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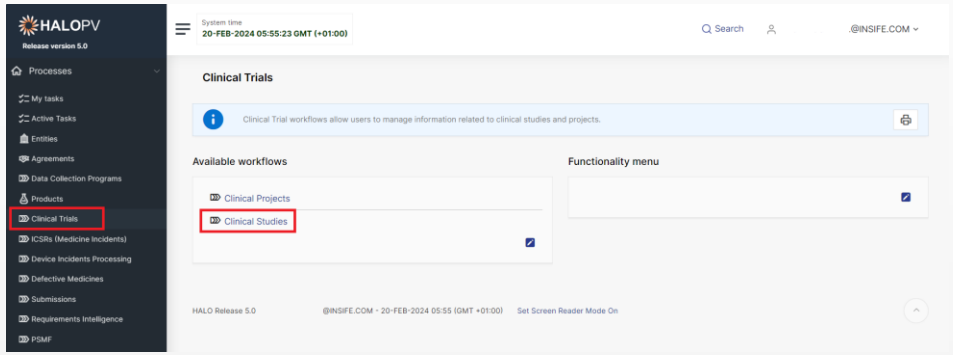
How to Configure a Study and Project

Version 1.0, For HALOPV 5.0

About Clinical Studies



Clinical trials are research studies that test a medical, surgical, or behavioral intervention in people. These trials are the primary way that researchers determine if a new form of treatment or prevention, such as a new drug, diet, or medical device (for example, a pacemaker), is safe and effective in people. Often, a clinical trial is designed to learn if a new treatment is more effective or has less harmful side effects than existing treatments.

- There are two main types of clinical research: observational studies and clinical trials.
  - Observational studies monitor people in normal settings. Researchers gather information from people and compare changes over time.
  - Clinical trials are research studies that test a medical, surgical, or behavioral intervention in people.

HALOPV supports all types and clinical and observational studies, across all phases of research projects.

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Content

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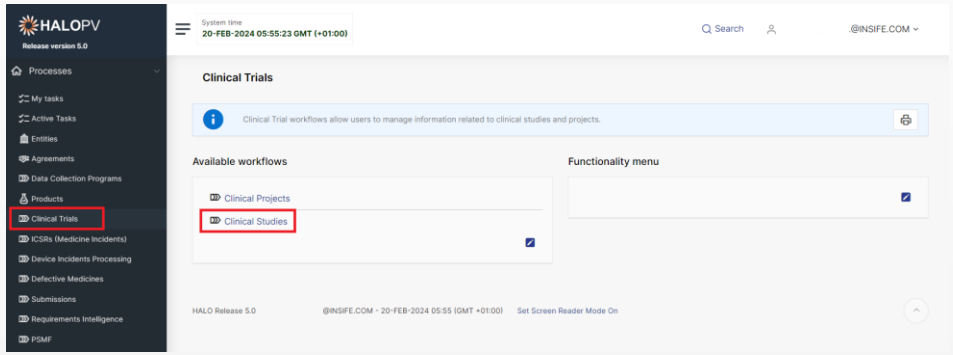
Prerequisites

Configuring a Study or Project



Pre-requisite to be able to configure a Clinical Study or Clinical Projects are –

- To Configure a ‘Clinical Study’ –
  - The user must have access to the ‘Clinical Trials’ module with ADD/ EDIT permissions
  - The user must have access to the ‘Clinical Studies’ workflow with ADD/ EDIT permissions
- To add a Site to a Study –
  - The user must have access to the ‘Entities’ module with ADD/ EDIT permissions
  - The user must have access to the ‘Entities (Internal)’ and ‘Entities (External)’ workflow with ADD/ EDIT permissions
- To Configure a ‘Clinical Project’ –
  - The user must have access to the ‘Clinical Trials’ module with ADD/ EDIT permissions
  - The user must have access to the ‘Clinical Projects’ workflow with ADD/ EDIT permissions
- Users must have access to complete the respective workflow tasks (i.e. Create / Review / Approve (as applicable))

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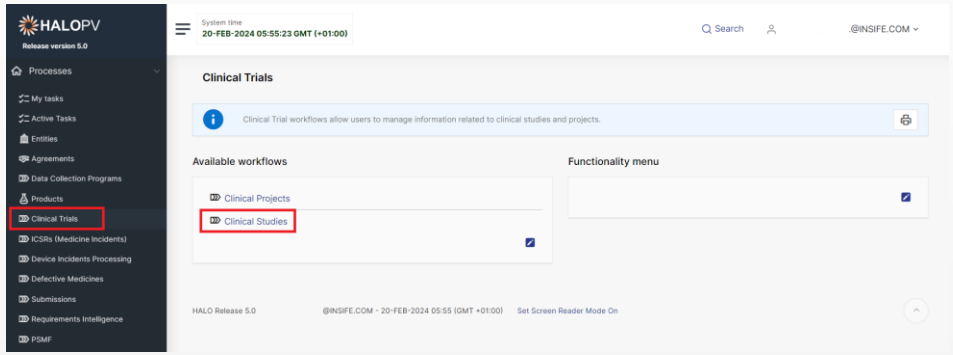
Navigating to Clinical Studies and Projects



- On the HALOPV main menu (left-hand side of the screen Deep Sea Blue), under “Processes” parent menu there will be a submenu -
  - Clinical Trials – this menu is used to configure/ review –
    - Clinical Projects
    - Clinical Studies.
- Click on ‘Clinical Trials’ menu and then click on workflow ‘Clinical Studies’ to Review/ Create a new Clinical Study.

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Review Existing Clinical Projects

The user can review an existing Clinical Project by clicking on the ‘Clinical Projects’ workflow.

- At the top of the page, you will see the ‘Clinical Projects’ workflow (Breadcrumb).
- Followed by the process and workflow description (Stages).
- Followed by Records Status/ Stage filter checkboxes –
  - Completed records? – Select to view the completed records (Studies in this case) (Reviewed and Approved).
  - In workflow records? – Default Selected, select to view the records which are in progress.
  - Assigned to others? – Select to view the records assigned to other users (not you).
- Based on the selected record status, application will list the records fall in the status in the Records Grid.
  - You can view/ review/ approve Any records (Project in this case) in the grid by using the links available in the “Record ID” Or “Title/ Identifier” column, followed by Opening the data form using “Data Forms” link.

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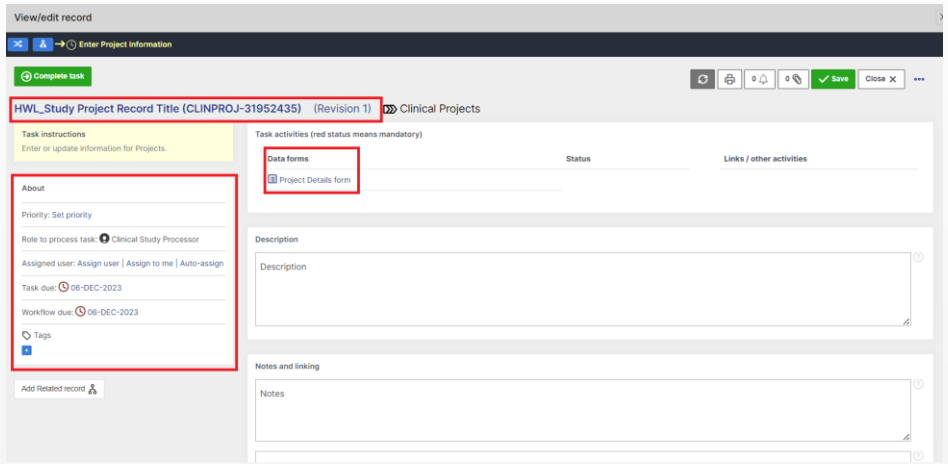
Creating Project - Details



Once you create a new project or select a project from Records Grid, you can view the basic details of the project in the “View/ edit record” popup.

- At the top you will see the study workflow (Breadcrumb)/ workflow description (Stages).
  - Workflow stages are configurable, please contact HALOPV support to create your own workflow.
- You can click on the Project Name Link to view/ update the basic details like project name, due date etc.
- Further on the Left Bottom you can View/ Update the Assigned User for the record and the Tags (if any).
- At the centre of the page there are links for –
  - Data Forms – This link opens the Project Form. It allows entering, updating and viewing the required information captured for a clinical project, patient support program or observational study.
  - Links/ other activities – This link can be used to link the project with other Workflows of the application.
    - Workflow stages are configurable, please contact HALOPV support to create your own workflow.
- Click on “Data Form” link to view/ update the project data form where you can enter project details and link project with a study.

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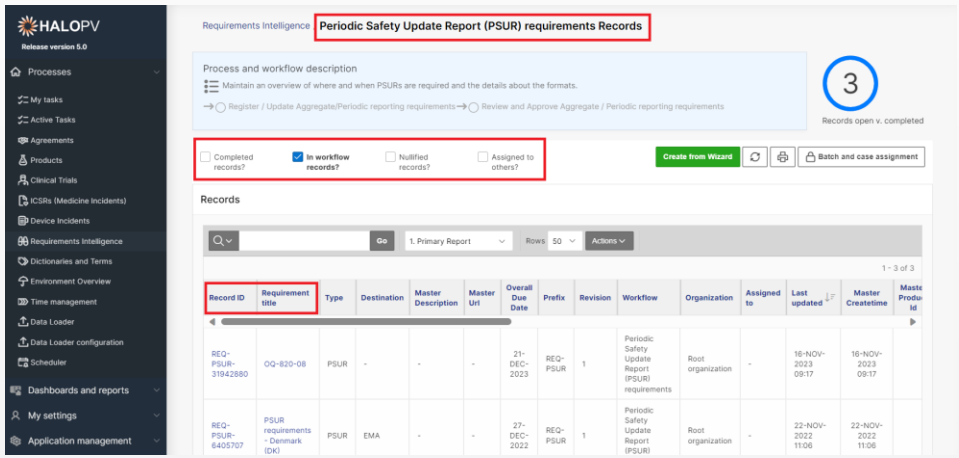
Review Existing Clinical Studies



User can review an existing Clinical Study by selecting/ clicking on the 'Clinical Studies' workflow.

- At the top of the page, you will see the 'Clinical Studies' workflow (Breadcrumb).
- Followed by the process and workflow description (Stages).
- Followed by Records Status/ Stage filter checkboxes –
  - Completed records? – Select to view the completed records (Studies in this case) (Reviewed and Approved).
  - In workflow records? – Default Selected, select to view the records which are in progress.
  - Assigned to others? – Select to view the records assigned to other users (not you).
- Based on the selected record status, application will list the records fall in the status in the Records Grid.
  - You can view/ review/ approve Any records (Study in this case) in the grid by using the links available in the "Record ID" Or "Clinical Study Title" column, followed by Opening the data form using "Data Forms" link.

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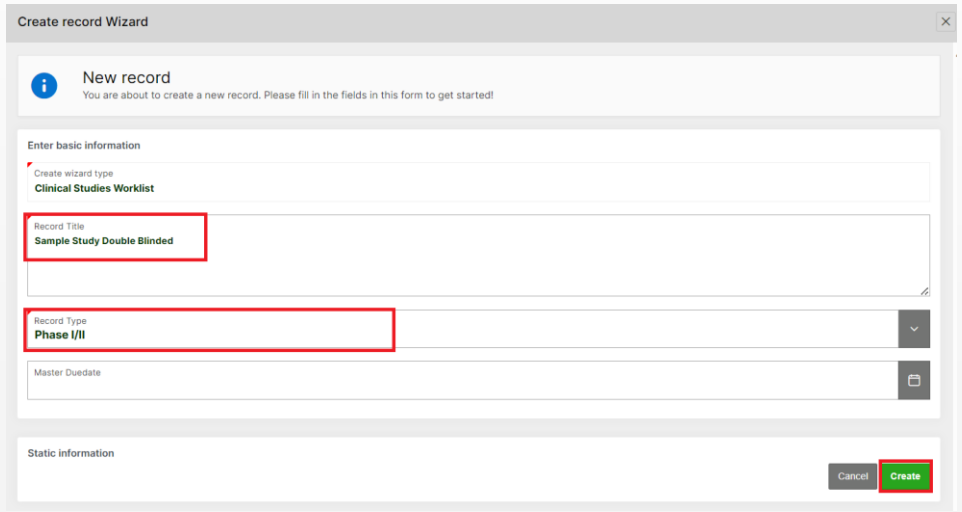
Creating A new Study - Record



The first step of creating a new Clinical Study is Creating a Study record.

- On the top of Records Grid, you can find the CREATE FROM WIZARD button (in Green colour).
  - On click on the button Application opens “Create record Wizard” popup.
- Enter the basic details like –
  - Record Title
  - Record Type – Select the Study Phase.
    - HALOPV Supports all the Pre and Post marketing Clinical Study Phases.
- Click on CREATE button to create a record.

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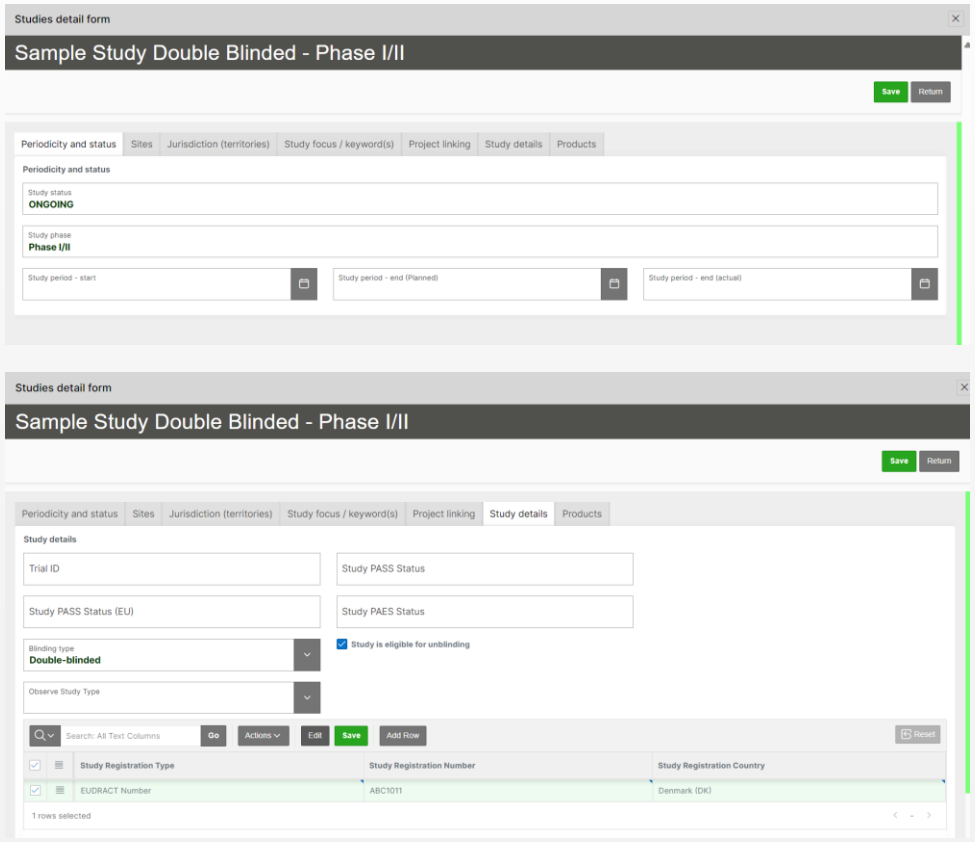
Creating Study - Data Form - I



The second Step in creating a Study is to complete the Study Data Form which contains various placeholder fields to capture the detains on study.

- Few Key Details are –
  - Study Status - Enter the current status of the study, e. g. planned, ongoing or completed
  - Study Period – start, end (planned), end (actual).
  - Add Country - Select the country(ies) that the study is conducted in
  - Other Fields - Protocol No, Protocol Title, Study Project ID, EudraCT Number, EU Trial Number, Objective(s), Keyword(s), Focus, Enrollment, etc.
  - Blinding Type - Select the blinding type of the study, e. g. double-blinded.
  - Study is eligible for unblinded.

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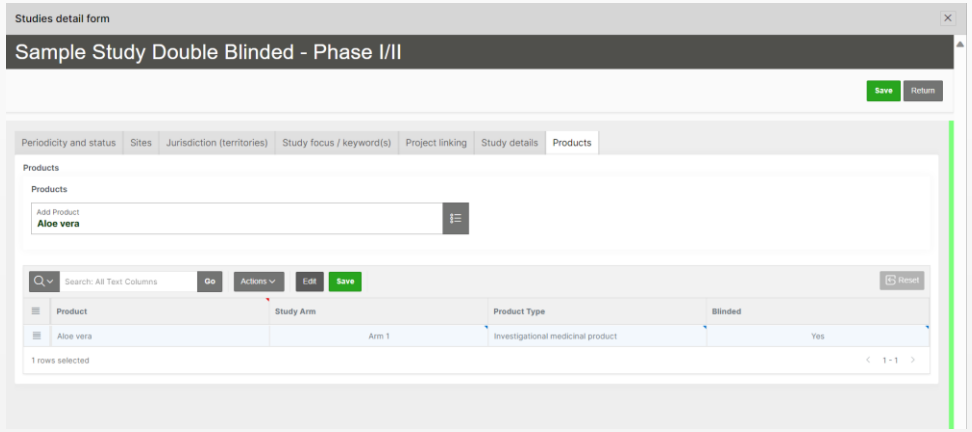
Creating Study - Data Form - II



The second Step in creating a Study is to complete the Study Data Form which contains various placeholder fields to capture the detains on study.

- Few Key Details are –
  - Products - 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

Note – HALOPV allows cross workflow linkage, for example linking a Study to Products, Sites or Projects which are separate workflows in HALOPV.

- Click on SAVE button to save the changes.
- Click on RETURN to return to “View/ edit record” popup.

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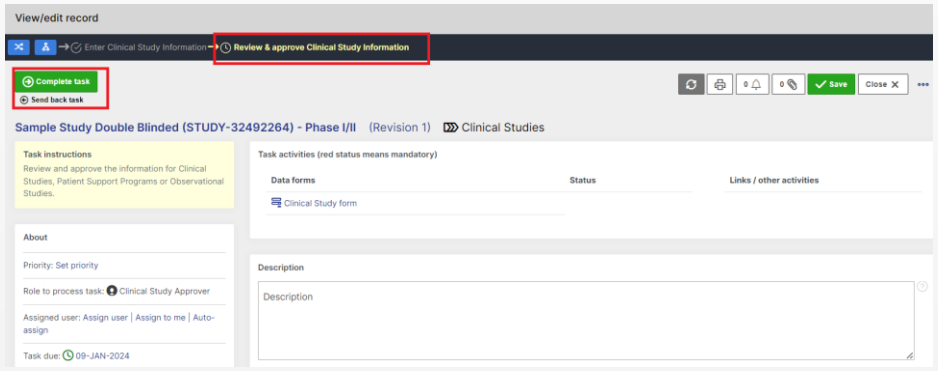
Creating Study - Complete WF



The third and final Step in creating a Study is to complete its workflow (WF) stages, i.e. Review and Approval.

- On the “View/ edit Record” popup there is a COMPLETE TASK button at top right corner (Green Colour).
  - Based on your role may not be able to Complete Task/ move the study into next workflow stage.
  - Please contact your system administrator to get the required role.
- Click on COMPLETE TASK button.
- Now, the Record Reviewer/ Approver will be able to –
  - Review approve or send back the study using respective buttons.
- Once a Study is Approved using the COMPLETE TASK button by Approver the record will reach Lock state (cannot be edited can only be up-versioned) and will be visible in “Completed Record?” list of records.

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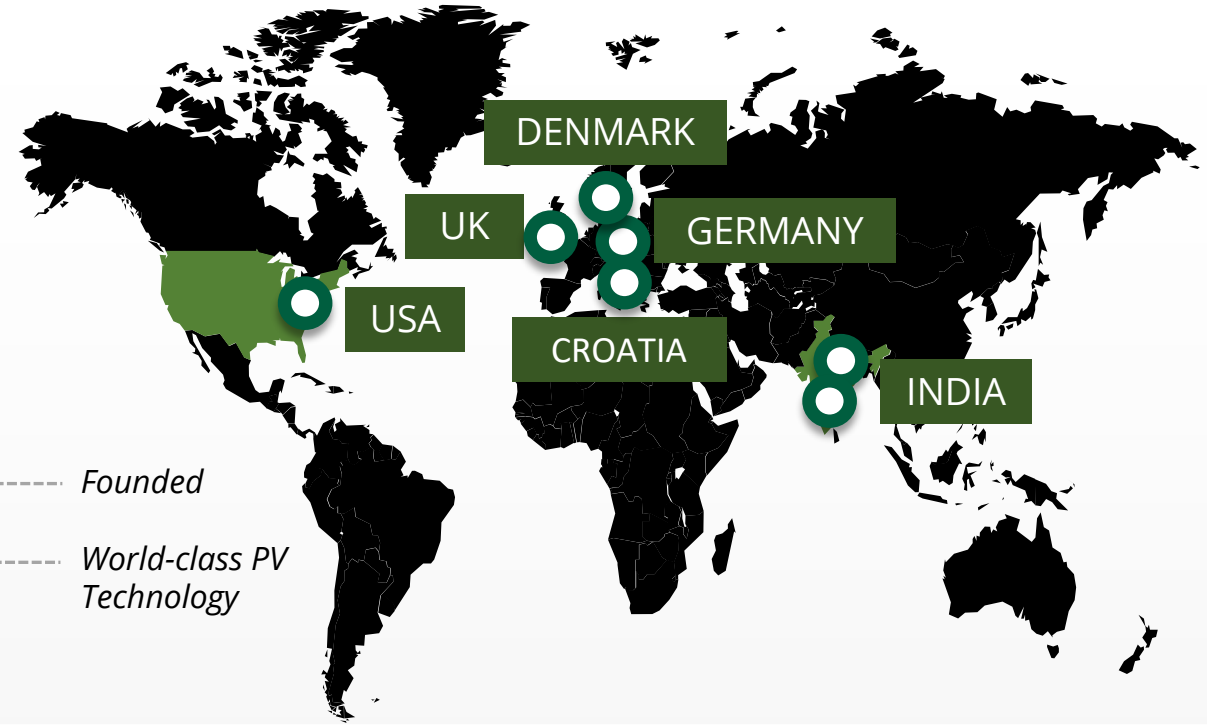
About Insife

Game-changing drug safety **technology and consulting**

Insife are supporting our clients with best-in-class technology and domain expertise from our global footprint

Insife consists of approx. 100 PV FTEs across the world, making us the biggest Europe-based company of its kind

We are ISO 9001, ISO 27001, ISO 14001 and GDPR certified



2017 --------- *Founded*

2023 --------- *World-class PV Technology*

Who are using our technologies?

5
Tier-1 Pharma companies

2
Tier-1 Regulatory Agencies

20+
SME pharma /biotechs

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THE FUTURE IS GREEN

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