'Add investigator / CRA', or 'Add committee'** button to add a blank row to the respective table, then click in each of the fields to enter the required information. Press **'Save'** to save.

Links / other Activities	Description
	Figure 12 Adding a new Ethics Committee

Figure 13 Managing Study Sites and Ethics Committees and Investigators

Using the **Attachment** icon [0 📎], Users can either upload documents to the **GxP area** or the **Working files (Sharepoint/OneDrive)**.

Figure 14 Document Attachment screen

Press **'Save'** to save the data in the record. Once your task is completed, click '**Complete Task**' to move the record forward in the workflow to the next task step. Click on '**Close X**' to close the record session. Otherwise, the record will be locked by your user, and the role in the next step will not be able to perform the task.

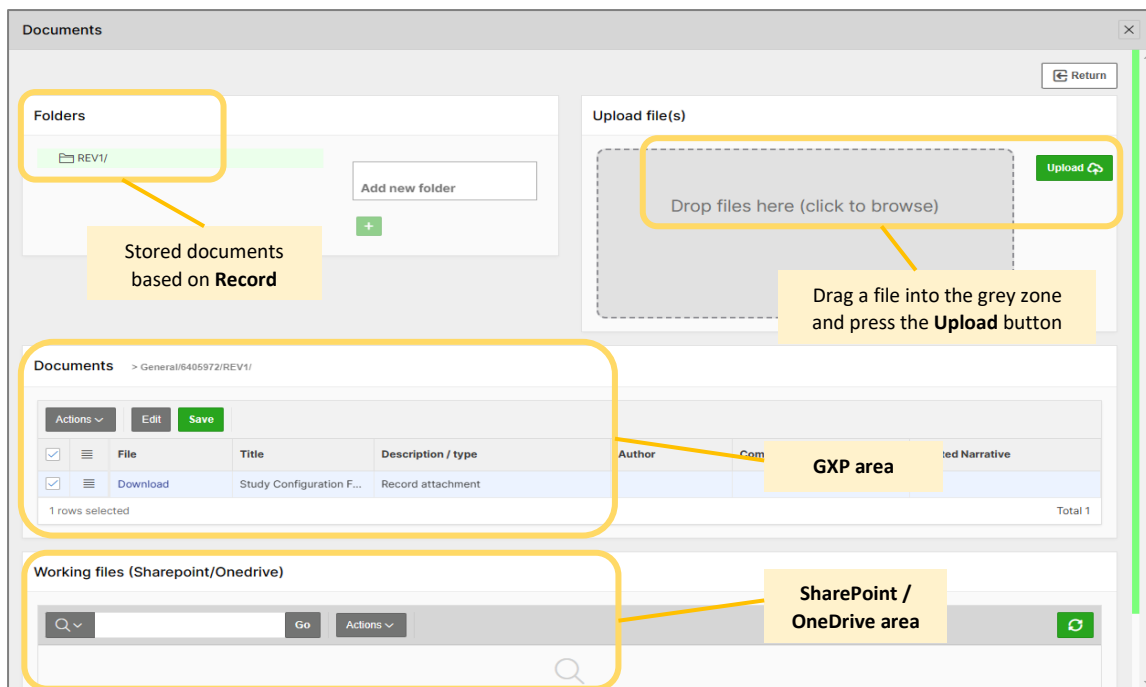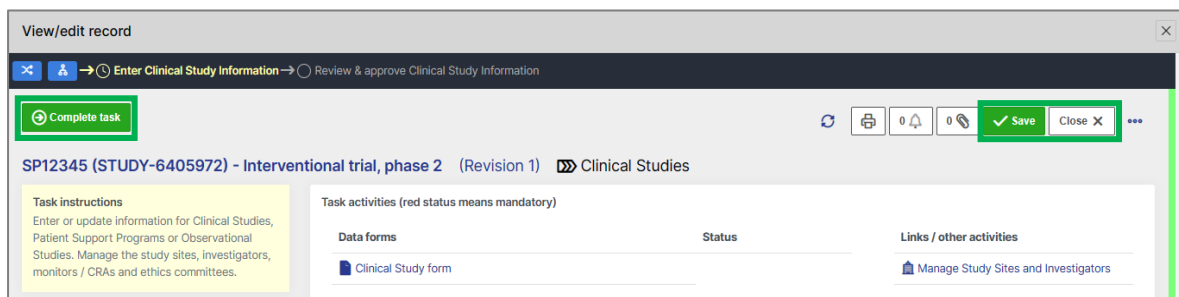*Figure 15 Saving data and completing a task*

HALOPV will send out a notification email that the Clinical Studies record has been created in the workflow step, using the following configurations:

Email Notification	Email Recipient	Subject	Message
On Complete	Clinical Study Approver	Clinical Study {MAIL_MASTER_TITLE} created in HALOPV	A new Clinical Study has been created in HALOPV: {MAIL_MASTER_TITLE} {STANDARDLINK}. Please review and approve the record.

Figure 16 Notification email

> It is important to note that the email may be configured to local requirements in your HALOPV setup.

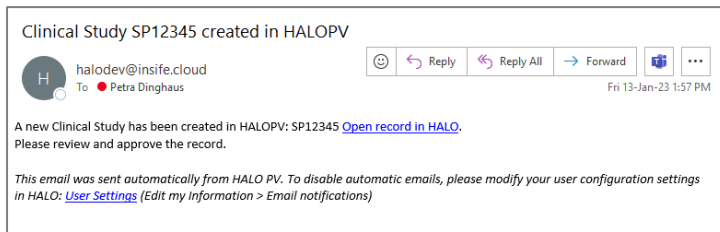## 4.4.2 Review & approve Clinical Study Information (Step 2)

The **Review & approve Clinical Study Information** step allows the user with a different user role to review the entered data for the record, make any updates if necessary and approve the record (i. e. perform a peer review).

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step.
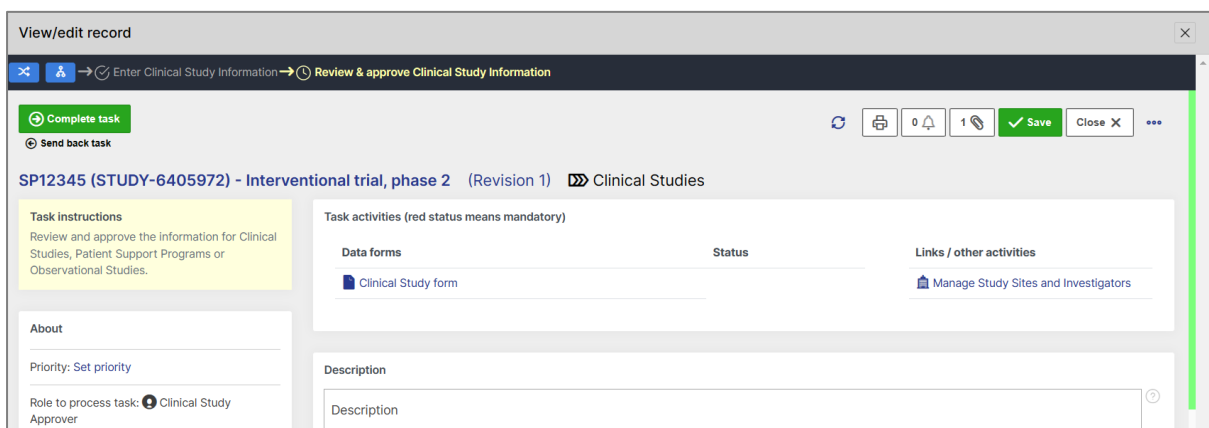

Figure 17 Clinical Studies, step 2

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

> **Role to process task:** Clinical Study Processor
>
> **Task instructions (as shown in the application):** Review and approve the information for Clinical Studies, Patient Support Programs or Observational Studies.

The task step contains the following data forms:

Data form	Description
Clinical Study form	This form allows entering, updating and viewing the required information captured for a clinical study, patient support program or observational study. The form is divided into several tabs, e. g. **Periodicity and status, Sites or Study Details**. Each tab contains a variety of data fields, e. g. Study status, Study period – start, Product, Blinding Status.

Key Fields	Instructions
Study Status	Enter the current status of the study, e. g. planned, ongoing or completed
Study Phase	Enter the phase of the study, e. g. II
Study Period – start, Study Period – end (planned), Study Period – end (actual)	Enter the start and end dates of the study
Add Country	Select the country(ies) that the study is conducted in
Protocol No	Enter the Protocol Number or ID
Protocol Title	Enter the Protocol Title
Study Project ID	Enter the Project ID that the study belongs to
EudraCT Number	Enter the EudraCT Number
EU Trial Number	Enter the EU Trial Number
Blinding Type	Select the blinding type of the study, e. g. double-blinded
Study has been unblinded	Check if the study has been unblinded
Add Product	Select the Product(s) that are used in the study per Protocol
Study Arm	Select the Study Arm for the Product, e. g. Arm 1, Arm 2 or n/a
Product Type	Select the type of the Product, Investigational Medicinal Product, Placebo, Comparator or Non-Investigational Medicinal Product
Blinded	Select Yes/No to indicate if the Product is blinded

Figure 18 Clinical Study form

The task step contains the following activities:

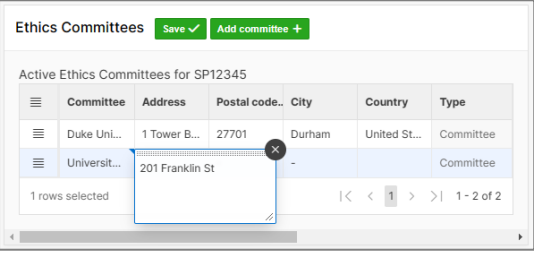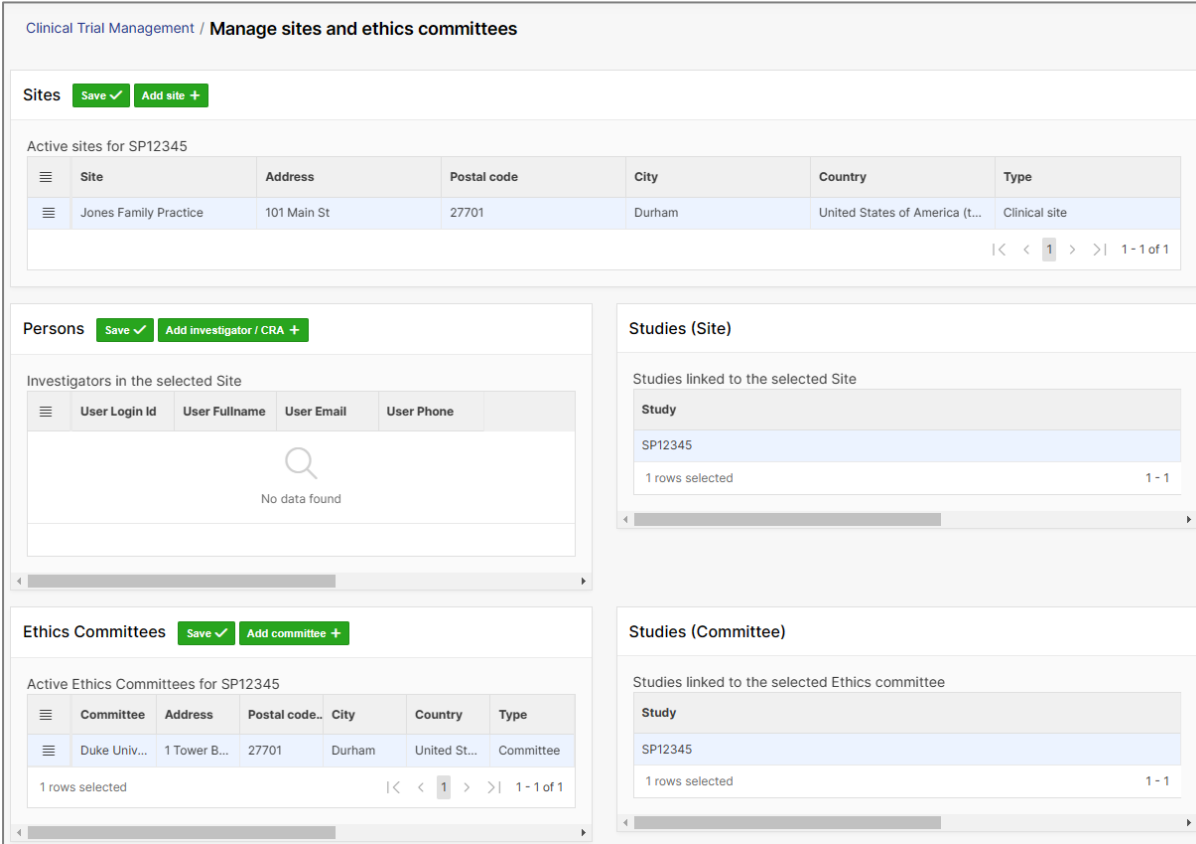| Links / other Activities	Description
Manage Study Sites and Investigators	This screen allows the user to add **Study Sites, Ethics Committees, and Investigators** to the study. Records entered in this screen will be available in the **Entities** module.

Links / other Activities	Description
	Press the **'Add site'**, **'Add investigator / CRA'**, or **'Add committee'** button to add a blank row to the respective table, then click in each of the fields to enter the required information. Press **'Save'** to save. *Figure 19 Adding a new Ethics Committee*

Figure 20 Managing Study Sites and Ethics Committees and Investigators

Using the **Attachment** icon , Users can either upload documents to the **GxP area** or the **Working files (Sharepoint/OneDrive)**.
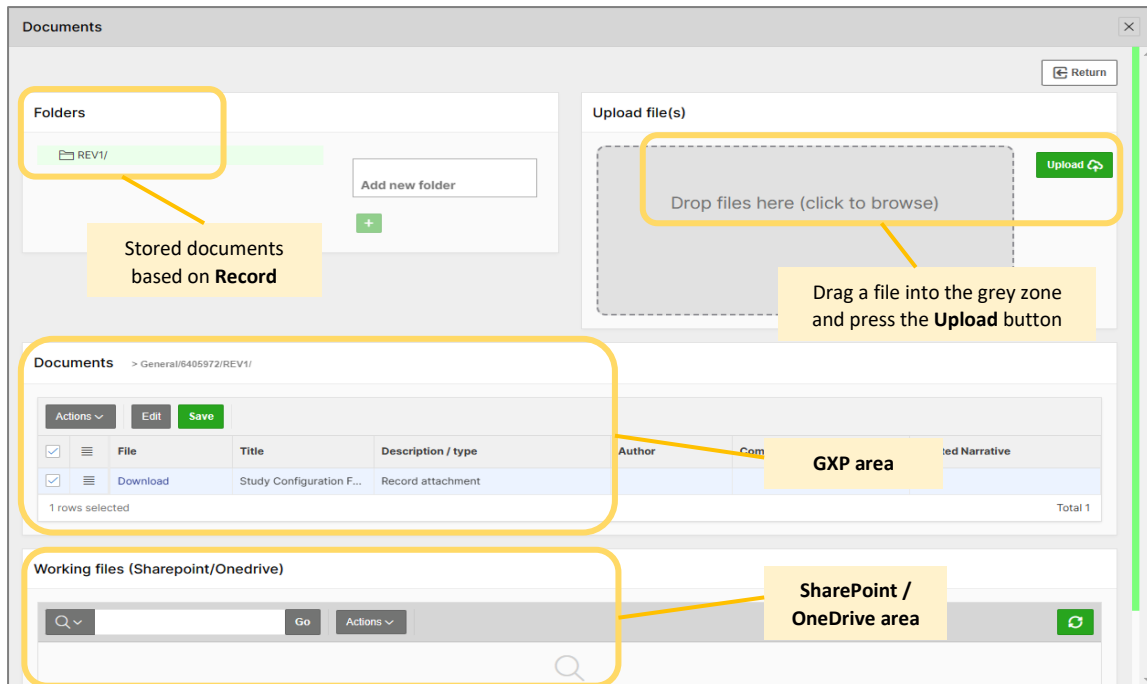
Figure 21 Document Attachment screen

Press **'Save'** to save the data in the record. Once your task is completed, click '**Complete Task**' to move the record forward to complete the workflow Click on '**Close X**' to close the record session. Otherwise, the record will be locked by your user, and the role in the next step will not be able to perform the task.
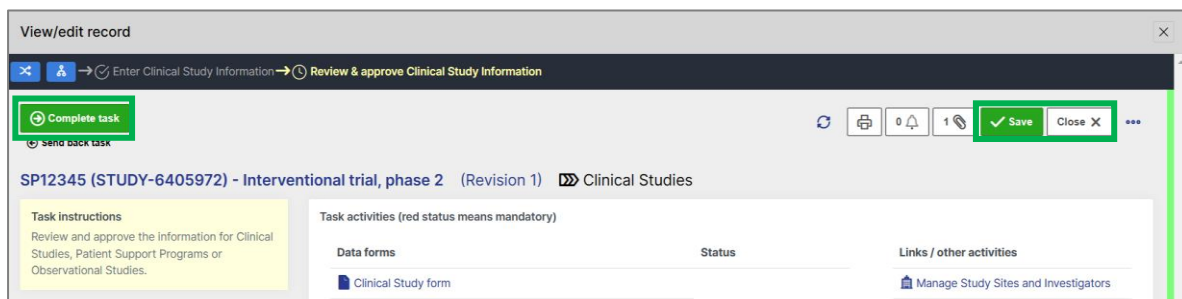

Figure 22 Saving data and completing a task and the workflow

Once task actions are completed, click on **Complete task**. The Clinical Study record is now finalized, and the workflow is at rest.