



sanofi

Externally Sponsored Research (ESR)

Investigator Sponsored Studies (ISS) | Externally Sponsored Collaborations (ESC)

ESR APPLICANT

Member of the External Sponsor / Principal Investigator team

iEnvision® 2.8 User Guide

Using This Guide

NAVIGATION

Quickly navigate through the guide using the icons in the top-right corner of each page



Guide Main Menu



Last Page Viewed

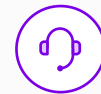
SUPPORT RESOURCES



To access the iEnvision ESR system, please click the link below:
[iEnvision ESR](#)



For **general ESR questions**, please liaise with your Sanofi Medical Contact

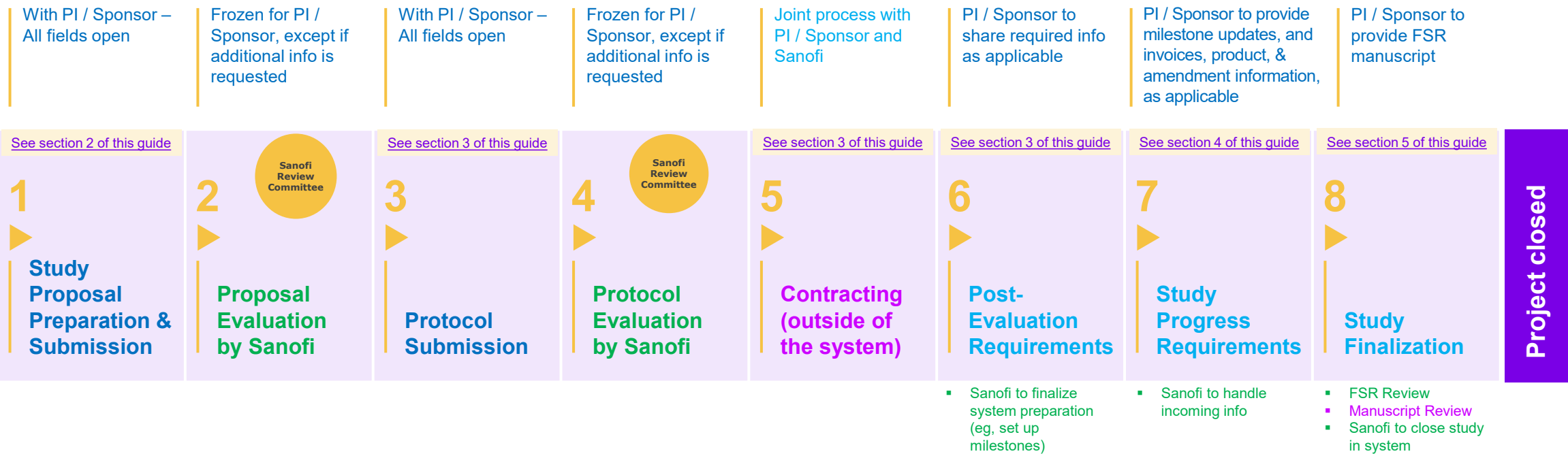


For **iEnvision ESR system support**, please contact:
Email: helpdesk@envisionpharmasupport.com

Welcome!

- The schema below outlines the Sanofi ESR process, from Proposal Submission to Study Finalization, including Final Study Report and Publications, especially Primary Manuscript. **Blue text** above the schema provides you with some insights of your edit rights at the various steps. **Green text** below the schema highlights actions done by Sanofi at the latest steps.

Click the **purple** boxes below to navigate directly to related information in this guide, or use the Guide Content hyperlinks on the next page



STATUS	For all studies			For human studies		For all studies		
	• Incomplete	• Proposal Evaluation • In Review*	• Protocol Submission	• Protocol Evaluation • In Review*		• Project Setup • In Review**	• Active • In Review**	• Project Closure • In Review***

Note: Decline at any step stops the process

Under certain circumstances, the proposal and protocol may be submitted concurrently

Dark Blue text = PI / Sponsor
Green text = Sanofi
Aqua text = PI / Sponsor and Sanofi
Purple text = Outside ESR system

In Review status
* of initial proposal or of protocol, respectively
** of amendment, if any
*** of final study report

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01 | REGISTRATION AND ACCESS

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Access the iEnvision ESR Portal



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System Login

User Name

Password

Log In

Register for New Account

Forgot Password?

Forgot Login ID?

Contact Us

Email: helpdesk@envisionpharmasupport.com

Externally Sponsored Research Studies

Sanofi is committed to supporting medically and scientifically sound research aimed at the advancement of therapeutic areas of interest to Sanofi with the goal of advancing care. Sanofi receives, reviews, and responds to requests from healthcare professionals (HCPs), scientists, and researchers or institutions (i.e., external sponsor) for research support.

There are two types of proposals:

- Investigator Sponsored Studies** are defined as unsolicited research originating from an external sponsor entity, institution or organization and include studies also known as investigator sponsored trials (IST), expert initiated research (EIR) or any other term which may reference investigator sponsored or investigator-initiated research.
- Externally Sponsored Collaborations** are conducted in collaboration with an institution or organization and are based on a jointly defined research where regulatory sponsorship is held externally to Sanofi.

The external sponsor must not be a pharmaceutical company or a vendor. Individual investigators are not eligible to enter into an ESC with Sanofi. Prior to submitting your study proposal, please be sure to review our "Areas of Support" section below. Also, at the top of the page, you will want to familiarize yourself with our "FAQs" and "How to Apply" documents.

Report any adverse events to contact information below. Please email us at CL-CPV-Receipt@sanofi.com

All products except Vaccines

Vaccines

Email: PV.outsourcing@sanofi.com

For technical assistance with please email us at helpdesk@envisionpharmasupport.com

Our Mission Areas of Support Resources

From EPG site: © 2016 Envision Pharma Limited. "Envision Pharma Group", "Envision Technology Solutions", "Dataquest", "Pharmatrace", "Clear", "Executive Window", "MediInfo", "Envision", "Envision Scientific Solutions", "Evidence Scientific Solutions", "Engage Scientific Solutions", "Excel Scientific Solutions", "ProScribe", "Envision Market Access Solutions", and "MSLsolve" are registered trademarks or trademarks of Envision Pharma Limited or its affiliate/group companies. All rights reserved.

For Externally Sponsored Research Studies (ESR) applications, navigate to the Sanofi ESR Portal landing page:

[iEnvision ESR](#)

APPLICANTS ALREADY HAVING ACCESS

Log into the Sanofi ESR Portal by entering your credentials in the **System Login** section

NEW APPLICANTS

Must first create an account by selecting the **Register for New Account** link

HELP DESK SUPPORT

Support for login and technical inquiries

Log Into iEnvision ESR (1 of 2)

New Applicants must complete registration to create an account before proceeding with applications for ESR studies

To register for a new account:

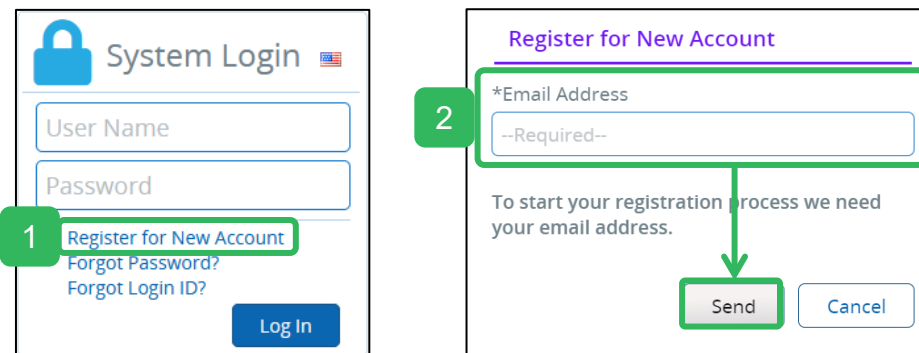
1. Self-register for an account by clicking the **Register for New Account** link on the right-hand side of the Sanofi ESR Portal
2. Enter your ***Email Address** and then click **Send** to open the **User Registration Form**

Note: The system will only accept official organizational email addresses; please do not register using your personal email address

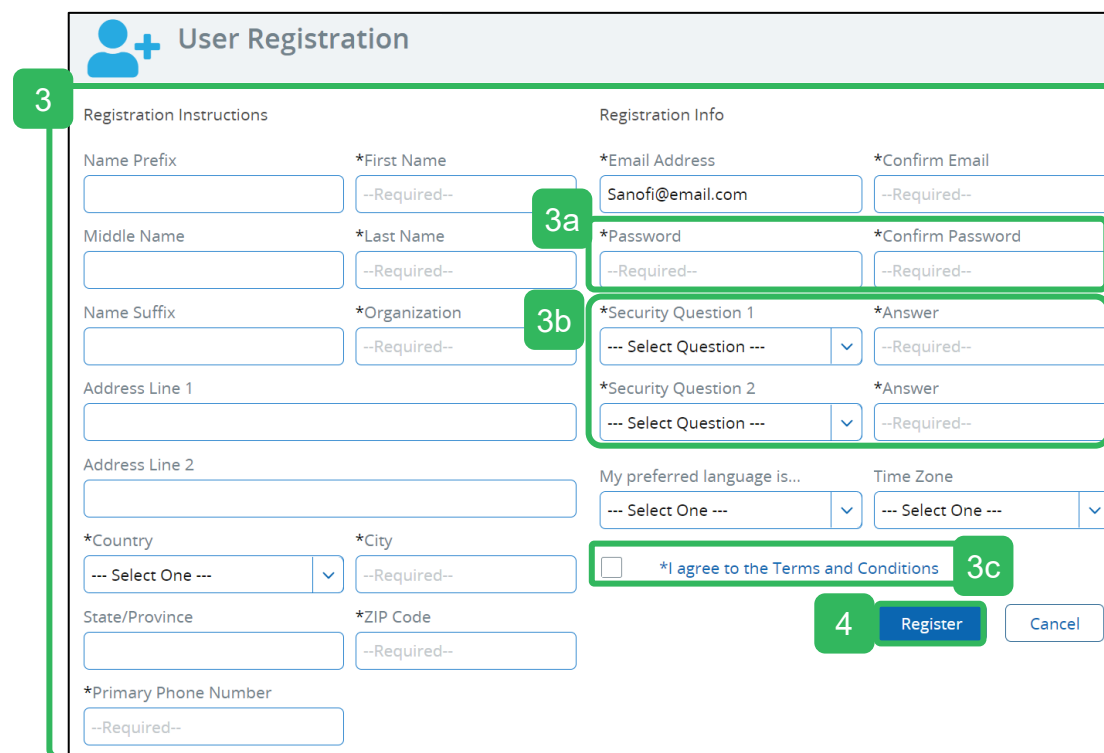
3. Complete the **User Registration** form, including all required fields marked with an asterisk (*) and the following:
 - a. Create a Password with a minimum of eight characters with at least one lowercase and one uppercase letter
 - b. Select two security questions and their respective answers
 - c. Agree to the **Terms and Conditions** by selecting the checkbox

4. Click **Register** to submit your **User Registration** form

Note: You will receive an email containing an activation link. Click the link to activate your account.



The image shows two side-by-side screenshots. The left screenshot, titled 'System Login', has a green box labeled '1' around the 'Register for New Account' link. The right screenshot, titled 'Register for New Account', has a green box labeled '2' around the '*Email Address' field and the 'Send' button. A green arrow points from the 'Send' button to the 'User Registration' form below.

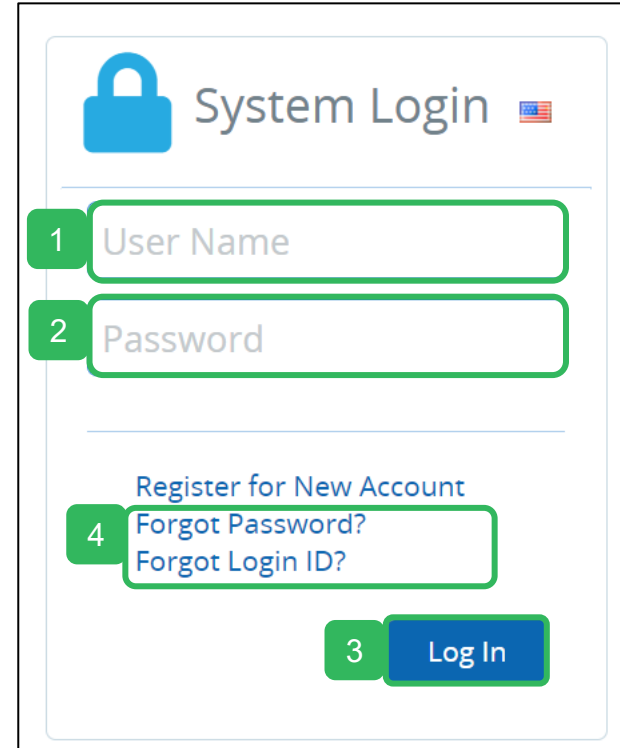


The image shows the 'User Registration' form with a green border. It is divided into 'Registration Instructions' and 'Registration Info'. The 'Registration Info' section contains several fields: Name Prefix, *First Name, *Email Address, *Confirm Email, Middle Name, *Last Name, *Password, *Confirm Password, Name Suffix, *Organization, *Security Question 1, *Answer, *Security Question 2, *Answer, Address Line 1, Address Line 2, My preferred language is..., Time Zone, *Country, *City, State/Province, *ZIP Code, *Primary Phone Number, and a checkbox for '*I agree to the Terms and Conditions'. Green boxes labeled '3a', '3b', and '3c' highlight the *First Name, *Last Name, and *I agree to the Terms and Conditions fields respectively. A green box labeled '4' highlights the 'Register' button.

Log Into iEnvision ESR (2 of 2)

Newly registered and returning applicants, log in to the system from the Sanofi ESR Portal landing page:

1. Enter the email address used in the registration process as your **User Name**
2. Enter your account **Password** (as entered on your **User Registration Form**)
3. Click **Log In**
4. If you forgot your **Login ID** or **Password**, use the **Forgot Password?** and **Forgot Login ID?** links to self troubleshoot



The image shows a 'System Login' form with a blue padlock icon and a small US flag. The form contains the following elements:

- 1** User Name (input field)
- 2** Password (input field)
- [Register for New Account](#) (link)
- 4** [Forgot Password?](#) and [Forgot Login ID?](#) (links)
- 3** Log In (button)

Sanofi's Global Privacy Policy Agreement

New ESR users will be asked to agree to Sanofi's **Global Privacy Policy** before they can access the portal

1. Read through the statement and click **Agree** to move forward to your ESR **Dashboard**

Note: If you select **Disagree** the system will automatically log you out and you will not be able to submit your application/request

GDPR

Agreement

Your personal data will be processed by the Sanofi Aventis Groupe in order to respond to your request for support for conducting an external research linked to Sanofi Therapeutic areas.

In order to achieve this purpose, your identification and contact Information will be processed on the basis of compliance with best practices and legal obligation.

Your data will be processed in a confidential and secure way and their authorized recipients are only processors used by Sanofi to achieve the purposes listed above and notably in some instances outsourced personnel.

Your data may be transferred outside of the European Economic Area. In such a case, Sanofi implements adequate safeguards such as the Standard Contractual Clauses. Your data will be kept during all the research duration, but also after the research completion, to comply with Audit purpose and in any case, will be archived for no longer than the global retention policy requires.

You can have an overview on how Sanofi processes personal data by visiting the Sanofi Global Privacy Policy [here](#).

According to applicable data protection law, you may have the rights to:

- * Access your personal data and ask for their portability
- * Ask for the rectification or erasure of your personal data
- * Restrict their processing or object to it

In order to exercise these rights, please click [here](#).

If you deem that your rights have not be respected, you have the right to lodge a complaint to the data protection authority in your country.

1**Agree**

Disagree

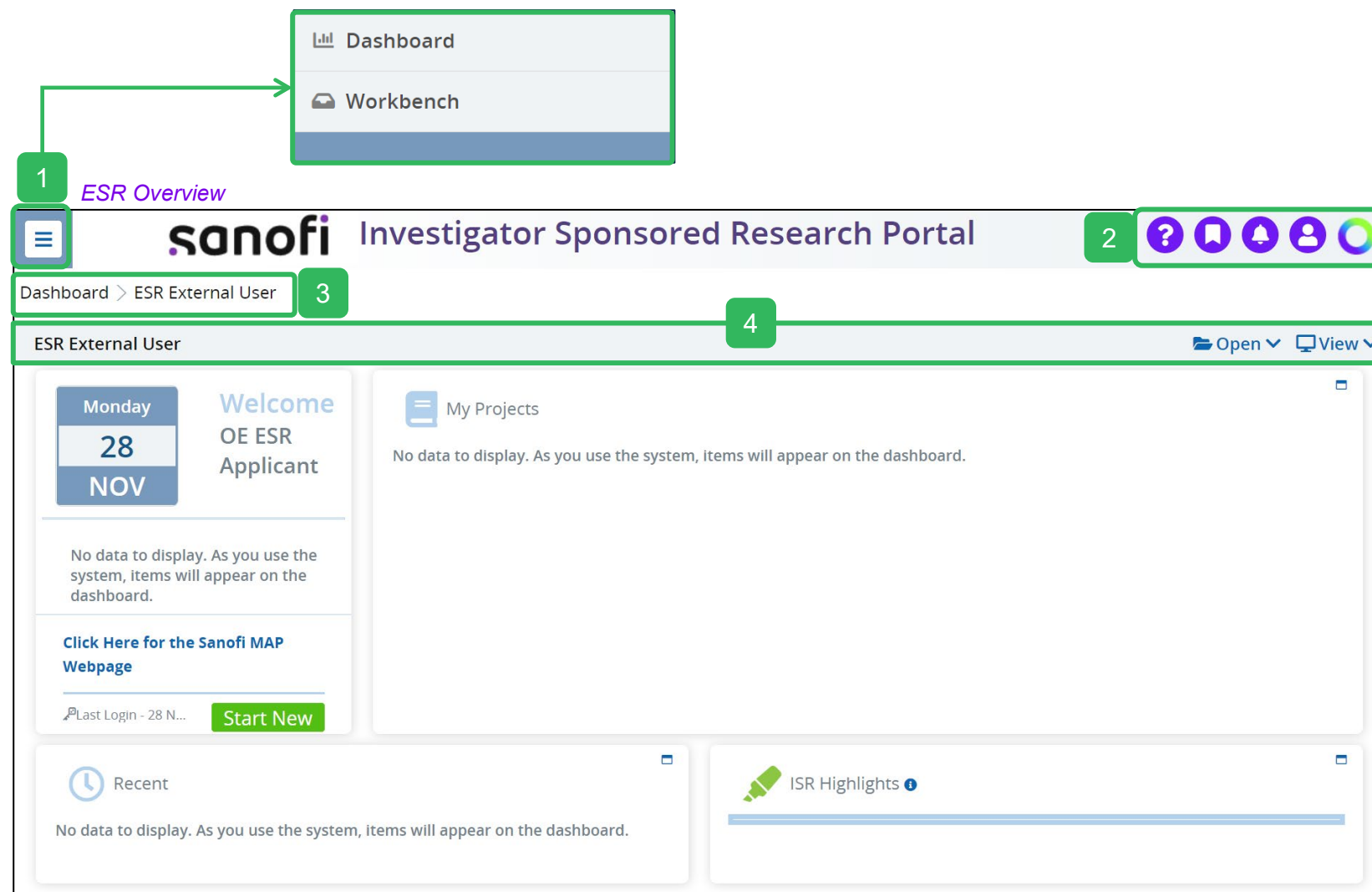
Navigation Overview

After logging in, the ESR **Applicant Dashboard** is your default landing page

To navigate the Sanofi ESR Portal:

1. Use the **Navigation Menu** to access features such as your **Workbench**
2. The **Global Tools** provide access to system support, bookmarks, notifications, and your user profile
3. The **Navigation Trail** shows your current location within the Sanofi ESR Portal, and the path taken
4. The **Context Bar** and **Context Menus** display a brief overview of your current screen location and allow you to interact with and action your tasks

Note: Use the back/forward buttons on your browser to move to/from a previous screen. The system will autosave when you make changes, but you can also save changes manually using the **Actions** menu.





02 | SUBMIT A NEW APPLICATION

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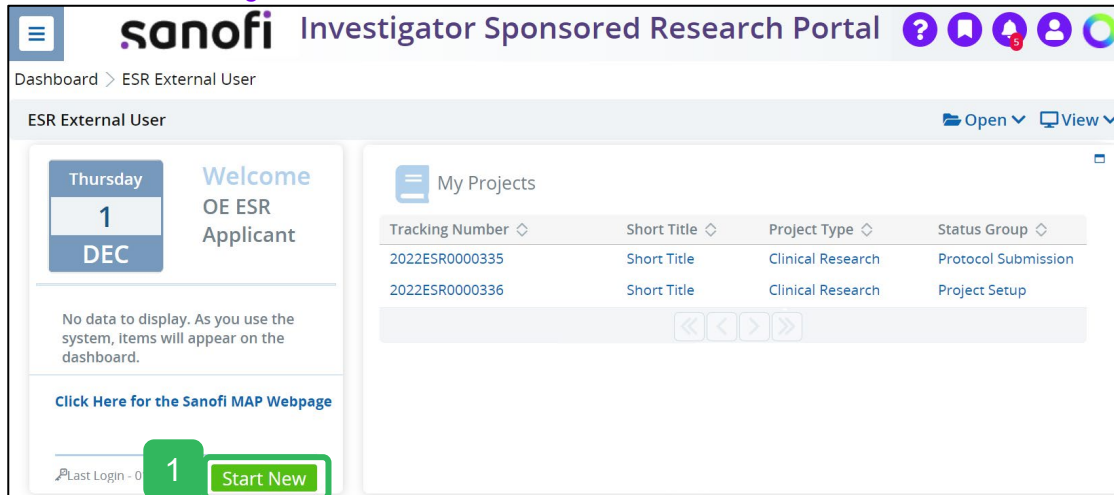
Start a New Application

Start a new ESR application from the **Welcome** section of your **Dashboard**:

1. Click the **Start New** button to open a **New Application**
2. Select the **Application Type** based on the provided definitions in the **New Application** window
 - **Clinical Research**
 - **Non-Clinical Research**
3. Click **Continue**

Note: It is important to ensure you start your application using the correct **Application Type**. If it is incorrect, you will need to start over and fill out the application again using the correct type.

ESR Welcome Widget



Sanofi Investigator Sponsored Research Portal

Dashboard > ESR External User

ESR External User

Thursday 1 DEC

Welcome OE ESR Applicant

No data to display. As you use the system, items will appear on the dashboard.

[Click Here for the Sanofi MAP Webpage](#)

Last Login - 0

1 Start New

My Projects

Tracking Number	Short Title	Project Type	Status Group
2022ESR0000335	Short Title	Clinical Research	Protocol Submission
2022ESR0000336	Short Title	Clinical Research	Project Setup

ESR Application Types



New Application OE ESR Applicant 01 Dec 2022 Actions

Application Type

Please indicate what you are applying for

2 ☒ **Clinical Research**
Clinical research consists of studies in humans subjects/patients. This covers the following types of studies:

Interventional study: Any in-human study whose protocol provides for the administration of an IMP and/or a deviation from established standard of care (off-label)

Non-Interventional study: Any in-human observational study including prospective or retrospective product or disease registries, requiring the administration of Sanofi product and does not deviate from standard of care (on-label). For Vaccines, may include safety and effectiveness pharmacoepidemiological studies

☐ **Non-Clinical Research**
Pre-Clinical Research consists of research conducted either in Vitro or in Vivo in animals, but not in humans

3 Continue

Acknowledgement

Once the application type has been selected, you will be prompted to read and accept the **Acknowledgement** statement:

1. Review the statement
2. Check the **Acknowledged** box to confirm consent to the processing of your personal information as described in the statement
3. Click **General Information** to open your application and begin providing details on your request for support

1



Acknowledgement

As a condition to the submission of your application, you, the Sponsor or the requestor acting on behalf of the sponsor, must read and certify the following:

I certify to the Company (Company refers to Sanofi or its affiliates) that to the best of my knowledge, information and belief after due inquiry:

The information in this application is truthful, accurate and complete, and I agree to supplement or change any information that is or becomes untrue, inaccurate or incomplete in any way;

I am duly authorized by the requestor and any partner or affiliated organization(s) identified above, to submit this application;

The undersigned, the requestor, affiliated or partner organizations' and individuals of any of them who oversee the organizations or will participate in the activities for which support is requested (hereafter collectively referred to as "requestor") do not appear on any national, state or federal research restriction or debarment list and are not disqualified from receiving support from pharmaceutical, biotech or medical device manufacturers.

I agree that both this request and any support I may receive from the Company is not in any way connected to, or conditioned upon, any past, present or future prescribing, purchasing, or recommending of any product manufactured or marketed by the Company.

With respect to requests for support for specific programs and activities, I affirm that this application is for a project or trial that will take place or occur in the future; projects or studies which are ongoing will only be supported in rare circumstances and completed project or study are not eligible for support.

I acknowledge that the Company does not commit to review any request within a specific period of time.

I acknowledge that the submission of my request does not mean that the request will be supported by the Company and that only an authorized review committee at the Company can approve or deny applications. I understand that the Company may agree to support for a lesser amount than that originally requested.

The idea to seek support is my own and no Company employee has suggested that I develop this IST/ISS proposal and seek support from the Company, nor provided input into the content of the IST/ISS proposal

I understand that if the Company decides to approve my request, the Sponsor-Investigator identified above will be held to the standards and obligations applicable to both those roles as set forth in all applicable guidelines, national or local laws and regulations and, if applicable, the ICH-E6 Good Clinical Practice guidelines and the US 21 CFR Part 312 and 21 CFR 312.3.

I acknowledge that the Company reserves the right, but does not have any obligation, to correct any administrative or technology-based errors which may occur during the application, submission or review processes.

I agree that the Company may contact me in the future, including by phone, fax, mail or email for the purpose of obtaining additional information regarding an application, reconciliation of the funds and/or products awarded, or for any other legitimate purpose. I understand and authorize that the Company will store the data submitted in this application into a database for periods of time as consistent with the Company's retention policy or such longer period of time as may be required for legal purposes, including compliance and documentation of the application and review process.

I voluntarily disclose my name and any other personal information or data submitted in this on-line application form or process, and authorize the Company, its respective employees, affiliates and contractors, to use my personal data, including processing my personal data inside and outside of my country of residence, medical or research practice for purposes related to the research support request, including any research application approved by the Company. I am aware that my personal data might be transferred to countries which may not require the same level of protection for my personal data as required in my country of residence, of medical or research practice.

I understand that iEnvision is not the system for reporting side effects, either actual or potential, associated with the use of drugs. I have to use the relevant procedure in my country.

By clicking here, I certify to the best of my knowledge, that the statements made in my submission are true, complete, and accurate and that I acknowledge the above-mentioned statements.

☒ *Acknowledged

3

[General Information→](#)

2

Application Overview

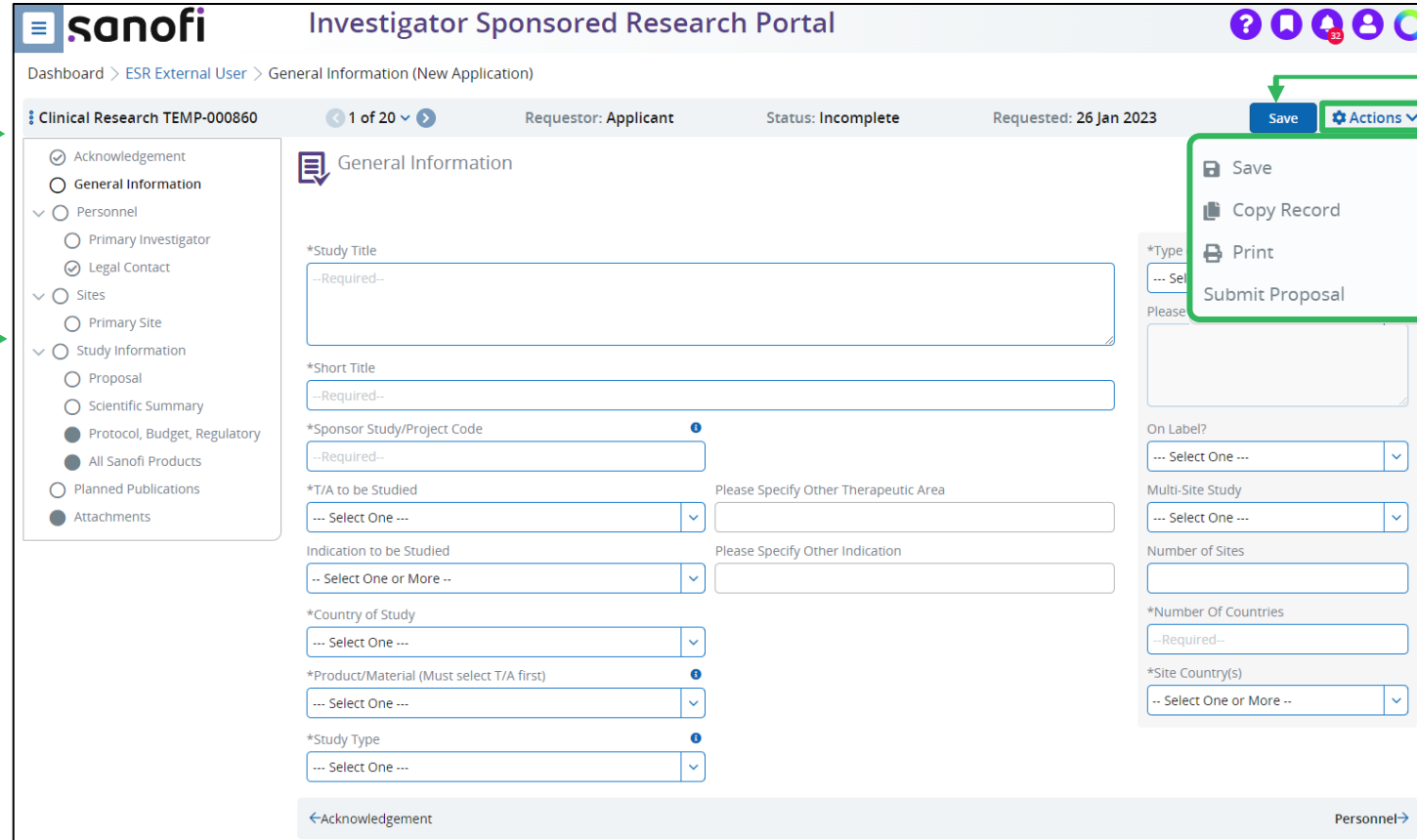
The **Context Bar** contains key information about application, including the **Application Number** and the current **Status**

Note: The TEMP number will be replaced by the Application Number once the application is submitted

The **Table of Contents** lists the nodes (pages/sections) that make up an application. The node you are on appears in bold. Additional nodes become available as the application progresses.

Table of Contents Icon Key:

-  The node has required fields that have not been completed
-  The node has required fields that have been completed
-  The node has no required fields
-  The node has fields that are not completed yet but required in order to progress the application



The screenshot shows the 'Investigator Sponsored Research Portal' interface. The top navigation bar includes the Sanofi logo and the title 'Investigator Sponsored Research Portal'. Below this, a breadcrumb trail reads 'Dashboard > ESR External User > General Information (New Application)'. The main header area displays 'Clinical Research TEMP-000860', '1 of 20' (with navigation arrows), 'Requestor: Applicant', 'Status: Incomplete', and 'Requested: 26 Jan 2023'. A 'Save' button and an 'Actions' dropdown menu are located on the right side of this header. The 'Actions' menu is open, showing options: 'Save', 'Copy Record', 'Print', and 'Submit Proposal'. The main content area is titled 'General Information' and contains several form fields, some marked with an asterisk (*) to indicate they are required. These fields include: '*Study Title' (text input), '*Short Title' (text input), '*Sponsor Study/Project Code' (text input), '*T/A to be Studied' (dropdown menu), 'Indication to be Studied' (dropdown menu), '*Country of Study' (dropdown menu), '*Product/Material (Must select T/A first)' (dropdown menu), and '*Study Type' (dropdown menu). There are also informational icons (i) next to some of these fields. On the left side, there is a 'Table of Contents' sidebar with a list of nodes: 'Acknowledgement' (checked), 'General Information' (bold, indicating it's the current page), 'Personnel' (expanded), 'Primary Investigator' (unchecked), 'Legal Contact' (checked), 'Sites' (expanded), 'Primary Site' (unchecked), 'Study Information' (expanded), 'Proposal' (unchecked), 'Scientific Summary' (unchecked), 'Protocol, Budget, Regulatory' (checked), 'All Sanofi Products' (checked), 'Planned Publications' (unchecked), and 'Attachments' (checked). At the bottom of the form, there are navigation arrows: '< Acknowledgement' and 'Personnel >'. A green arrow points from the 'Save' button in the header to the text 'Use the Save button to save your changes as you work'. Another green arrow points from the 'Actions' dropdown menu to the text 'The Actions menu is used to complete actions, such as manually saving and submitting your application. Different action items will appear as you progress through to different screens in the application.' A third green arrow points from the bottom navigation arrows to the text 'Move to the previous or next node using the navigation buttons at the bottom of the screen.'

Use the **Save** button to save your changes as you work

The **Actions** menu is used to complete actions, such as manually saving and submitting your application. Different action items will appear as you progress through to different screens in the application.

Move to the previous or next node using the navigation buttons at the bottom of the screen.

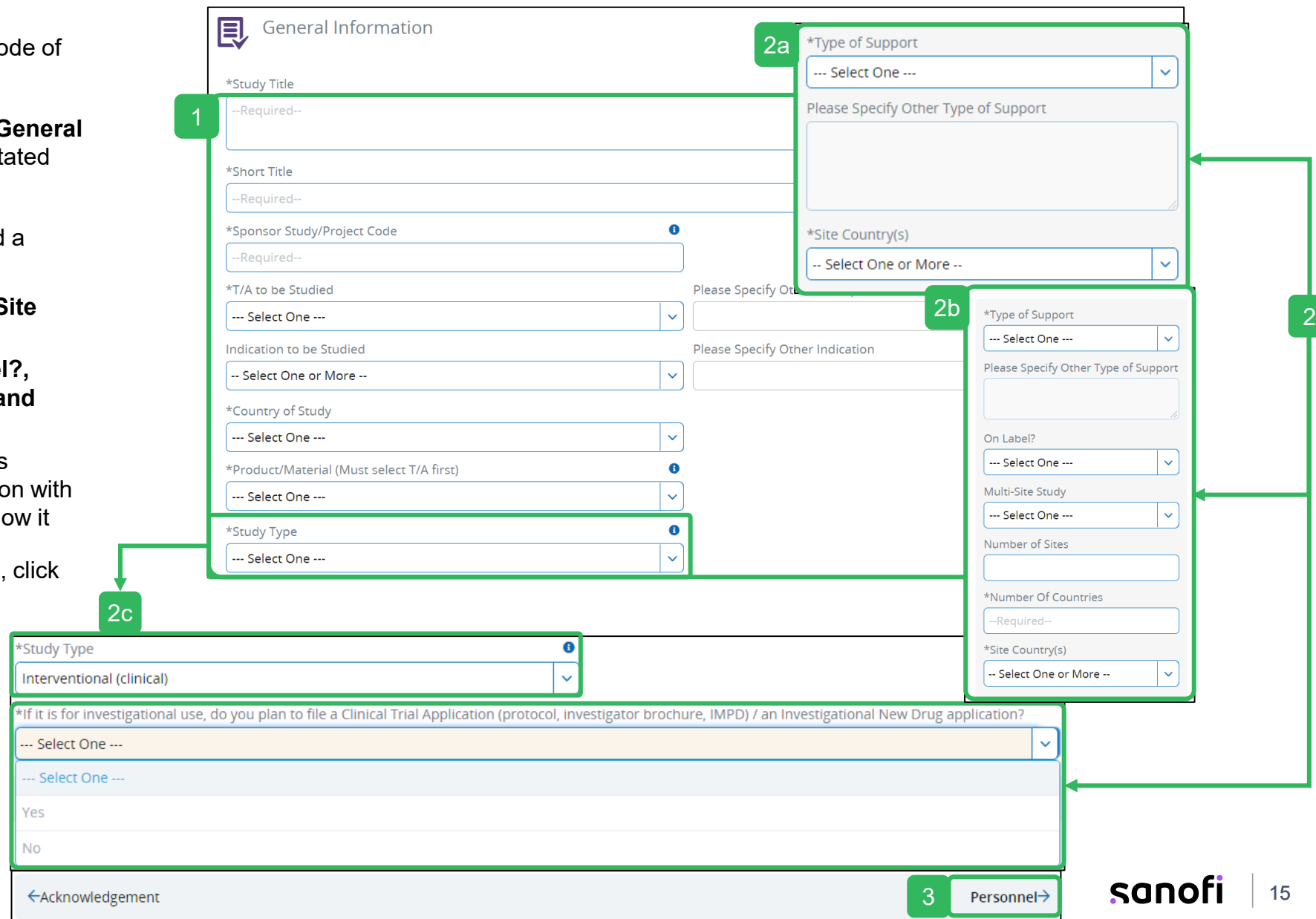
Throughout the system:

- Click the  icon to see further details regarding a field
- Click the  icon on the left-hand side of the **Context Bar** to show/hide the Table of Contents
- Required fields are marked with an asterisk (*)

General Information Node

The **General Information** node is the first node of the application to be completed

1. To begin, provide the information on the **General Information** node; required fields are notated with an asterisk (*)
2. Certain fields vary between a Clinical and a Non-Clinical application
 - a. **Non-Clinical:** Type of Support and Site Country(s)
 - b. **Clinical:** Type of Support , On Label?, Multi-Site Study, Number of Sites, and Number of Countries
 - c. **Clinical:** If **Interventional (clinical)** is selected for the **Study Type**, a question with a **Yes** or **No** dropdown will appear below it
3. When all mandatory fields are completed, click **Personnel** to continue to the next node



The screenshot shows the 'General Information' form with the following fields and annotations:

- Annotation 1:** Points to the *Study Title field.
- Annotation 2a:** Points to the *Type of Support dropdown.
- Annotation 2b:** Points to the *Type of Support dropdown in the Clinical section.
- Annotation 2c:** Points to the *Study Type dropdown, which is set to 'Interventional (clinical)'.
- Annotation 3:** Points to the 'Personnel' button at the bottom right.

The form includes the following fields:

- *Study Title (Required)
- *Short Title (Required)
- *Sponsor Study/Project Code (Required)
- *T/A to be Studied (Required)
- Indication to be Studied (Required)
- *Country of Study (Required)
- *Product/Material (Must select T/A first) (Required)
- *Study Type (Required)
- *Type of Support (Required)
- *Site Country(s) (Required)
- On Label? (Required)
- Multi-Site Study (Required)
- Number of Sites (Required)
- *Number Of Countries (Required)
- *Site Country(s) (Required)

The form also includes a section for 'If it is for investigational use, do you plan to file a Clinical Trial Application (protocol, investigator brochure, IMPD) / an Investigational New Drug application?' with a dropdown menu and 'Yes'/'No' options.

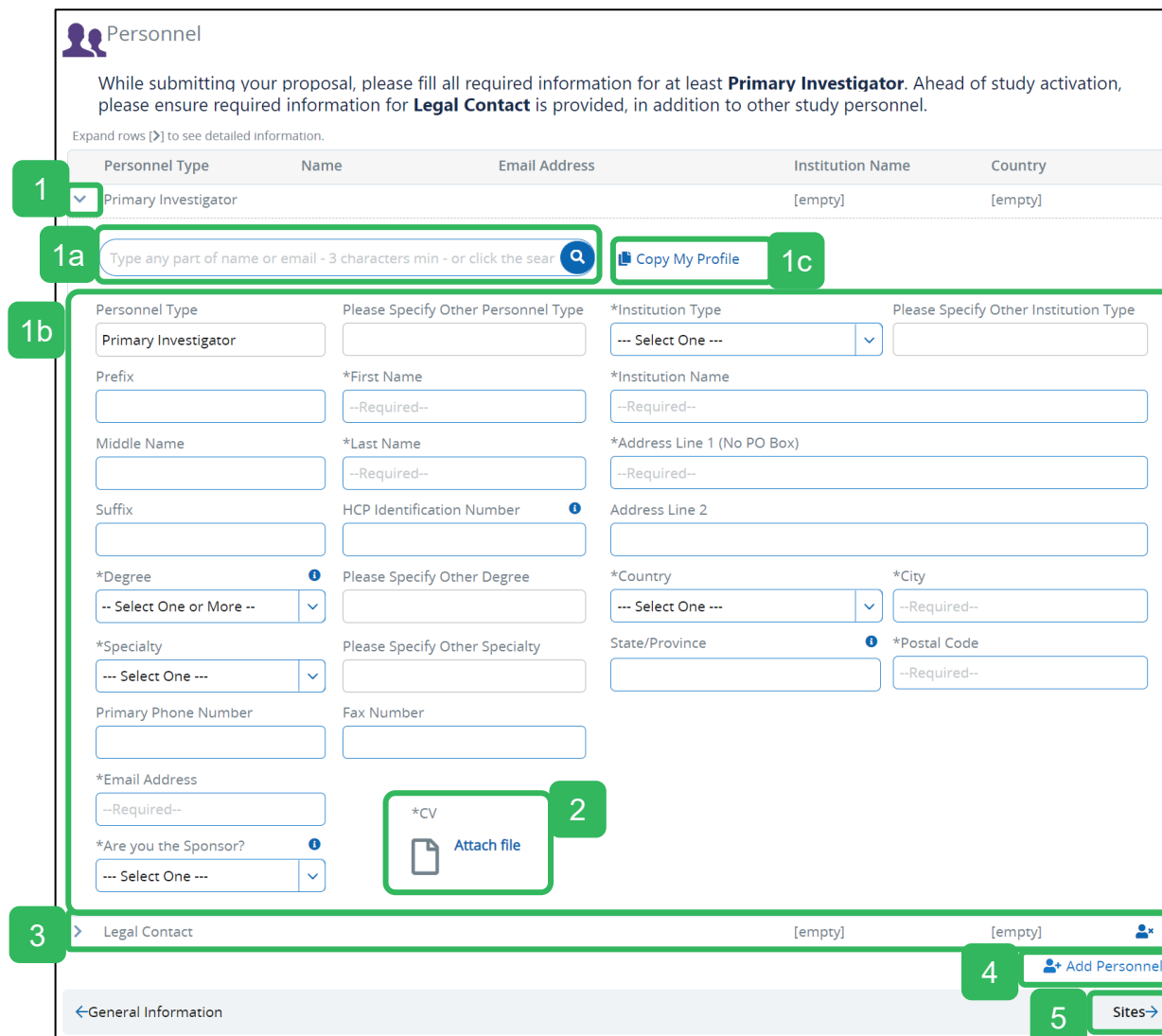
Personnel Node

The **Personnel** node is where you are required to enter all information on project personnel. At a minimum, the Primary Investigator must be entered, as the first entry. If the Primary Investigator is not the Sponsor, the Sponsor information must also be entered. Legal Contact details would have to be entered along with Protocol submission at the latest. Primary Investigator and Legal Contact are automatically started for you.

To enter the individual information:

- Expand the row you would like to work on and then use one of the following three options to add their information:
 - If the individual is in the system, search for them by entering three or more characters in the search field, then click the  icon to view and select them
 - Manually complete all required fields (*)

Note: Medical License is mandatory for Primary Investigator if located in the US
 - If your role matches the Personnel Type for which you are entering information, you can use the **Copy My Profile** to populate the contact details from your user profile
- In the CV field, attach a copy of the Curriculum Vitae for the Principal Investigator
- Fill in the details for the Legal Contact in the same way. This is not required until prior to Protocol submission.
- Click  **Add Personnel** to add another **Personnel** and follow the steps 1 and 2 to fill in their details. You will also have to select the appropriate value for Personnel Type.
- Click **Sites** to continue to the next node



Personnel

While submitting your proposal, please fill all required information for at least **Primary Investigator**. Ahead of study activation, please ensure required information for **Legal Contact** is provided, in addition to other study personnel.

Expand rows [X] to see detailed information.

Personnel Type	Name	Email Address	Institution Name	Country
1 	Primary Investigator		[empty]	[empty]

1a Type any part of name or email - 3 characters min - or click the search  **Copy My Profile** 1c

1b

Personnel Type: Primary Investigator

Please Specify Other Personnel Type:

*Institution Type: --- Select One --- 

Please Specify Other Institution Type:

Prefix: *First Name: --Required--

*Institution Name: --Required--

Middle Name: *Last Name: --Required--

*Address Line 1 (No PO Box): --Required--

Suffix: HCP Identification Number: Address Line 2:

*Degree: -- Select One or More --  Please Specify Other Degree:

*Country: --- Select One ---  *City: --Required--

*Specialty: --- Select One ---  Please Specify Other Specialty:

State/Province: *Postal Code: --Required--

Primary Phone Number: Fax Number:

*Email Address: --Required--

*Are you the Sponsor?  --- Select One ---

*CV  Attach file 2

3 > Legal Contact [empty] [empty] 

4  Add Personnel

5  Sites

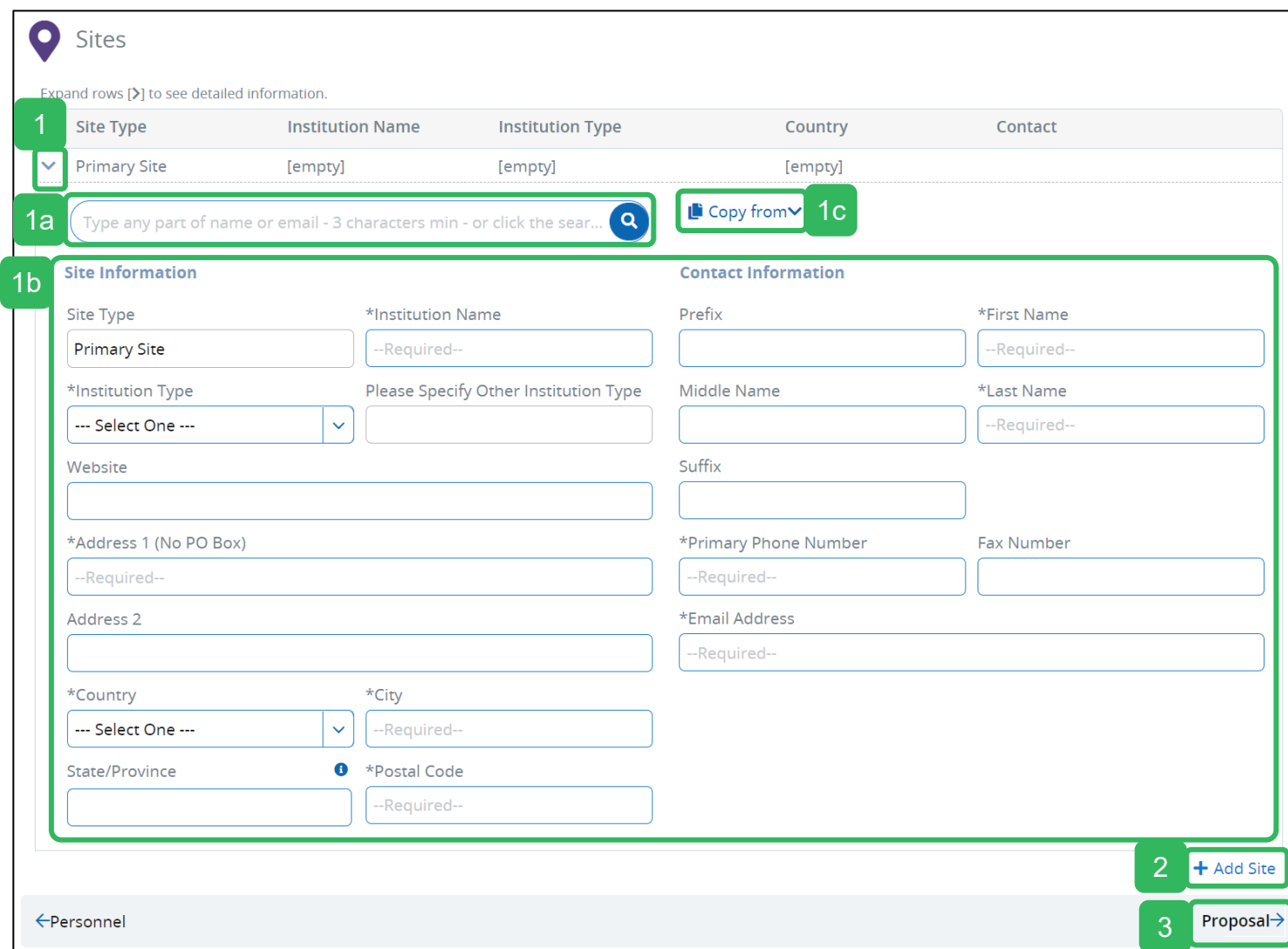
< General Information

Sites Node

The **Sites** node is where you are required to enter all information regarding the Primary Site. Additionally, you can enter in other sites as needed, and more specifically the Pharmacy depot where products will be sent if applicable.

For the information on the Primary Site:

- Expand the **Primary Site** row and then use one of the following three options to add information:
 - Search for a site by entering three or more characters in the search field and then click the  icon for additional options
 - Manually complete all required fields (*)
OR
 - Click **Copy From** to populate the fields from your profile or from the Primary Investigator information entered on the **Personnel** node
- Click **+ Add Site** to add additional sites such as drug shipment sites, if applicable, and other sites as needed; make sure to select the Site Type
- Click **Proposal** to continue to the next node



Sites

Expand rows [X] to see detailed information.

1	Site Type	Institution Name	Institution Type	Country	Contact
	Primary Site	[empty]	[empty]	[empty]	

1a Type any part of name or email - 3 characters min - or click the search icon  1c  Copy from

1b

Site Information

Site Type: Primary Site

*Institution Name: --Required--

*Institution Type: --- Select One ---

Website:

*Address 1 (No PO Box): --Required--

Address 2:

*Country: --- Select One ---

State/Province:

*City: --Required--

*Postal Code: --Required--

Contact Information

Prefix:

*First Name: --Required--

Middle Name:

*Last Name: --Required--

Suffix:

*Primary Phone Number: --Required--

Fax Number:

*Email Address: --Required--

2 + Add Site

3 Proposal

← Personnel

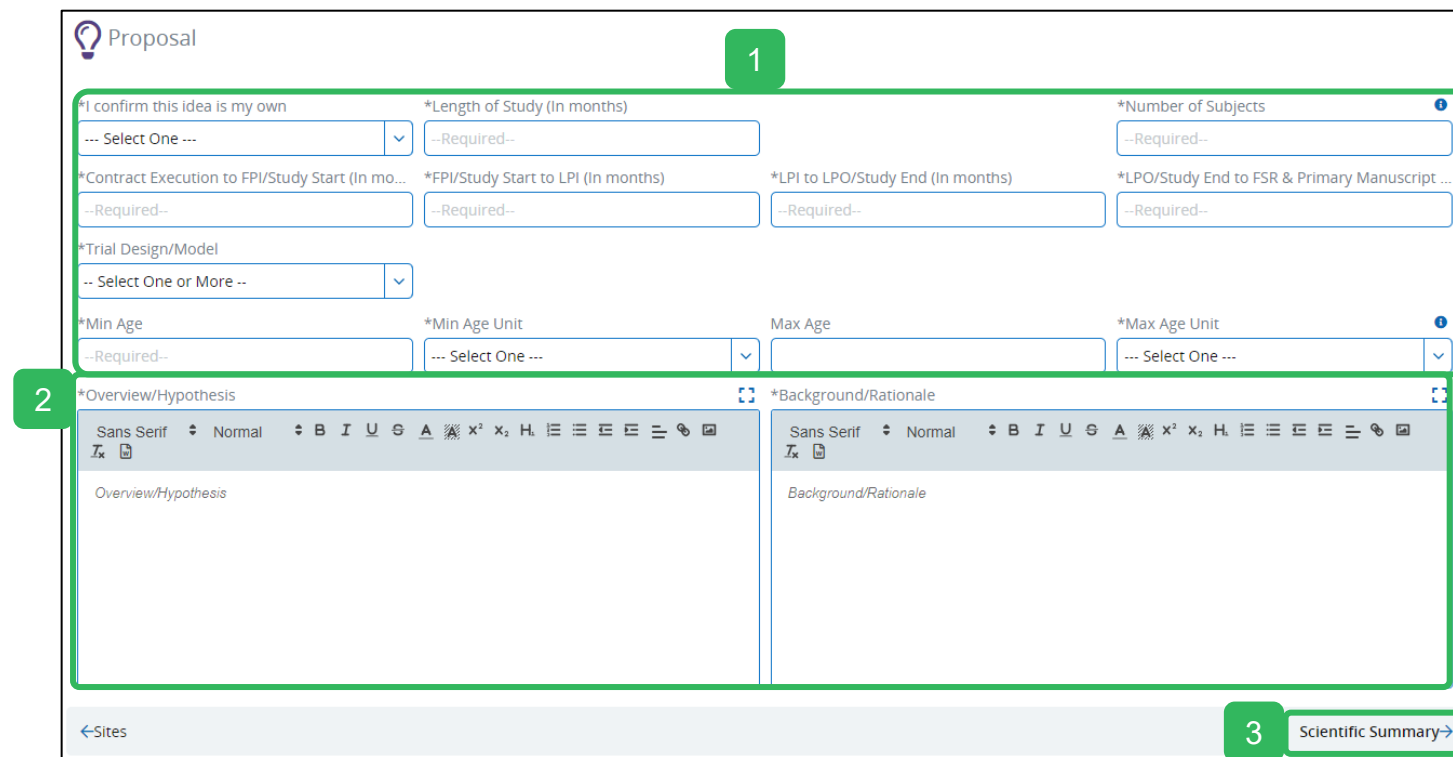
Proposal Node

Provide the required Proposal details in the **Proposal** node

The **Proposal** details include information on the study timing (in months) and design

1. Fill in the required fields (*) and any other relevant fields
2. Use the free-text fields to enter the **Overview/Hypothesis** and **Background/Rationale**
3. Click **Scientific Summary** to continue

Note: For Non-Clinical requests, the details captured on the Scientific Summary node (next slide) are included on the Proposal node



The screenshot shows the 'Proposal' form interface. A green box labeled '1' highlights the top section containing required fields marked with an asterisk (*):

- *I confirm this idea is my own (dropdown menu)
- *Length of Study (In months) (text field)
- *Number of Subjects (text field)
- *Contract Execution to FPI/Study Start (In months) (text field)
- *FPI/Study Start to LPI (In months) (text field)
- *LPI to LPO/Study End (In months) (text field)
- *LPO/Study End to FSR & Primary Manuscript (In months) (text field)
- *Trial Design/Model (dropdown menu)
- *Min Age (text field)
- *Min Age Unit (dropdown menu)
- Max Age (text field)
- *Max Age Unit (dropdown menu)

A green box labeled '2' highlights the bottom section with two large text areas:

- *Overview/Hypothesis (text area)
- *Background/Rationale (text area)

A green box labeled '3' highlights the bottom navigation bar, which includes a '← Sites' button and a 'Scientific Summary →' button.

Scientific Summary Node

Provide the required details on the **Scientific Summary** section:

- Enter the following information within the free-text fields
 - Primary/Secondary Objectives
 - Primary/Secondary Endpoints
 - Inclusion/Exclusion Criteria
 - Population
 - Sample Size/Statistical Power
 - Treatment Plan / Vaccination Schedule
 - PI Comments
- Click **Oncology Analysis** (which will appear if the **Oncology** option was selected from the **T/A to be Studied** drop-down menu on the General node) or **Protocol, Budget and Regulatory**

Scientific Summary

1

*Primary Objectives

Sans Serif Normal B I U S A x² x₂ H. | | | |

Primary Objectives

*Secondary Objectives

Sans Serif Normal B I U S A x² x₂ H. | | | |

Secondary Objectives

*Primary Endpoints

Sans Serif Normal B I U S A x² x₂ H. | | | |

Primary Endpoints

*Secondary Endpoints

Sans Serif Normal B I U S A x² x₂ H. | | | |

Secondary Endpoints

*Inclusion Criteria

Sans Serif Normal B I U S A x² x₂ H. | | | |

Inclusion Criteria

*Exclusion Criteria

Sans Serif Normal B I U S A x² x₂ H. | | | |

Exclusion Criteria

*Population

Sans Serif Normal B I U S A x² x₂ H. | | | |

Population

*Sample Size / Statistical Power

Sans Serif Normal B I U S A x² x₂ H. | | | |

Sample Size / Statistical Power

*Treatment Plan/Vaccination Schedule

Sans Serif Normal B I U S A x² x₂ H. | | | |

Treatment Plan / Vaccination Schedule

PI Comments

Sans Serif Normal B I U S A x² x₂ H. | | | |

PI Comments

← Proposal

2 Oncology Analysis→

Oncology Analysis Node

1. The **Oncology Analysis** node will appear only if the **Oncology** option was selected from the **T/A to be Studied** drop-down menu on the **General** node
2. On the **Oncology Analysis** screen, update the **Malignancy Types** and **Malignancy Stage** fields using the drop-down menus
3. Answer the question **Does this study involve a correlative study?**
4. If you answered **yes**, please describe the correlative study in the open text box
5. Click **Protocol, Budget, Regulatory** to progress to the next node

General Information

*Study Title
Sample Oncology Study - Michelle 12/15/22

*Short Title
Sample Oncology Study

*Sponsor Study/Project Code
Study Code 123

*T/A to be Studied
Oncology

Please Specify Other Therapeutic Area

Oncology Analysis

*Malignancy Types
-- Select One or More --

*Malignancy Stage
-- Select One or More --

*Does this study involve a correlative study?
--- Select One ---

If correlative study, please describe

Sans Serif Normal B I U S A x² x₂ H₁

← Scientific Summary

5 Protocol, Budget, Regulatory →

Protocol, Budget, and Define Regulatory Node

Provide the required **Protocol**, **Budget**, and **Regulatory** details on this node

1. Under the **Protocol** section, **Attach File**. The **Protocol** is mandatory at **Protocol** submission.

Note: If the final Protocol is already available, uploading it will shorten the review process

2. Complete the **Regulatory** fields. This can also be completed at a later date when submitting the **Protocol**.

3. Use the **Budget Template** by clicking **Click here to download the Budget Template** and upload the file by clicking **Attach File**

4. Select the **Requested Currency**, fill in the **Total Project Costs with Overhead**, **Amount Requested**, and **Other Funding Source Type**, as required. List all additional comments and funding sources in the free-text box **Budget Comments / Other Sources of Funding** (eg, additional supporters).

Note: % Requested will automatically be calculated after click **Save**

5. Click **All Sanofi Products** to continue to the next node


Protocol, Budget, Regulatory

Protocol
 Please specify Regulatory requirements. You can attach a copy of the protocol, if any, that aligns with the information already entered in the system

Budget
 Please attach a copy of the final budget that aligns with Proposal information

1 Protocol
 [Attach file](#)

2 Regulatory
 Is Regulatory Authorization Required?

 Is Project Disclosure Required?

 Is IRB/EC/ICUUC Required?

 IND number

3 Budget
 [Attach file](#)
[Click here to download the Non-Clinical Budget Template.](#)

4

*Requested Currency

*Total Project Costs with Overhead

*Amount Requested

% Requested

*Other Funding Source Type

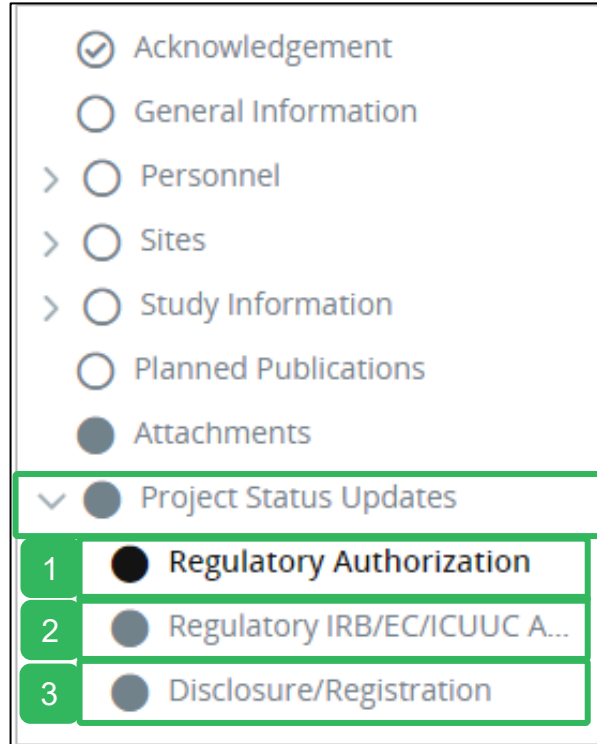
Budget Comments/Other Sources of Funding

[<Proposal](#)
[5 All Sanofi Products>](#)

Regulatory Nodes

If Yes was selected for any of the Regulatory questions from the **Protocol**, **Budget** and **Regulatory** node, additional nodes will appear under **Project Status Updates** which will be completed at a later stage once available

1. Regulatory Authorization
2. Regulatory IRB/EC/ICUUC Approval
3. Disclosure/Registration



A screenshot of a web application form. The form has a list of nodes with radio buttons. The first node, 'Acknowledgement', is selected with a checked radio button. Below it are 'General Information', 'Personnel', 'Sites', 'Study Information', 'Planned Publications', and 'Attachments', all with unselected radio buttons. The 'Project Status Updates' node is expanded, indicated by a downward arrow and a green border. It contains three sub-nodes, each with a numbered green box on the left and a radio button: '1 Regulatory Authorization' (selected), '2 Regulatory IRB/EC/ICUUC A...' (unselected), and '3 Disclosure/Registration' (unselected).

- ☒ Acknowledgement
- ☐ General Information
- > ☐ Personnel
- > ☐ Sites
- > ☐ Study Information
- ☐ Planned Publications
- ☐ Attachments
- ▼ ☐ Project Status Updates
 - 1 ☒ Regulatory Authorization
 - 2 ☐ Regulatory IRB/EC/ICUUC A...
 - 3 ☐ Disclosure/Registration

All Sanofi Products Node

You will be required to complete the **All Sanofi Products** node except, if your research does not involve any products (ie, secondary data analysis, epidemiological study)

Complete the **All Sanofi Products** node as follows:

1. Click **Add Product** to add the product to the Product table and use the drop-down menus to provide the following information

Note: The product entered on the **General Information** node will automatically be displayed

- **Product**
- **Are you requesting this Product?**

Note: If you answer “Yes” to this question, additional fields will appear for you to complete

- **Product Usage**

2. Use the fields at the bottom of the node to add information for any other **Requested** products if your answer is Yes to Are you requesting this Product

Note: In **Quantity**, indicate total amount of products for the whole study for all patients/subjects (digit only)

3. Click **Planned Publications** to continue to the next node


All Sanofi Products

Please list here all Sanofi product used in the study, and in the "Are you requesting this product" field make sure to choose 'yes' for any product Sanofi should provide you with

In "Quantity", indicate total amount of products for the whole study for all patients/subjects.

Please specify the product presentation you wish (e.g. vials, kits, or tablets) in the Product Comments field below.

Expand rows [X] to see detailed information.

Product	Formulation	Dosage	Quantity	Quantity of Placebo Drug	Product Comments
ALIROCUMAB [SAR236553]	[empty]	[empty]	[empty]	[empty]	

*Product

ALIROCUMAB [SAR...]

*Are you requesting this...

Yes

*Product Usage

--- Select One ---

2

The below information is only required for requested products

*Formulation

--- Select One ---

*Dosage

--Required--

*Qua...

--Req...

*Quantity of Placebo ...

--Required--

*Route of Administration

--- Select One ---

*Frequency of Shipments

--- Select One ---

*Product Type

--- Select One ---

*Label Type

--- Select One ---

*Frequency of Treatment

--Required--

Product Comments

+ Add Product

3

Planned Publications→

Planned Publications Node

Add planned and potential publications on the **Planned Publications** node

To add the publications:

1. Click **+ Add Journal/Congress**
2. Select the type of target (**Journal** or **Congress**)
3. Search for the target by
 - Entering at least three characters within the search field
 - If searching for a congress, you will have the option to set a time frame to narrow your search results
4. Click **Search**
5. Select the desired target from the search results. Click the  icon to view a detailed summary of the target, including the website, therapeutic areas, and submission timeline.
6. Click the circle next to the journal or congress and click **Add**

Note: If your target is not available, manually add it or request that it be added using the links below the search results
7. Confirm the **Publication Type** and **Anticipated Date** of submission and then **click the  icon** to add the publication to the table
8. Click **Attachments** to continue to the next node or [review and submit your application](#)

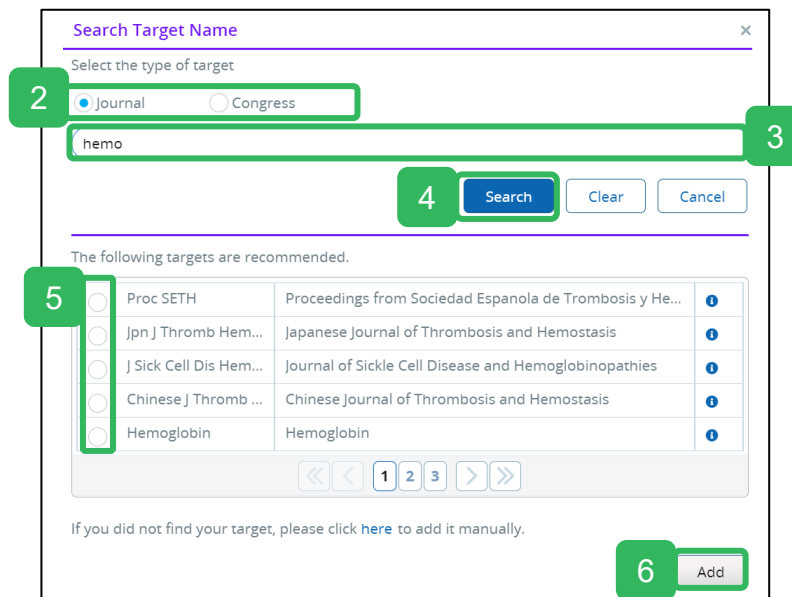


Planned Publications

1 **+ Add Journal/Congress**

Journal/Congress	Publication Type	Anticipated Date
No Line Items Found		

←All Sanofi Products Attachments→



Search Target Name

Select the type of target

2 ☒ Journal ☐ Congress

3 hemo

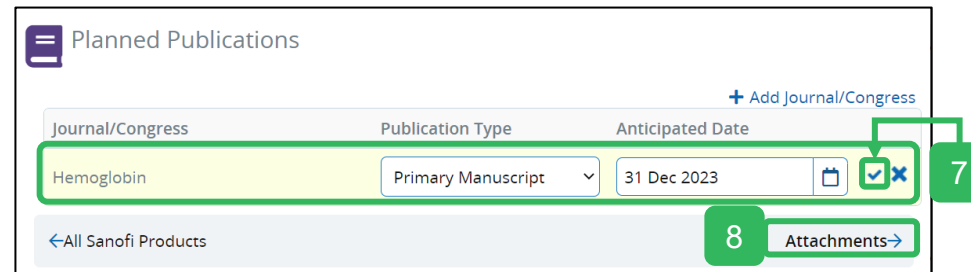
4 **Search** Clear Cancel

The following targets are recommended.

5 ☐ Proc SETH	Proceedings from Sociedad Espanola de Trombosis y He...	
☐ Jpn J Thromb Hem...	Japanese Journal of Thrombosis and Hemostasis	
☐ J Sick Cell Dis Hem...	Journal of Sickle Cell Disease and Hemoglobinopathies	
☐ Chinese J Thromb ...	Chinese Journal of Thrombosis and Hemostasis	
☐ Hemoglobin	Hemoglobin	

6 **Add**

If you did not find your target, please click [here](#) to add it manually.



Planned Publications

+ Add Journal/Congress

Journal/Congress	Publication Type	Anticipated Date	
Hemoglobin	Primary Manuscript	31 Dec 2023	7  

8 Attachments→

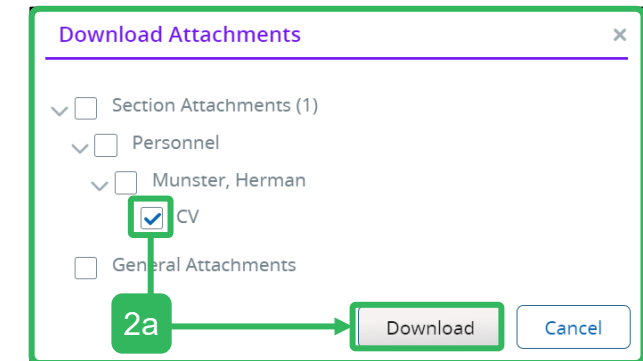
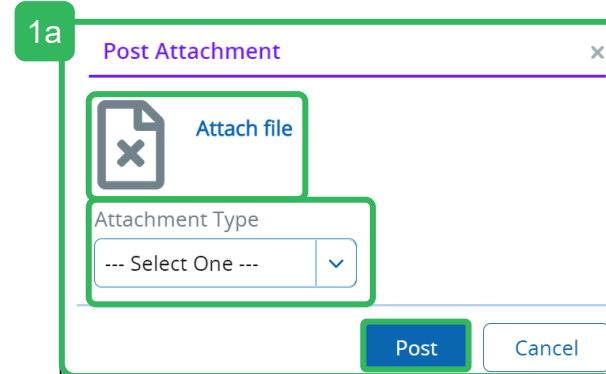
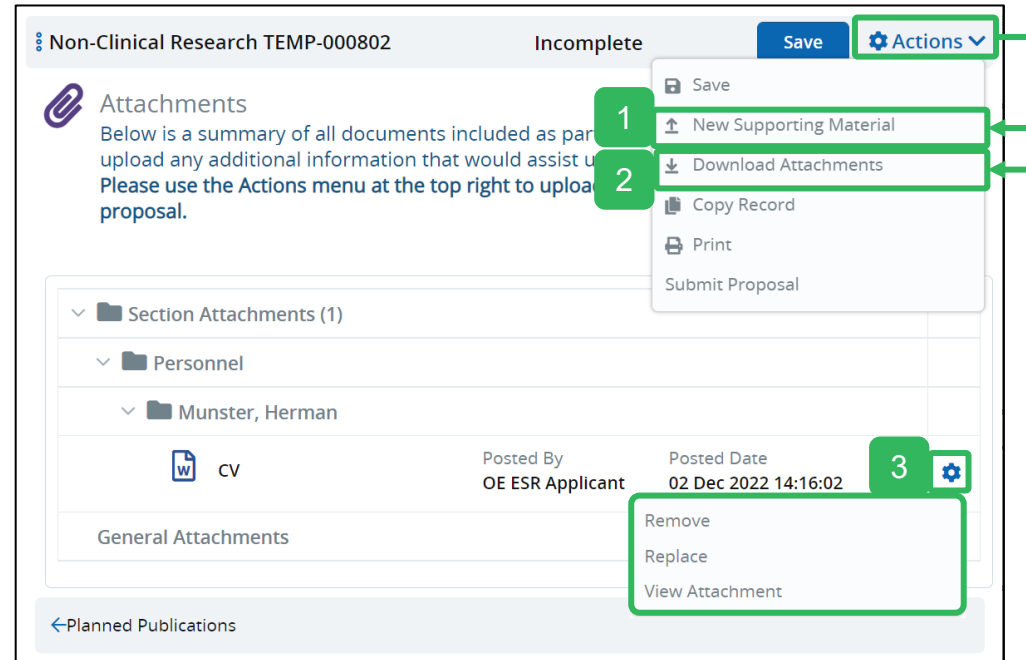
Attachments Node

Use the **Attachments** node to view all documents uploaded throughout the application

From the **Actions** menu, you can:

1. Click **New Supporting Material** to open the **Post Attachment** window and upload a new supporting material to the project record
 - a. Upload the file, select the **Attachment Type**, and click **Post**; any type of attachment may be uploaded (Excel, Word, PowerPoint, PDF, etc.)
2. Click **Download Attachments** to open the **Download Attachments** window and download a selection of supporting materials from the application
 - a. Select which attachments you would like to download by checking the boxes and then click **Download**
3. You can **Remove**, **Replace**, and **View Attachment** by clicking the  icon on the document row

Note: You CANNOT upload attachments during the review states (ie, *after* you have submitted your request and *before* Sanofi has come back to you). Please ensure all uploads are made before or after a review.

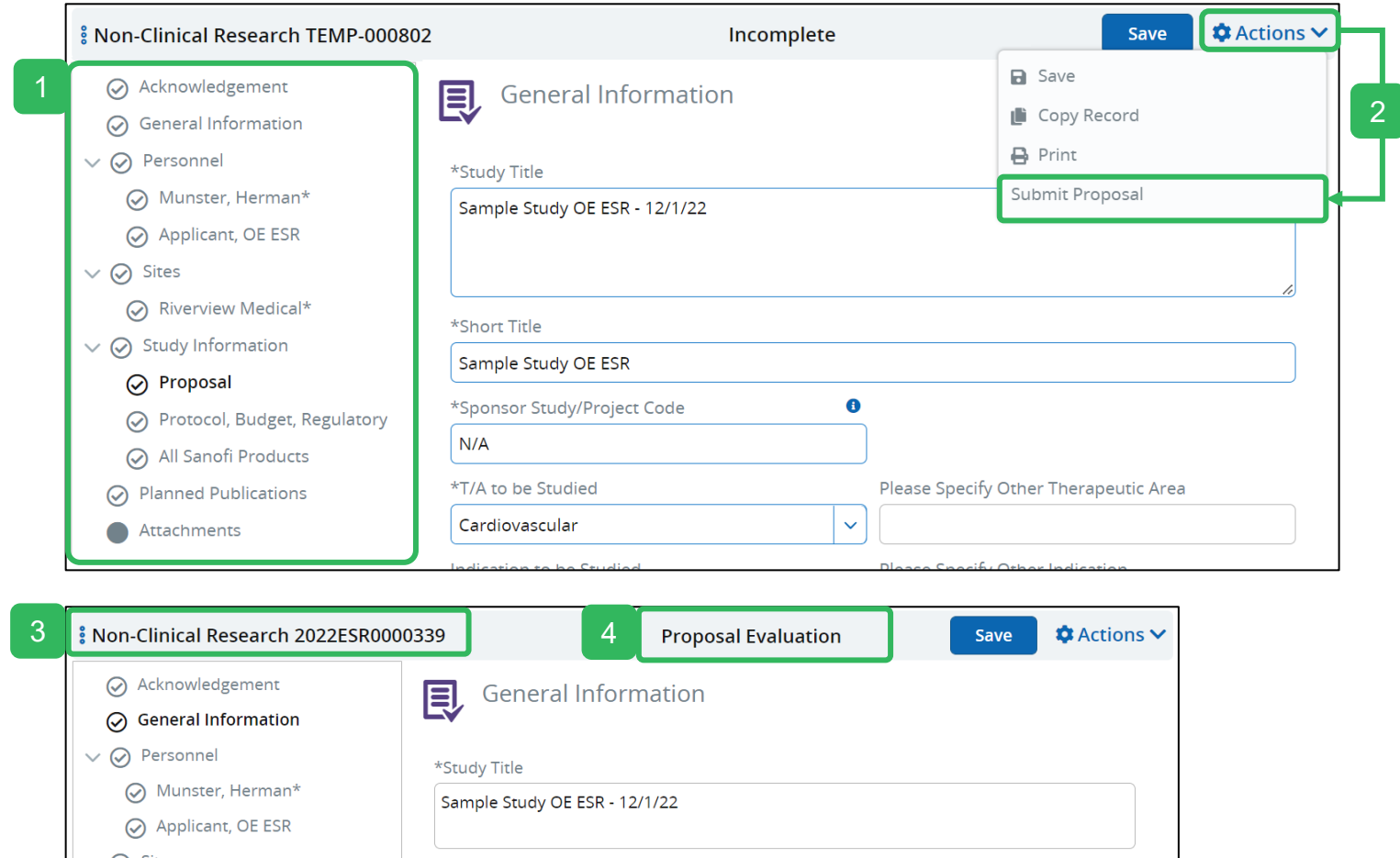


Submit the Application

When all the required information has been entered, you can submit the application for review and approval

To submit the application:

1. Check that all required information has been entered. Completed sections will be indicated with a  checkmark.
2. From the **Actions** menu, select **Submit Proposal**
Note: If there are required fields that must be completed in order to submit your application, they will be highlighted in red, and the section will be marked with an  icon
3. Your project will be assigned a **Tracking Number**
4. The **Status** will be updated to **Proposal Evaluation**



The screenshot illustrates the application submission process in two stages, with green callouts 1 through 4 corresponding to the instructions on the left.

Top Screenshot (Incomplete State):

- Callout 1:** Points to the left sidebar menu where all sections (Acknowledgement, General Information, Personnel, Sites, Study Information, Proposal, Protocol, Budget, Regulatory, All Sanofi Products, Planned Publications, Attachments) are marked with a checkmark, indicating they are completed.
- Callout 2:** Points to the 'Actions' dropdown menu in the top right corner, where 'Submit Proposal' is highlighted.
- Header:** Shows 'Non-Clinical Research TEMP-000802' and 'Incomplete' status.
- Form Fields:** Includes 'General Information' with fields for '*Study Title' (Sample Study OE ESR - 12/1/22), '*Short Title' (Sample Study OE ESR), '*Sponsor Study/Project Code' (N/A), and '*T/A to be Studied' (Cardiovascular).

Bottom Screenshot (Proposal Evaluation State):

- Callout 3:** Points to the header area where the application ID is updated to 'Non-Clinical Research 2022ESR0000339'.
- Callout 4:** Points to the header area where the status is updated to 'Proposal Evaluation'.
- Form Fields:** The 'General Information' section is still visible, with the '*Study Title' field containing 'Sample Study OE ESR - 12/1/22'.



03 | PRIOR TO PROJECT ACTIVATION

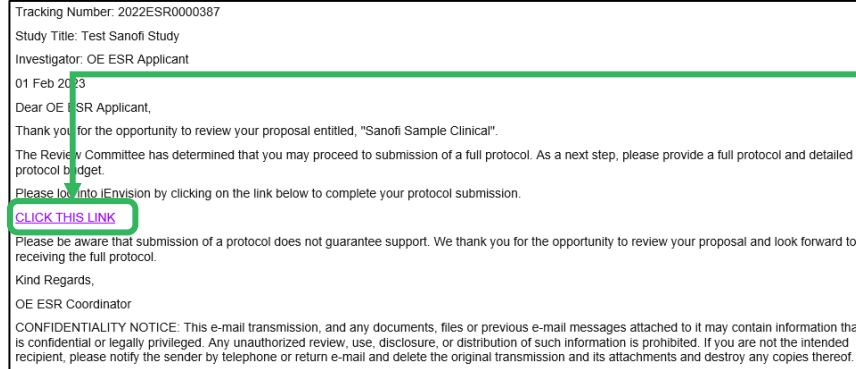
- [Submit Protocol, Budget, and Define Regulatory Information](#)
- [Additional Information Requested](#)
- [Submit Regulatory Information](#)
- [Withdraw or Cancel a Support Request](#)

Submit Protocol, Budget and Define Regulatory Information (1 of 2)

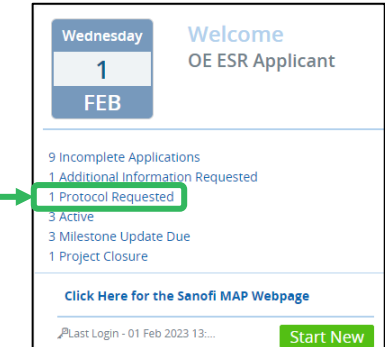
After your proposal is accepted, you will receive an email and a system notification to provide the **Protocol** and other information as applicable, eg, **Budget**, define **Regulatory** needs

1. Access the request by clicking the link in the notification email or by clicking the **Regulatory Information Requested** task on the Welcome widget
2. Use the Table of Contents to navigate to the **Protocol, Budget, Regulatory** node
3. Upload the **Protocol** document by clicking **Attach File**

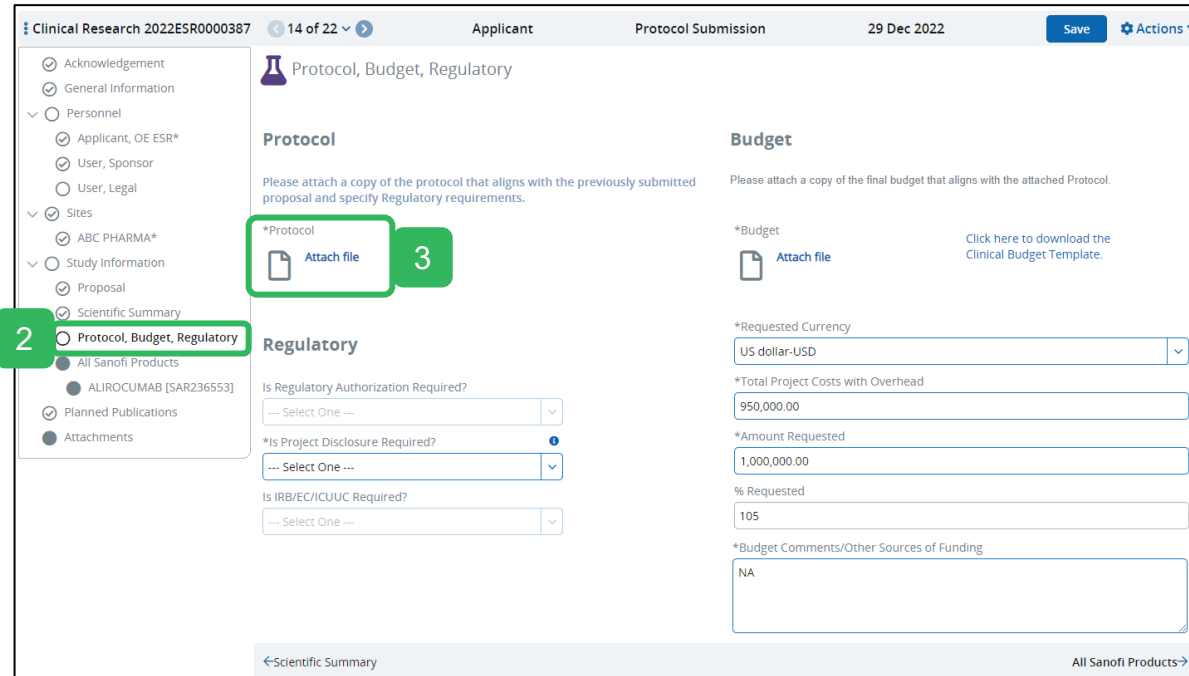
Email Notification



Welcome Widget on Dashboard



Application – Protocol, Budget, Regulatory Node



Clinical Research 2022ESR0000387 14 of 22 Applicant Protocol Submission 29 Dec 2022 Save Actions

Protocol, Budget, Regulatory

Protocol
Please attach a copy of the protocol that aligns with the previously submitted proposal and specify Regulatory requirements.
*Protocol
[Attach file](#)

Budget
Please attach a copy of the final budget that aligns with the attached Protocol.
*Budget
[Attach file](#) [Click here to download the Clinical Budget Template.](#)

*Requested Currency
US dollar-USD

*Total Project Costs with Overhead
950,000.00

*Amount Requested
1,000,000.00

% Requested
105

*Budget Comments/Other Sources of Funding
NA

Regulatory
Is Regulatory Authorization Required?
--- Select One ---
*Is Project Disclosure Required?
--- Select One ---
Is IRB/EC/ICUUC Required?
--- Select One ---

[Scientific Summary](#) [All Sanofi Products](#)

Submit Protocol, Budget and Define Regulatory Information (2 of 2)

4. If your request support type includes **Funding**, use the link under the **Budget** column to download the Sanofi budget template and update your budget line items. Once saved locally, post your budget details to iEnvision using the **Attach File** link.

5. Define the **Regulatory** needs for your study by:

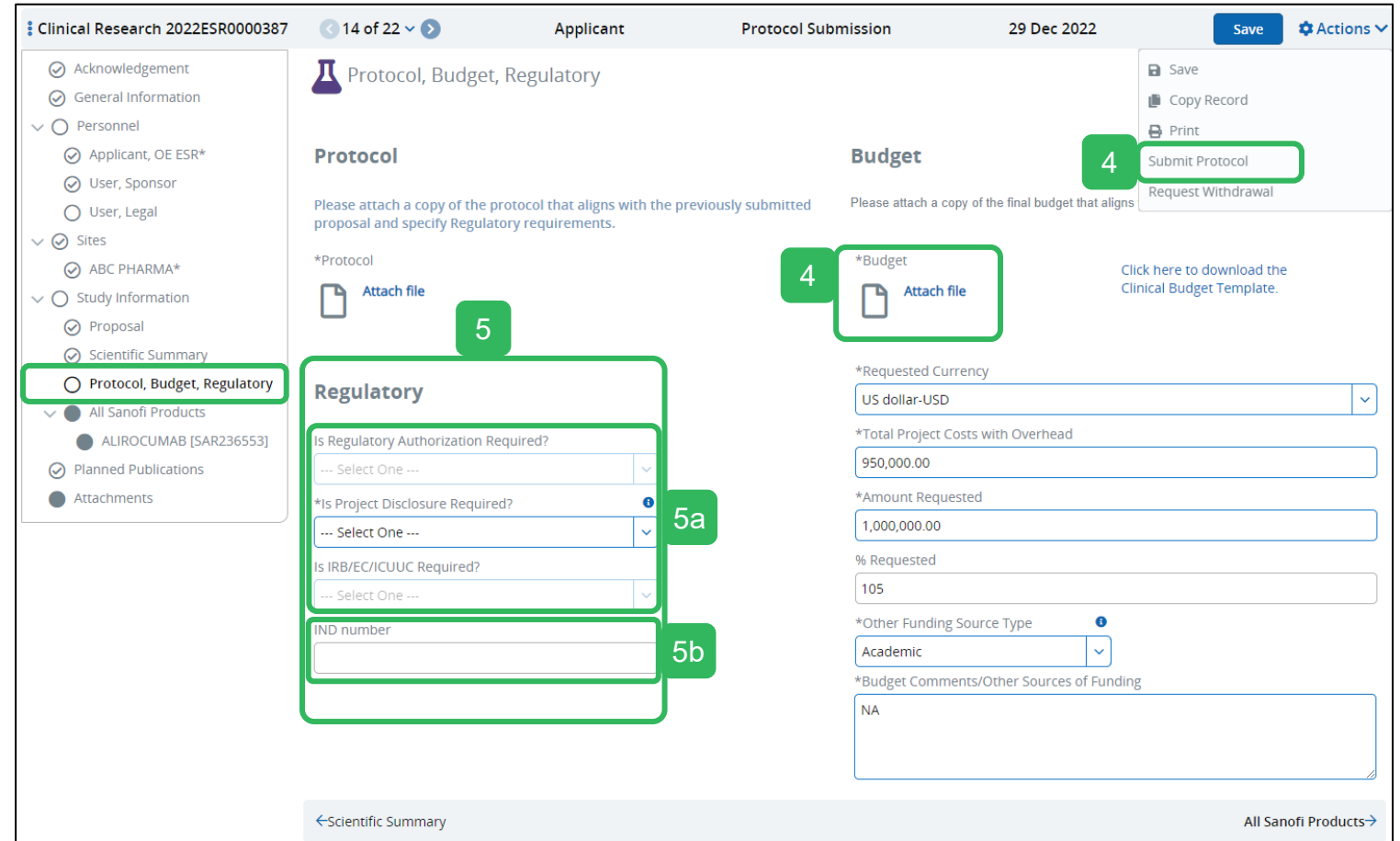
- Selecting **Yes** or **No** to the three questions
- Completing the **IND** number if applicable

Note: This may have already been completed at the Proposal stage

- In **Europe**, many **EC** Approvals do not expire like **IRB**'s do in the **US**, therefore, list the date of the next Periodic EC Review or the planned trial closure date
- If the **IRB/EC** does not issue an **IND** number, you should enter either the unique Protocol Number or "N/A" in this field

6. Select **Submit Protocol** from the **Actions** menu

Application – Protocol, Budget, Regulatory Node



Clinical Research 2022ESR0000387 14 of 22 Applicant Protocol Submission 29 Dec 2022 Save Actions

Protocol, Budget, Regulatory

Protocol

Please attach a copy of the protocol that aligns with the previously submitted proposal and specify Regulatory requirements.

*Protocol

Attach file

Budget

Please attach a copy of the final budget that aligns

*Budget

Attach file

Click here to download the Clinical Budget Template.

Regulatory

Is Regulatory Authorization Required?

--- Select One ---

*Is Project Disclosure Required?

--- Select One ---

Is IRB/EC/ICUUC Required?

--- Select One ---

IND number

*Requested Currency

US dollar-USD

*Total Project Costs with Overhead

950,000.00

*Amount Requested

1,000,000.00

% Requested

105

*Other Funding Source Type

Academic

*Budget Comments/Other Sources of Funding

NA

←Scientific Summary All Sanofi Products→

Additional Information Requested

After your application has been submitted, you may be asked to provide **Additional Information**

To address a request for additional information:

1. You will be notified by both email and a system notification that there is a request for additional information. To access the application:
 - a. Click the link in the notification email
OR
 - b. Click the **Additional Information Requested** link in the **Welcome** widget of your **Dashboard**
2. View the request in the **Additional Information Questions** window and make the updates within the application, using the nodes on the left of your screen to navigate to the necessary section
Note: If the window is closed, you can open it by clicking the **i** icon in the **Context Bar**
3. After making your updates, select **Submit Additional Proposal Info** from the **Actions** menu

Email Notification

Tracking Number: 2022ESR0000339
 Study Title: Sample Study OE ESR - 12/1/22
 Investigator: Herman Munster
 Product: ALIROCUMAB [SAR236553]
 Country: United States
 02 Dec 2022

Dear OE ESR Applicant,

This communication is to inform you that additional information regarding your study proposal "Sample Study OE ESR" is being requested.

Please provide full Primary Investigator information.

Please log into iEnvision by clicking on the link below to complete your update as soon as possible and no later than 02 Dec 2022.

[CLICK THIS LINK](#) **1a**

Kind Regards,
 OE ESR Coordinator

CONFIDENTIALITY NOTICE: This e-mail transmission, and any documents, files or previous e-mail messages attached to it may contain information that is confidential or legally privileged. Any unauthorized review, use, disclosure or distribution of such information is prohibited. If you are not the intended recipient, please notify the sender by telephone or return e-mail and delete the original transmission and its attachments and destroy any copies thereof.

ESR Dashboard

Friday
2
 DEC

Welcome
 OE ESR
 Applicant

1 Additional Information Requested **1b**

[Click Here for the Sanofi MAP Webpage](#)

Last Login - 02 Dec ... [Start New](#)

Non-Clinical Research 2022ESR0000339

Proposal Evaluation

2

3

General Information

*Study Title

Additional Information Questions

Please provide full Primary Investigator information.

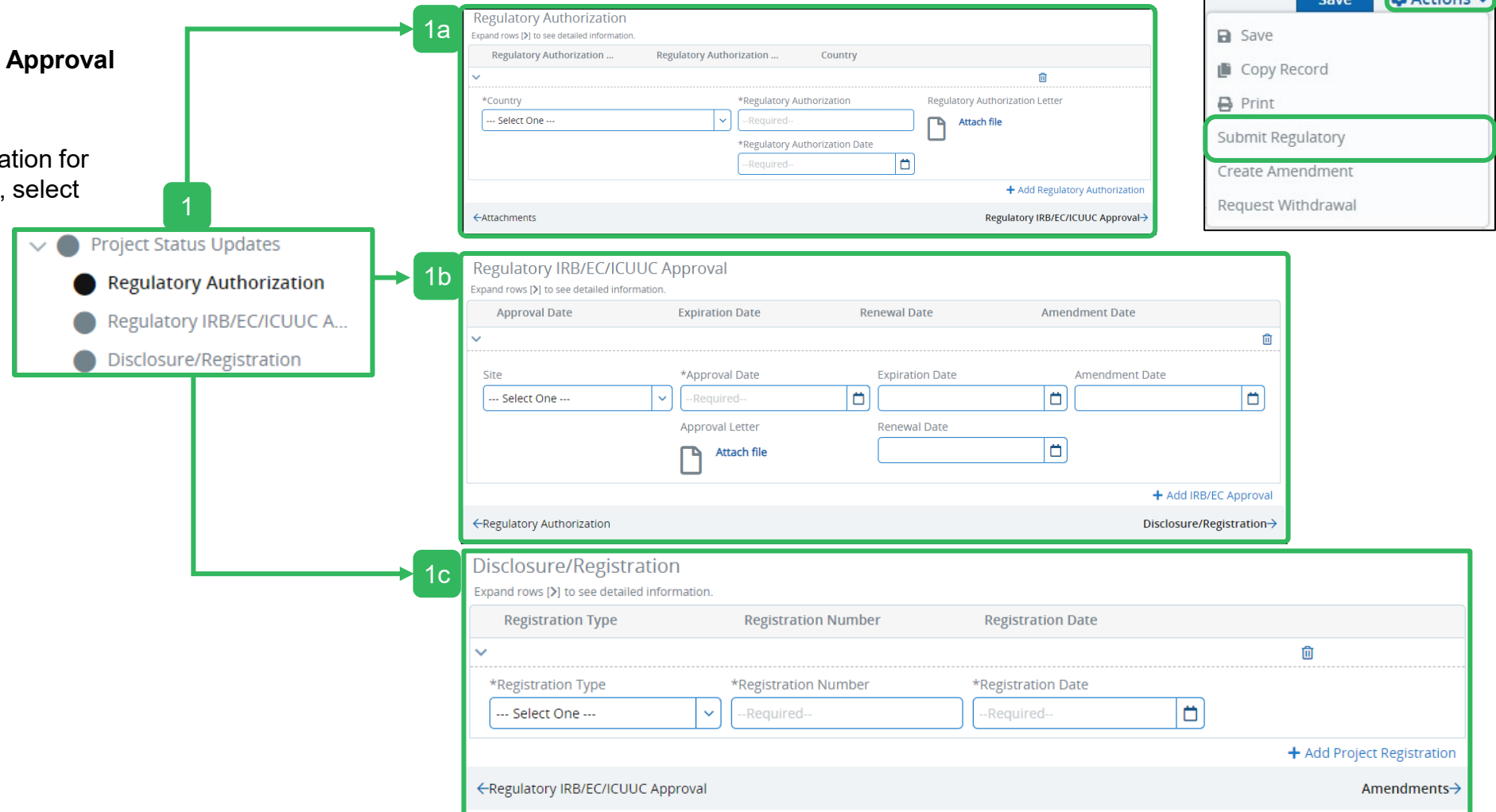
Save **Actions**

Save
 Addtl. Info Requested
 Copy Record
 Print
Submit Additional Proposal Info
 Request Withdrawal

Specify Other Therapeutic Area

Submit Regulatory Information

1. Complete all fields for each **Regulatory** node under **Project Status Updates**
 - a. **Regulatory Authorization**
 - b. **Regulatory IRB/EC/ICUUC Approval**
 - c. **Disclosure/Registration**
2. To send the **Regulatory** information for review, from the **Actions** menu, select **Submit Regulatory**



1

1a Regulatory Authorization

Expand rows [X] to see detailed information.

Regulatory Authorization ...	Regulatory Authorization ...	Country
*Country --- Select One ---	*Regulatory Authorization --Required--	Regulatory Authorization Letter Attach file
	*Regulatory Authorization Date --Required--	

+ Add Regulatory Authorization

← Attachments Regulatory IRB/EC/ICUUC Approval →

1b Regulatory IRB/EC/ICUUC Approval

Expand rows [X] to see detailed information.

Approval Date	Expiration Date	Renewal Date	Amendment Date
Site --- Select One ---	*Approval Date --Required--	Expiration Date	Amendment Date
	Approval Letter Attach file	Renewal Date	

+ Add IRB/EC Approval

← Regulatory Authorization Disclosure/Registration →

1c Disclosure/Registration

Expand rows [X] to see detailed information.

Registration Type	Registration Number	Registration Date
*Registration Type --- Select One ---	*Registration Number --Required--	*Registration Date --Required--

+ Add Project Registration

← Regulatory IRB/EC/ICUUC Approval Amendments →

2

Save Actions

- Save
- Copy Record
- Print
- Submit Regulatory
- Create Amendment
- Request Withdrawal



04 | ACTIVE PROJECT

- [Withdraw or Cancel a Support Request](#)
- [Submit Milestone Updates](#)
- [Submit Invoices](#)
- [Submit Publication Information](#)
- [Request Product Shipment](#)
- [Submit an Amendment](#)

Withdraw or Cancel a Support Request

After your Proposal has been submitted, you may withdraw your support request based on the status of the ESR project record

During the Proposal and Protocol evaluation process, the ESR project record can be withdrawn. Once the study has reached the Active status and onward, the ESR project record can be cancelled.

To withdraw the ESR project record:

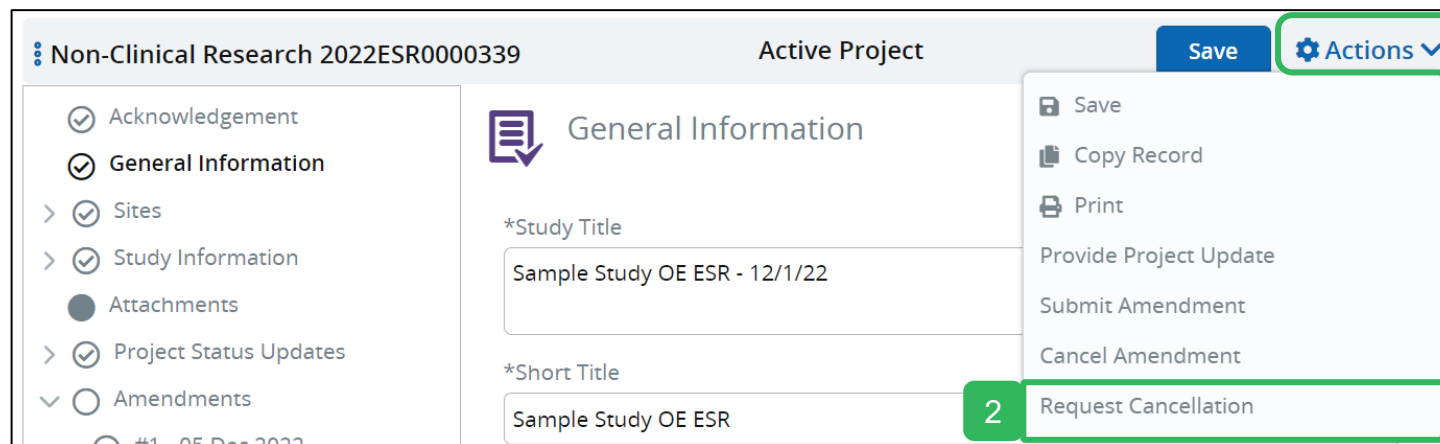
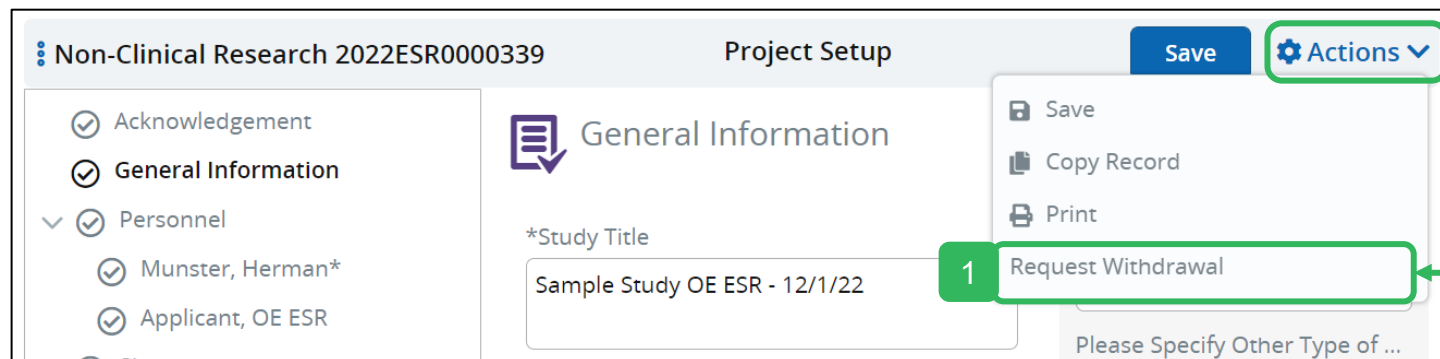
1. From the **Actions** menu, select **Request Withdrawal**

Note: An email will be sent to the Sanofi ESR Manager who will confirm the withdrawal

To cancel the ESR project record:

2. From the **Actions** menu, select **Request Cancellation**

Note: An email will be sent to the Sanofi ESR Manager who will confirm the cancellation



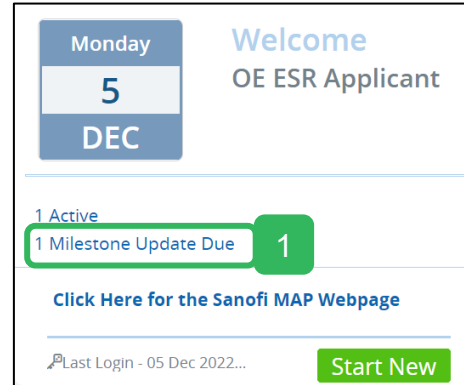
Submit Milestone Updates (1 of 2)

When your study is activated, you will be reminded to provide key **Milestone Updates** via a **Milestone Update Due** task on your Dashboard **Welcome** widget

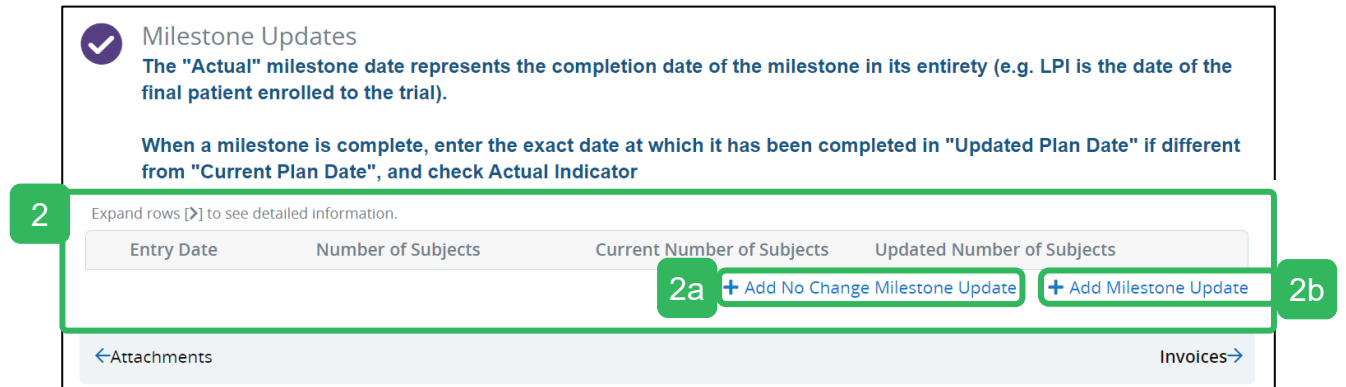
To submit **Milestone Updates**:

1. Access the application milestones by clicking the **Milestone Update Due** task on the **Welcome** widget
2. Add a milestone update as either:
 - a. A **No Change Milestone Update** if there are no changes since the last update
 - OR**
 - b. A **Milestone Update** if there are changes to report

Welcome Widget on Dashboard



Application – Milestone Updates Node

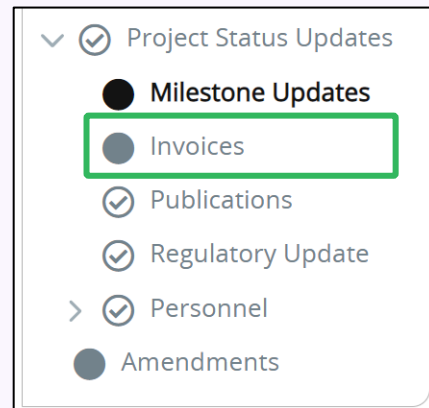


Submit Milestone Updates (2 of 2)

Populate the milestone table as follows:

1. Add any subject updates, noting that **Number** refers to the cumulative total of that specific field
2. Update any of the **Updated Plan Dates** and check/tick the **Actual** box if the milestone has been completed
Note: **Updated Plan Date** cannot be in the past unless the milestone has been met and the **Actual** box is checked/ticked
3. Submit the milestone updates from the **Actions** menu by selecting **Provide Project Update**

Be sure to upload any invoices associated with each milestone on the **Invoices** section



ISR Application – Milestone Updates Node

Non-Clinical Research 2022ESR0000339 Active Project Save Actions

☒ Milestone Updates
 The "Actual" milestone date represents the completion date of the milestone. The date of the final patient enrolled to the trial.
 When a milestone is complete, enter the exact date at which it has been completed. If different from "Current Plan Date", and check Actual Indicator.

Expand rows [>] to see detailed information.

Entry Date	Number of Subjects	Current Number of Subjects	Updated Number of Subjects
05 Dec 2022	0		

1. Current Number of Subjects: 0 Updated Number of Subjects:

Milestone	Current Plan Date	Updated Plan Date	Actual
FPI/Study Start	06 Dec 2022		☐
LPLV/Study End	07 Dec 2022		☐
Primary Manuscript submission to Sanofi	08 Dec 2022		☐
Contract Start	09 Dec 2022		☐
Contract Executed	12 Dec 2022		☐
Primary Manuscript submission to Journal	13 Dec 2022		☐
FSR/Final Research Report Submission to Sanofi	14 Dec 2022		☐

2.

+ Add No Change Milestone Update + Add Milestone Update

← Attachments Invoices →

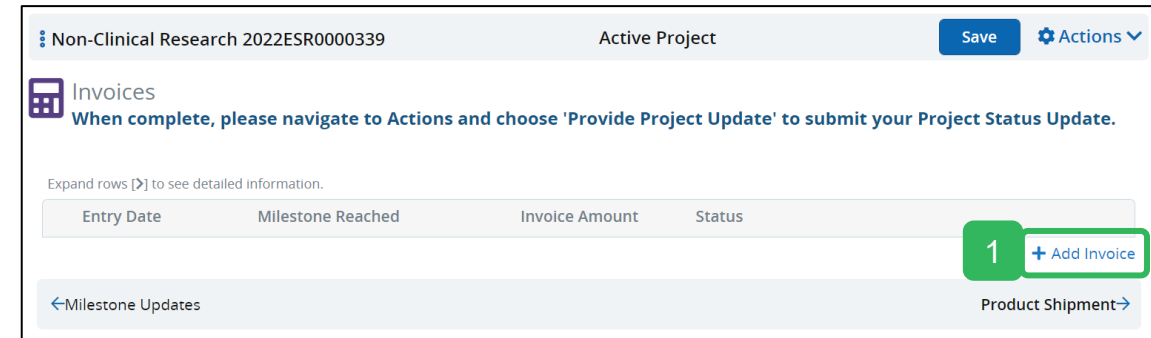
Submit Invoices

As part of the milestone update process, invoices should be submitted on the **Invoices** node

To submit an invoice:

1. Click **+ Add Invoice** to add an entry to the invoice table
 - a. The **Invoice Status** will update to **Unsubmitted**
2. A dated entry will be added to the Invoice table; click the arrow to expand the Invoice
3. Select the type of **Milestone Reached** from the drop-down menu, enter the **Invoice Amount**, and upload the invoice by clicking **Attach file**
4. Use the check box to indicate if **you have met the conditions of this milestone**
5. Add **Invoice Comments**, as necessary
6. Submit the invoice from the **Actions** menu by selecting **Provide Project Update**

Invoices Node



Non-Clinical Research 2022ESR0000339 Active Project Save Actions

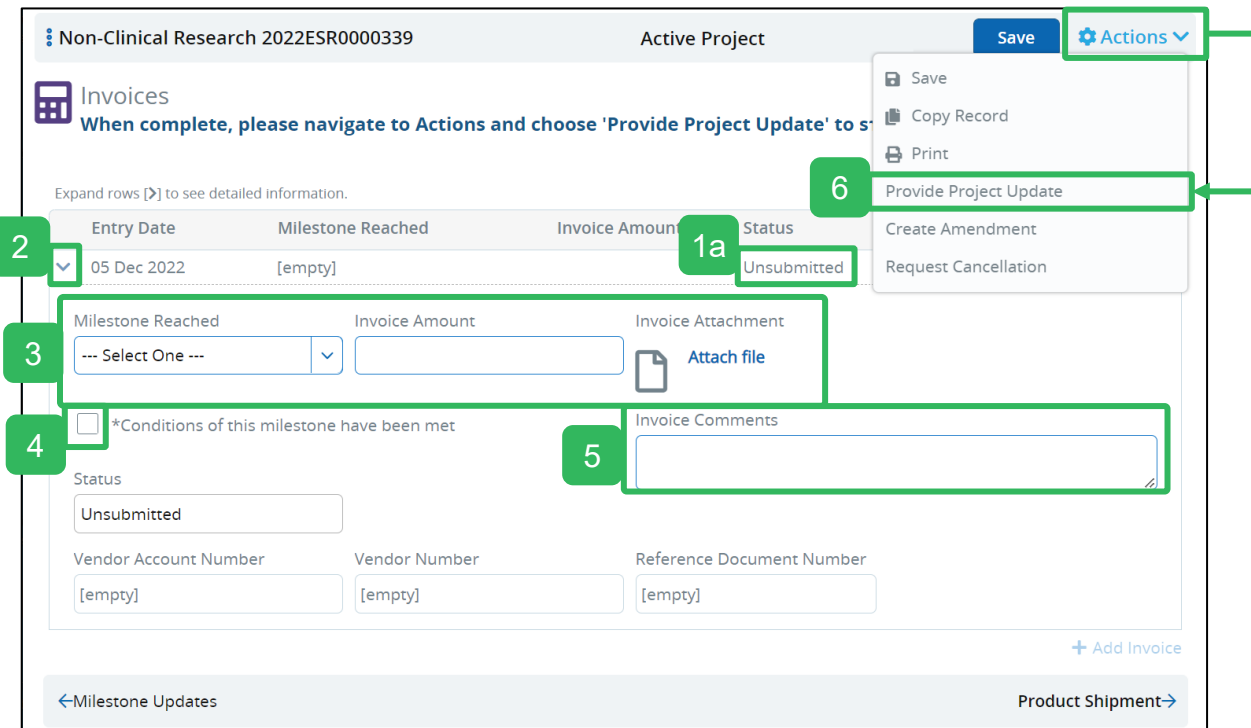
Invoices
When complete, please navigate to Actions and choose 'Provide Project Update' to submit your Project Status Update.

Expand rows [>] to see detailed information.

Entry Date	Milestone Reached	Invoice Amount	Status

1 + Add Invoice

← Milestone Updates Product Shipment →



Non-Clinical Research 2022ESR0000339 Active Project Save Actions

Invoices
When complete, please navigate to Actions and choose 'Provide Project Update' to submit your Project Status Update.

Expand rows [>] to see detailed information.

Entry Date	Milestone Reached	Invoice Amount	Status
05 Dec 2022	[empty]		Unsubmitted

2 ▼

3 --- Select One --- Invoice Amount Attach file

4 ☐ *Conditions of this milestone have been met

5 Invoice Comments

6 Provide Project Update

1a Unsubmitted

Status: Unsubmitted

Vendor Account Number: [empty] Vendor Number: [empty] Reference Document Number: [empty]

+ Add Invoice

← Milestone Updates Product Shipment →

Submit Publication Information

While the project is active, you can update and submit publication information updates on the **Publications** node (refer to [Planned Publications Node](#))

To make publication updates:

1. Add to or update the **Planned Publications** table using the  icon or the **+ Add Journal/Congress** link
2. Add to the **Actual Publications** table by clicking **+ Add Journal/Congress**
 - a. Add the publication information, attach the **Publication**, and provide the **Submission Date to Sanofi**
3. Submit all updates from the **Actions** menu by selecting **Provide Project Update**

Note: Publication date will be completed at a later stage, once the publication is published. At that time, the status will also have to be updated to **Published**.

Publications Node

 **Publications**
When complete, please navigate to Actions and choose 'Provide Project Update' to submit your Project Status Update.

Planned Publications

Journal/Congress	Publication Type	Anticipated Date	
Hemoglobin	Primary Manuscript	31 Dec 2023	 

Actual Publications

Expand rows [X] to see detailed information.

Entry Date	Journal/Congress	Publication Type	Publication Date	Publication Status

←Product Shipment

Personnel→

Actual Publications

Expand rows [X] to see detailed information.

Entry Date	Journal/Congress	Publication Type	Publication Date	Publication Status
05 Dec 2022	Hemoglobin	[empty]	[empty]	[empty]

2a

*Journal/Congress: Hemoglobin

*Publication Type: --- Select One ---

*Publication Status: --- Select One ---

*Actual Publication Title: --Required--

*Submission Date to Sanofi: --Required--

Submission Date to Journal or C...:

*Publication: Attach file

Publication Date:

Save Actions

3

Provide Project Update

Create Amendment

Request Cancellation

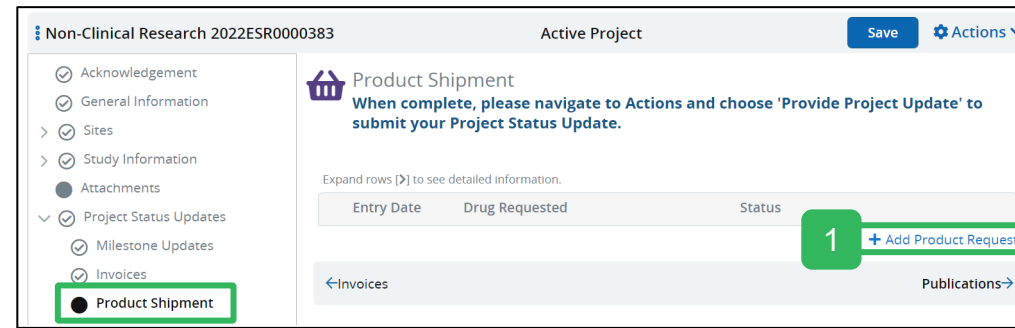
Request Product Shipment

You can request additional products when your project is in the **Active** state

1. On the **Product Shipment** node, click the **Add Product Request** link
2. Fill in the fields, as necessary, and ensure the **Need by Date** is updated

Note: In **Product Quantity**, indicate the total amount of products for the whole study for all patients/subjects (digits only)

3. From the **Actions** menu, select **Provide Project Update**



Non-Clinical Research 2022ESR0000383 Active Project Save Actions

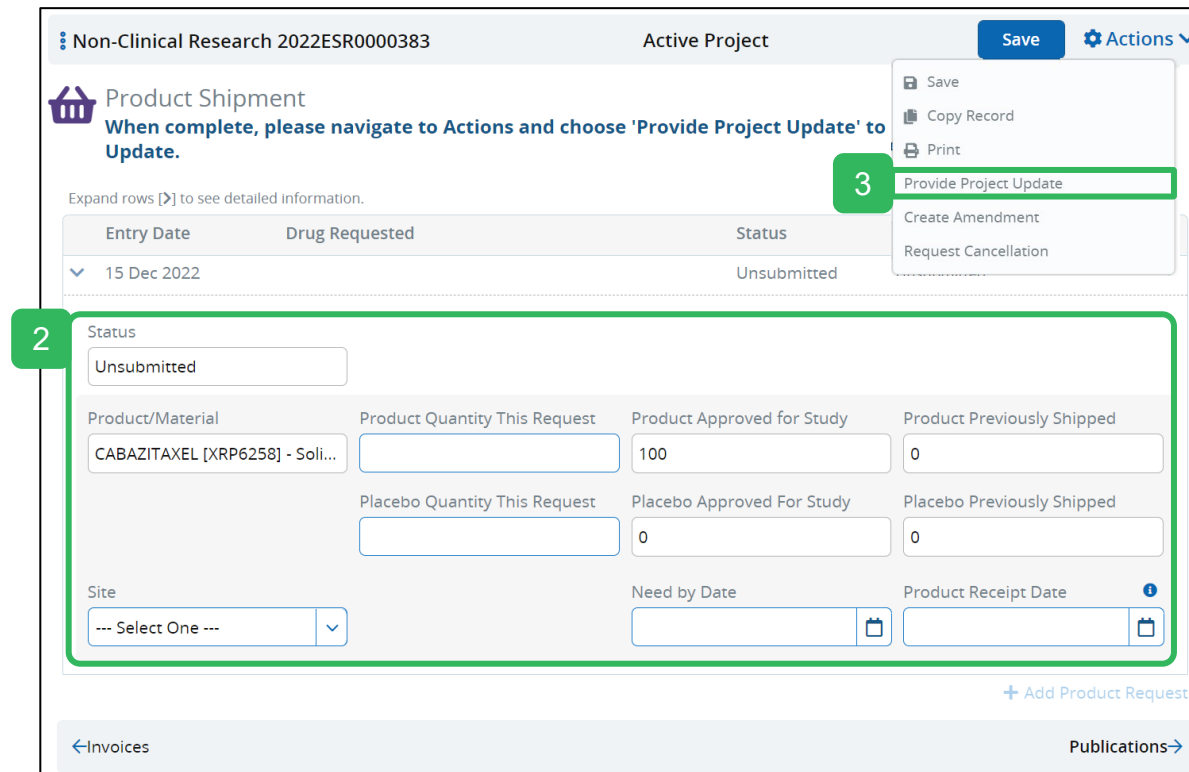
Product Shipment
When complete, please navigate to Actions and choose 'Provide Project Update' to submit your Project Status Update.

Expand rows [X] to see detailed information.

Entry Date	Drug Requested	Status

←Invoices Publications→

1 + Add Product Request



Non-Clinical Research 2022ESR0000383 Active Project Save Actions

Product Shipment
When complete, please navigate to Actions and choose 'Provide Project Update' to Update.

Expand rows [X] to see detailed information.

Entry Date	Drug Requested	Status
15 Dec 2022		Unsubmitted

3 Provide Project Update
Create Amendment
Request Cancellation

2

Status: Unsubmitted

Product/Material	Product Quantity This Request	Product Approved for Study	Product Previously Shipped
CABAZITAXEL [XRP6258] - Soli...		100	0

Placebo Quantity This Request	Placebo Approved For Study	Placebo Previously Shipped
	0	0

Site: --- Select One ---

Need by Date:

Product Receipt Date:

+ Add Product Request

←Invoices Publications→

Submit an Amendment

While a study is in the status of **Active** or **Project Update**, a change request can be submitted to share amendments to key study documents, such as Protocol, Contract and Budget (where applicable). Sanofi will review the amendment before it is implemented.

To submit an amendment:

1. From the **Actions** menu, select **Create Amendment**
2. Complete the **Amendments** section by filling out the required fields (*). Upload the Amendment Track Changes and Amendment Final by clicking **Add Attachments**.
3. Submit the amendment from the **Actions** menu by selecting **Submit Amendment**
4. **Status**, **Decision Date**, and **Additional Amount Approved** will be updated by the Sanofi ESR Internal Team

View current and previous amendments in the **Amendments** section of the table of contents

☒	Acknowledgement
☒	General Information
> ☒	Sites
> ☒	Study Information
☒	Attachments
> ☒	Project Status Updates
☒	Amendments
☐	#1 - 05 Dec 2022

Amendments Node

Non-Clinical Research 2022ESR0000339

Active Project

Save

Actions

Amendments

Please note that the following documents are required: the amendment, a Summary of Changes document, and an updated FMV Budget (if applicable)

1

Save

Copy Record

Print

Provide Project Update

Create Amendment

Request Cancellation

3

Save

Copy Record

Print

Provide Project Update

Submit Amendment

Cancel Amendment

Request Cancellation

Non-Clinical Research 2022ESR0000339

Active Project

Save

Actions

Amendments

Please note that the following documents are required: the amendment, a Summary of Changes document, and an updated FMV Budget (if applicable)

Expand rows [X] to see detailed information.

Amendment Number	Status	Additional Amount Requested	Additional Amount Approved	Decision Date
✓ #1 - 05 Dec 2022	New	[empty]	[empty]	[empty]

2

*Description of change

--Required--

*Reason

-- Select One or More --

Please Specify Other Reason

Additional Amount Requested

Amendment Attachments

+ Add Attachments

File Name	Type	Posted D...	Posted By
No records found.			

4

Status

Decision Date

Additional Amount Approved

New

[empty]

[empty]

Total Amendment Approved

USD 0.00

Total Amendment Approved (Corporate)

EUR 0.00



05 | PROJECT CLOSURE

- [Submit Final Study Report \(FSR\)](#)
- [Submit Draft Primary Manuscript](#)

Submit Final Study Report (FSR)

Once all milestones are complete and the study record is ready to be closed, you will receive a request for **Project Closure** information

- To access the application, use one of the following methods:
 - Click the link in the notification email
 - OR
 - Click the **Project Closure** task in the **Welcome** widget of your **Dashboard**
- Complete the **Project Closure** section as follows:
 - Attach the **Final Study Report (FSR)**
 - Answer the question, **Was There Unused Product/Material?**
 - Confirm **All Funds Were Used per Contract**
 - If your answer to 2b was “Yes”, you must attach a copy of the **Drug Destruction Certificate**
 - Provide any **Closure Notes**
- Close the project from the **Actions** menu by selecting **Submit Project Closure**

Email Notification

Tracking Number: 2022ESR0000339
 Study Title: Sample Study OE ESR - 12/1/22
 Investigator: Herman Munster
 05 Dec 2022

Dear OE ESR Applicant,
 This communication is to inform you that your study titled Sample Study OE ESR requires closure information.
 Please log into the application with the web address below to provide your update.
[CLICK THIS LINK](#)

Please contact me with questions or for assistance.
 Kind Regards,
 OE ESR Coordinator

CONFIDENTIALITY NOTICE: This e-mail transmission, and any documents, files or previous e-mail messages attached to it may contain information that is confidential or legally privileged. Any unauthorized review, use, disclosure or distribution of such information is prohibited. If you are not the intended recipient, please notify the sender by telephone or return e-mail and delete the original transmission and its attachments and destroy any copies thereof.

ESR Applicant Dashboard

Monday
5
DEC

Welcome
OE ESR
Applicant

1 Project Closure

[Click Here for the Sanofi MAP Webpage](#)

Last Login - 05 Dec ... [Start New](#)

ESR Application – Project Closure Node

Non-Clinical Research 2022ESR0000339 Project Closure [Save](#) [Actions](#)

 **Project Closure**
 To provide Primary Manuscript, please navigate to the Publications node and Click on the bottom of the page (in the Actual Publications section)

Please attach a copy of the Final Study Report.

*Final Study Report [Attach file](#)

*Was There Unused Product/Material?
 --- Select One ---

*All Funds Were Used per Contract
 --- Select One ---

Please attach a copy of the Drug Destruction Certificate.
 Drug Destruction Certificate [Attach file](#)

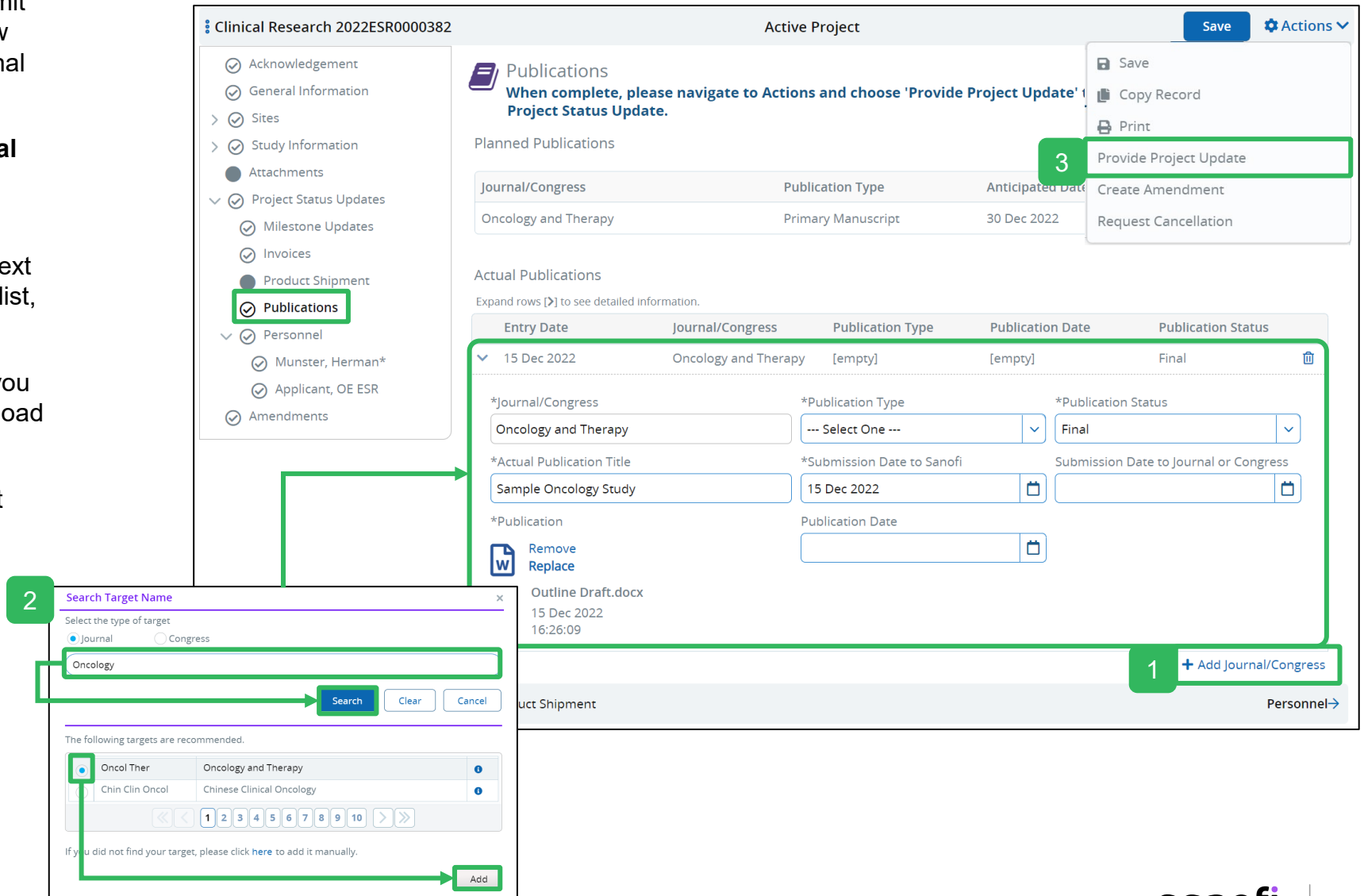
Closure Notes

[Submit Project Closure](#)

Submit Draft Primary Manuscript

Before the project closes, you will need to submit your Draft Primary Manuscript for Sanofi review prior to its submission for publication to a Journal (refer to [Submit Publication Information](#))

1. On the **Publications** node, under the **Actual Publications** table, click the **Add Journal/Congress** link
2. Type the name of the **Journal** in the open text field and click **Search**. From the populated list, select the target and click **Add**.
3. The Journal will appear in the table where you can now make updates to the fields and upload your final primary manuscript
4. When you are finished with the table, select **Provide Project Update** from the **Actions** menu



Clinical Research 2022ESR0000382 Active Project

Publications
When complete, please navigate to Actions and choose 'Provide Project Update' Project Status Update.

Planned Publications

Journal/Congress	Publication Type	Anticipated Date
Oncology and Therapy	Primary Manuscript	30 Dec 2022

Actual Publications
Expand rows [D] to see detailed information.

Entry Date	Journal/Congress	Publication Type	Publication Date	Publication Status
15 Dec 2022	Oncology and Therapy	[empty]	[empty]	Final

Annotations:

- 1:** + Add Journal/Congress (link in the bottom right of the Actual Publications table)
- 2:** Search Target Name (modal window showing search results for "Oncology")
- 3:** Provide Project Update (action in the Actions menu)

Search Target Name Modal:

Select the type of target
☒ Journal ☐ Congress

Oncology

Search Clear Cancel

The following targets are recommended.

Target	Target Name
☒	Oncol Ther Oncology and Therapy
☐	Chin Clin Oncol Chinese Clinical Oncology

1 2 3 4 5 6 7 8 9 10

If you did not find your target, please click [here](#) to add it manually.

Add



SANOFI ESR APPLICANT SUPPORT RESOURCES



To **access the iEnvision ESR system**, please click the link below:
[iEnvision ESR](#)



For **general ESR questions**, please liaise with
your Sanofi Medical Contact



For **iEnvision ESR system support**, please contact:
Email: helpdesk@envisionpharmasupport.com