MSD INVESTIGATOR STUDIES PROGRAM (MISP)

Applicant Guide

iEnvision® User Guide

MISP PORTAL / REGISTRATION

NEW MISP APPLICATIONS

POST SUBMISSION ACTIVITIES

March 2026

Using This Guide

MISP PORTAL / REGISTRATION
NEW MISP APPLICATIONS
POST SUBMISSION ACTIVITIES

NAVIGATION

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

Guide Main Menu

Last Page Viewed

This feature is only available when viewing the guide in PowerPoint presentation mode or when viewing the PDF version of this guide

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SUPPORT RESOURCES

To access the MISP Applicant Portal, click the link below:
https://mrk.envisionpharma.com/ienv_mrk/visiontracker/portal/login.xhtml?pgm=ISR

For general MISP questions, or to request system access support, please contact: vt_support@msd.com

For technical support, contact the Envision Pharma Helpdesk:

US: +1 860-266-4944 UK & EU: +44 1403-322095
Email: helpdesk@envisionpharmasupport.com

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01 | MISP Portal and Registration

- [MISP Portal Overview]
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MISP Portal Overview

1. NEW ACCOUNT REGISTRATION

Home | How to Apply | FAQs

Investigator Studies Program (MISP)

The iEnvision Grant Management website is now open for Investigator Initiated Study submissions. Please refer to the details on the Investigator Studies Program site for more information.

Prior to submitting your request, please reference Investigator Studies Program for the "Areas of Interest". Also, at the top of the page, you will want to familiarize yourself with our "FAQs" and "How to Apply" documents.

For technical assistance with the grant management system, please email us at helpdesk@envisionpharmasupport.com

System Login

User Name

Password

Register for New Account
Forgot Login ID?

Log In

Returning Applicants enter credentials in the **System Login** section

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

Contact Us

Email: vt_support@msd.com

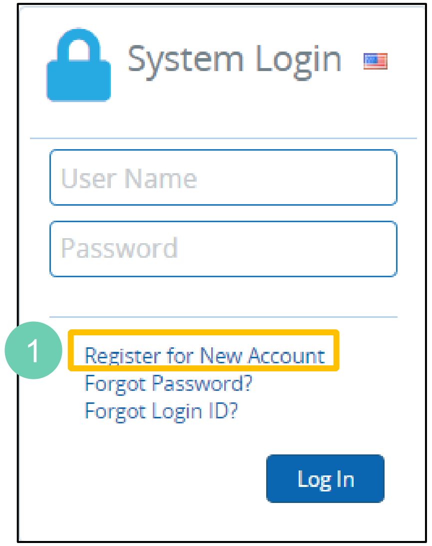
Envision Pharma Helpdesk: helpdesk@envisionpharmasupport.com

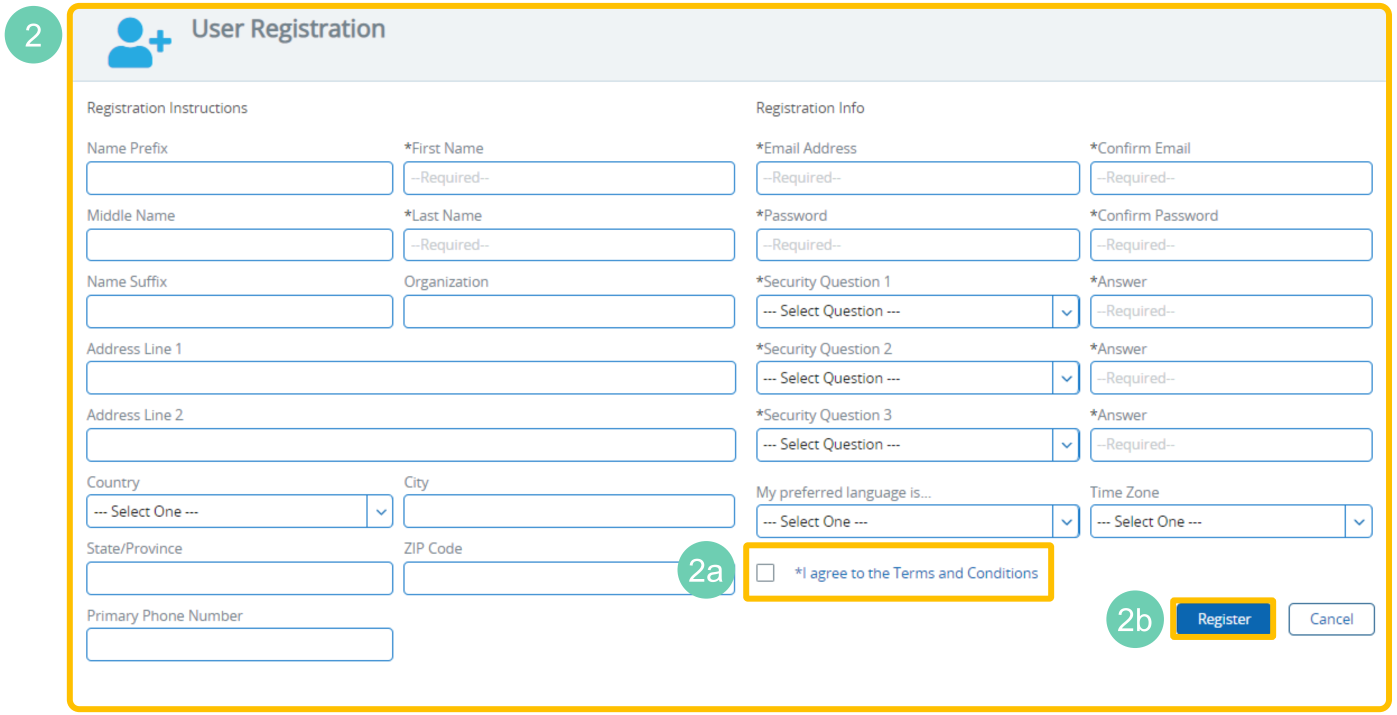
System support can be found in the **Contact Us** section

Register for a New MISP Account

Applications for MISP support are submitted through the MISP portal. Before applying, you must first register for an account:

1. Self-register for an account by clicking the **Register for New Account** link on the right-side of the MISP Portal
2. Complete the **User Registration** form; required fields are marked with an asterisk (*)
   a. Read and agree to the **Terms and Conditions** by selecting the checkbox
   b. Click **Register**





MISP PORTAL / REGISTRATION
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New Account Activation

Once the registration form is submitted, the next step is to activate your account:

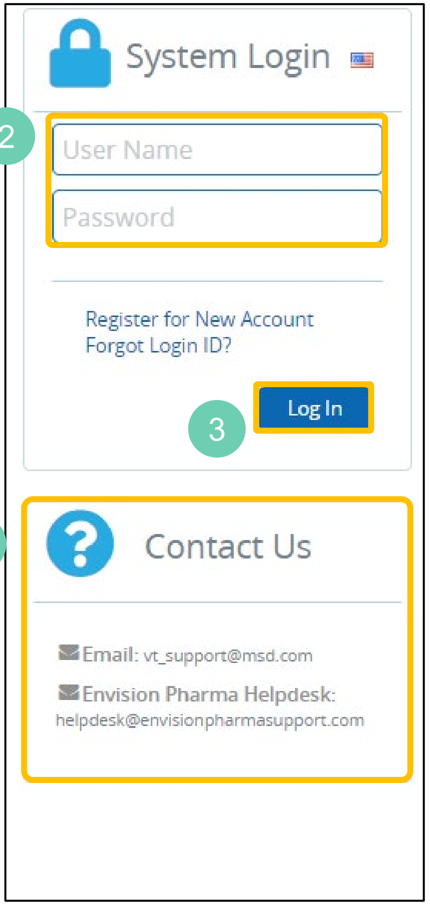
1. You will receive an email containing an activation link. Click the link to activate your account.
2. Enter your email address as your **User Name** and the **Password** you selected at registration
3. Click **Log In**
4. For login issues, contact the [Envision Pharma Helpdesk]using the email address or phone number found under **Contact Us**

1

Dear MISP Applicant,

Welcome to iEnvision. To complete your registration, please click the link below.

<Link to MISP Portal>



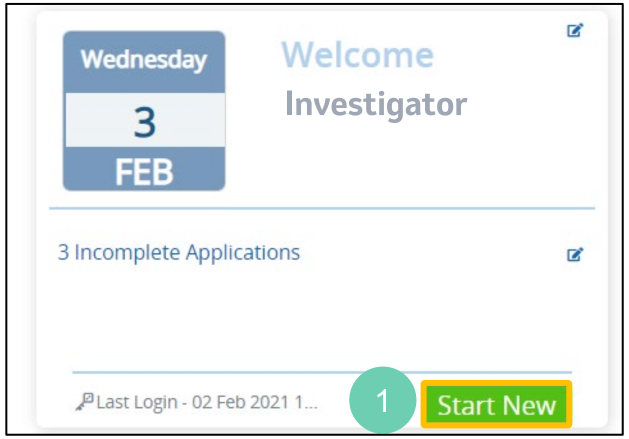
02 | Completing a New Application

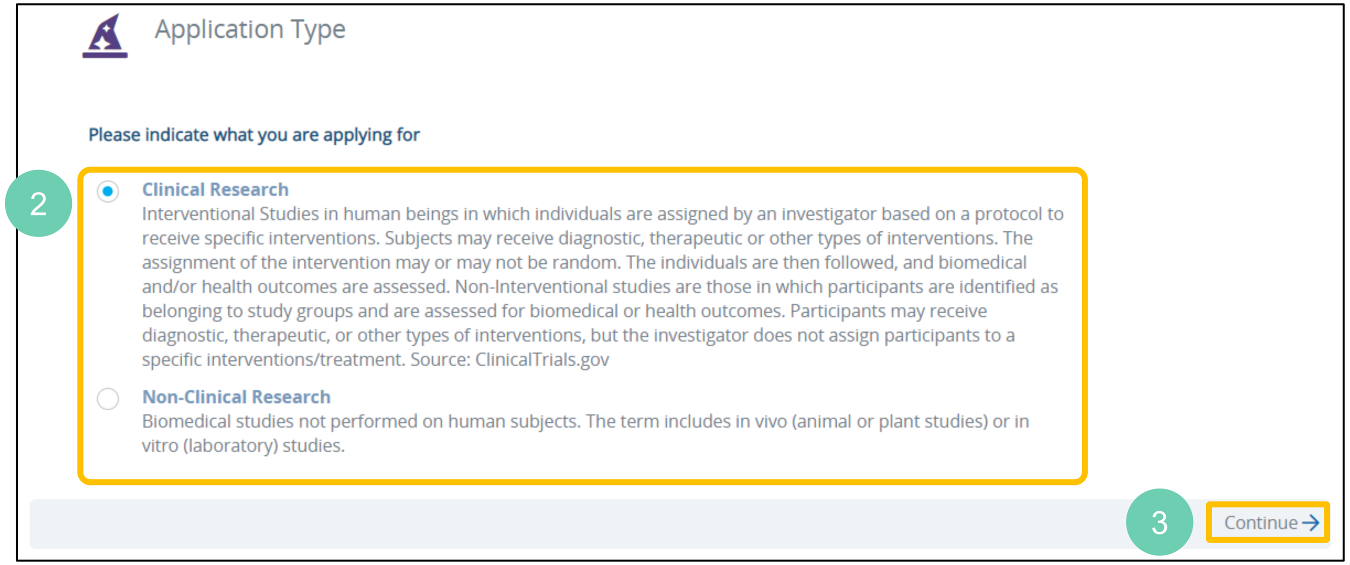
Starting a New Application

After logging in, you will arrive on your home page

From here you can start a new application:

1. Click the **Start New** button found on the **Welcome** panel
2. Select the **Application Type**, Clinical or Non-Clinical, based on the provided definitions
3. Click **Continue**

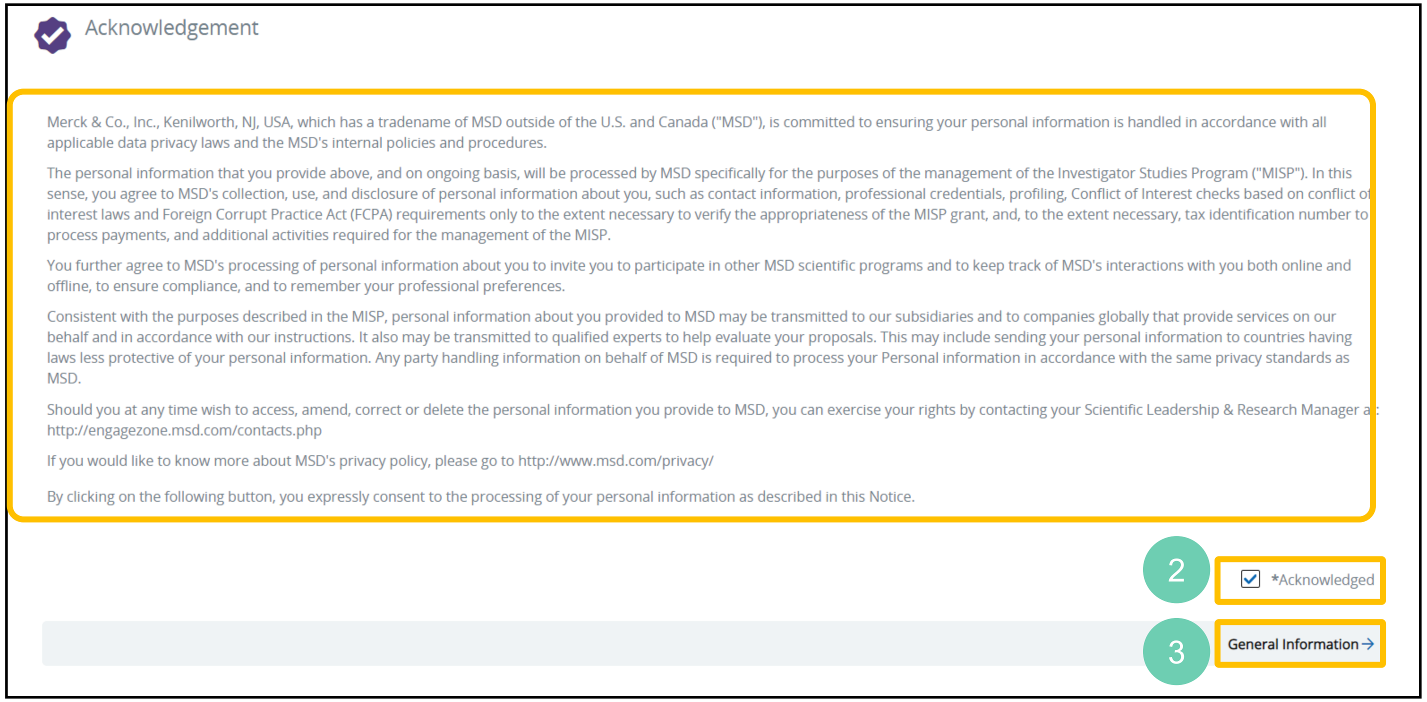




Acknowledgement

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 around your request for support



MISP PORTAL / REGISTRATION
NEW MISP APPLICATIONS
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Public

Application Screen Overview

MISP PORTAL / REGISTRATION
NEW MISP APPLICATIONS
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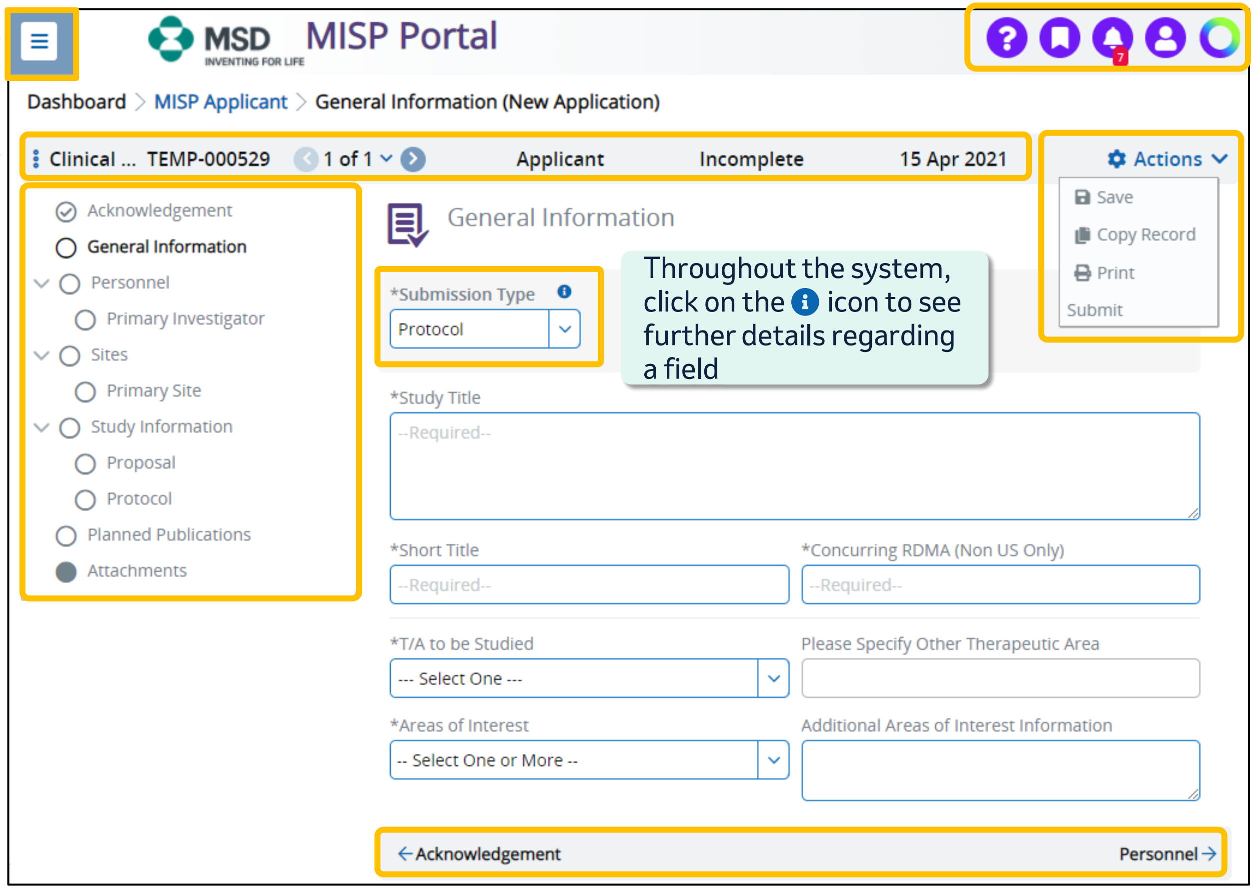
Use the **Navigation** menu to navigate across the MSD platform

Global Tools provide access to system support, bookmarks, notifications, and profile management

The **Context Bar** contains the application number, the name of the Applicant and the application status and date

The **Actions menu** is used to complete actions, such as submitting your application

The **Table of Contents** lists the sections, referred to as nodes, that make up an application. The node you are on appears in bold



- 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 required fields that must be completed** in order to progress the application

Move to the **previous** or **next node** using the navigation buttons at the bottom of the screen. As you move from node to node, the system will automatically save your work

Public

General Information Node

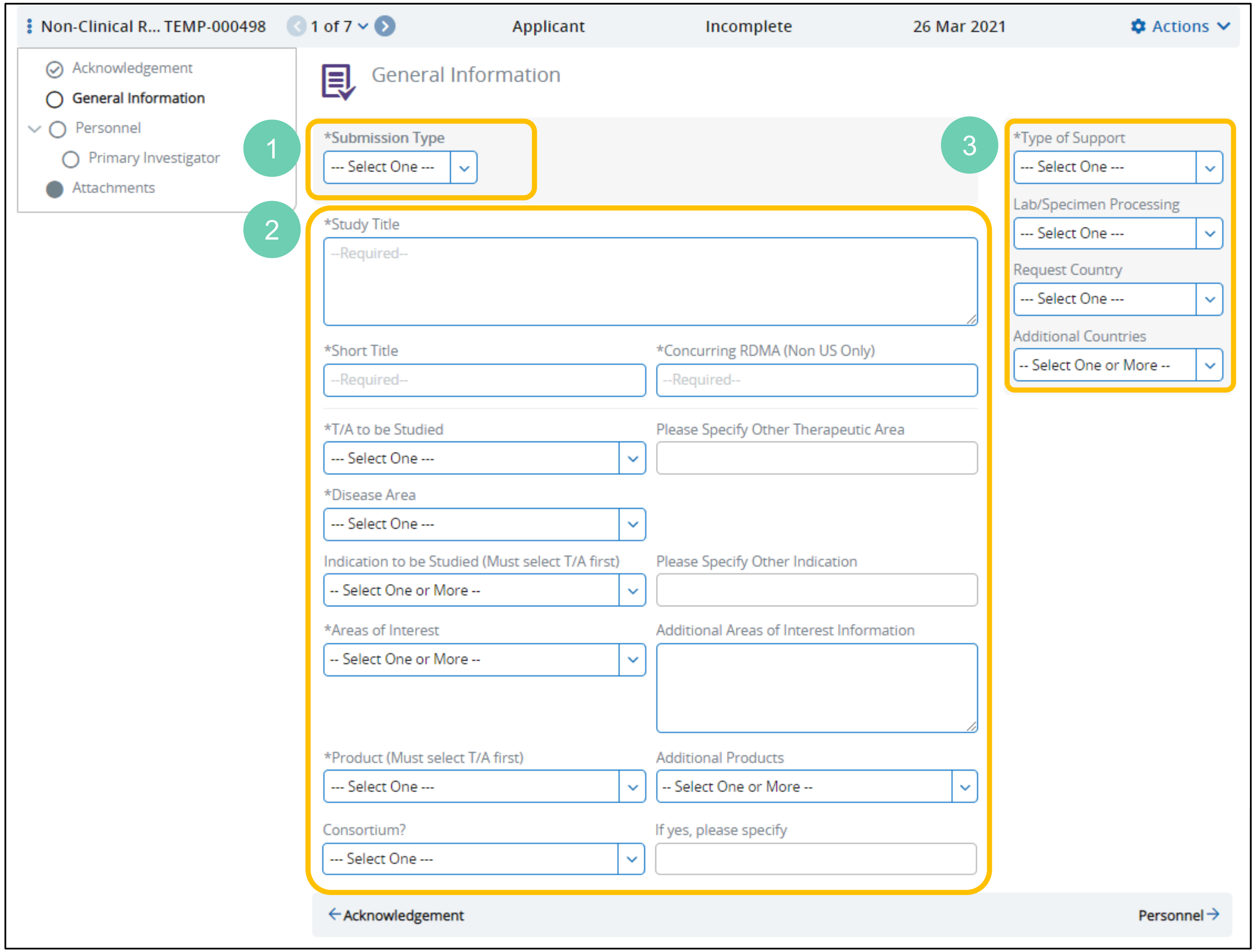
The first section of your application is the **General Information** node

1. Start by selecting your **Submission Type**
   - Proposal (Oncology Only) ONCOLOGY
   - Protocol (ID / GenMed / Vaccines / Pt Engagement)

   For more information on Submission Types refer to the MISP Portal

2. Next, provide the study details
   - Choosing a **T/A to be Studied** will populate the **Indication** and **Product/Material** fields

3. Listed on the right-hand-side of the screen are the type of support you are requesting and whether the study will be **On-Label** and/or **Multi-Site**



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Personnel Node

1. Add the **Primary Investigator** information on the **Personnel** node using one of the following three options:
   a. **Search** for a Primary Investigator, enter three or more characters in the search field, then click the 🔍 icon for additional options

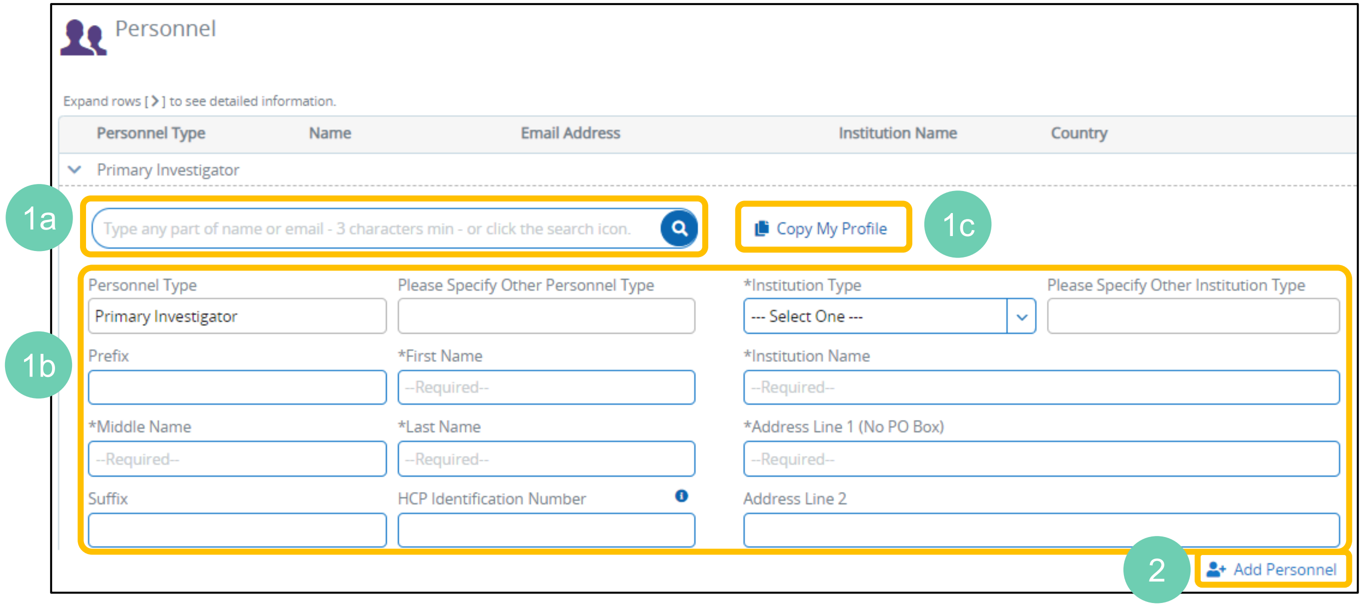
      OR

   b. Complete all required fields the Primary Investigator information manually

      OR

   c. If you are one of the key personnel, you can click **Copy My Profile** to populate the fields with your information

2. Click **+ Add Personnel** to add additional key personnel such as the Grant Administrator, Drug Supply Contact and Study Coordinator as appropriate



Primary Site Node

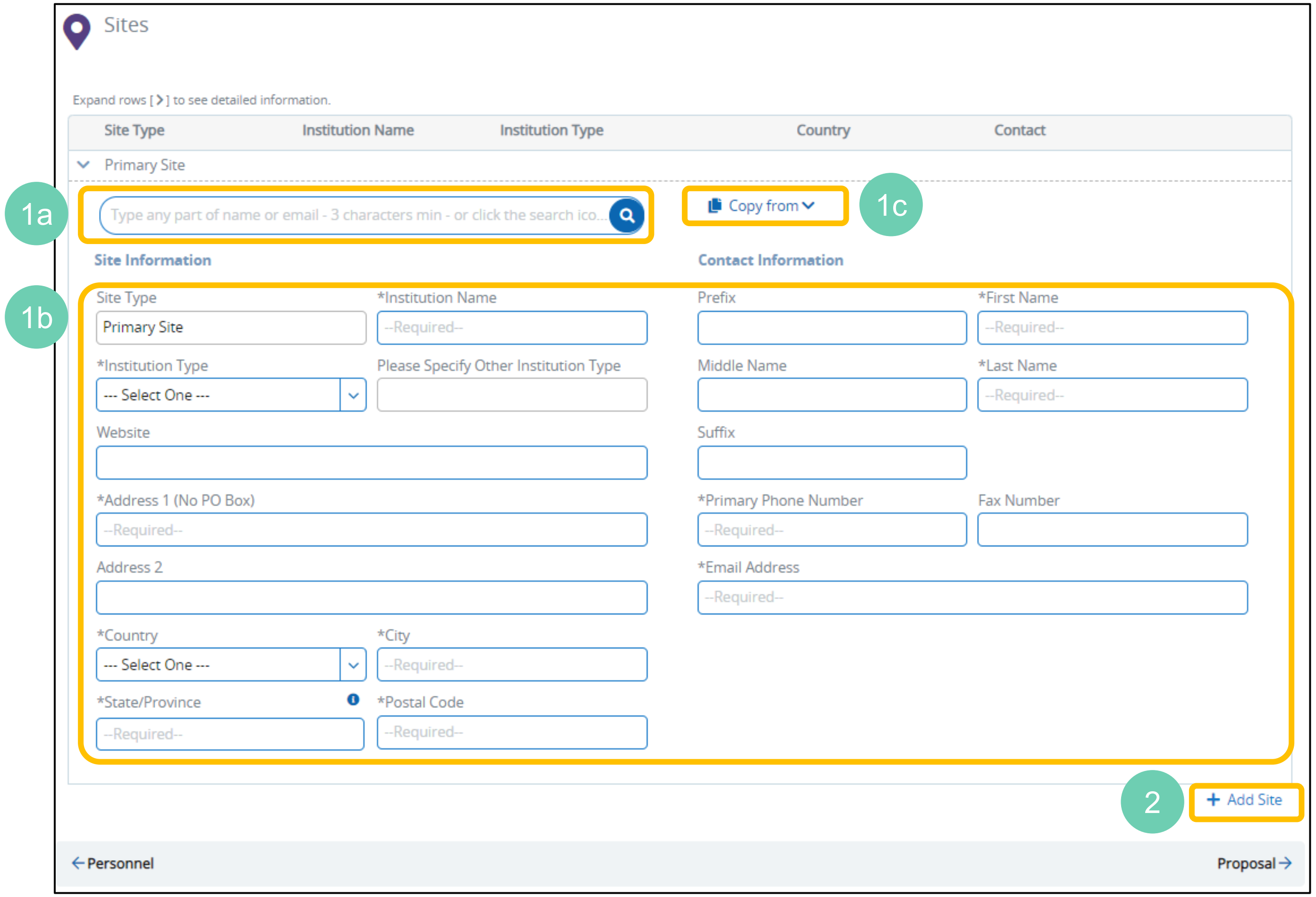
1. Add the **Primary Site** information on the **Sites** node using one of the following three options:
   a. Search for a site by entering at least three characters in the search field then click the 🔍 icon for additional options

      OR

   b. Enter the site information manually

      OR

   c. Click **Copy From** to populate the fields from a profile or primary investigator
2. Add additional sites by clicking **+ Add Site** (such as all secondary and drug shipment sites)



NEW APPLICATION

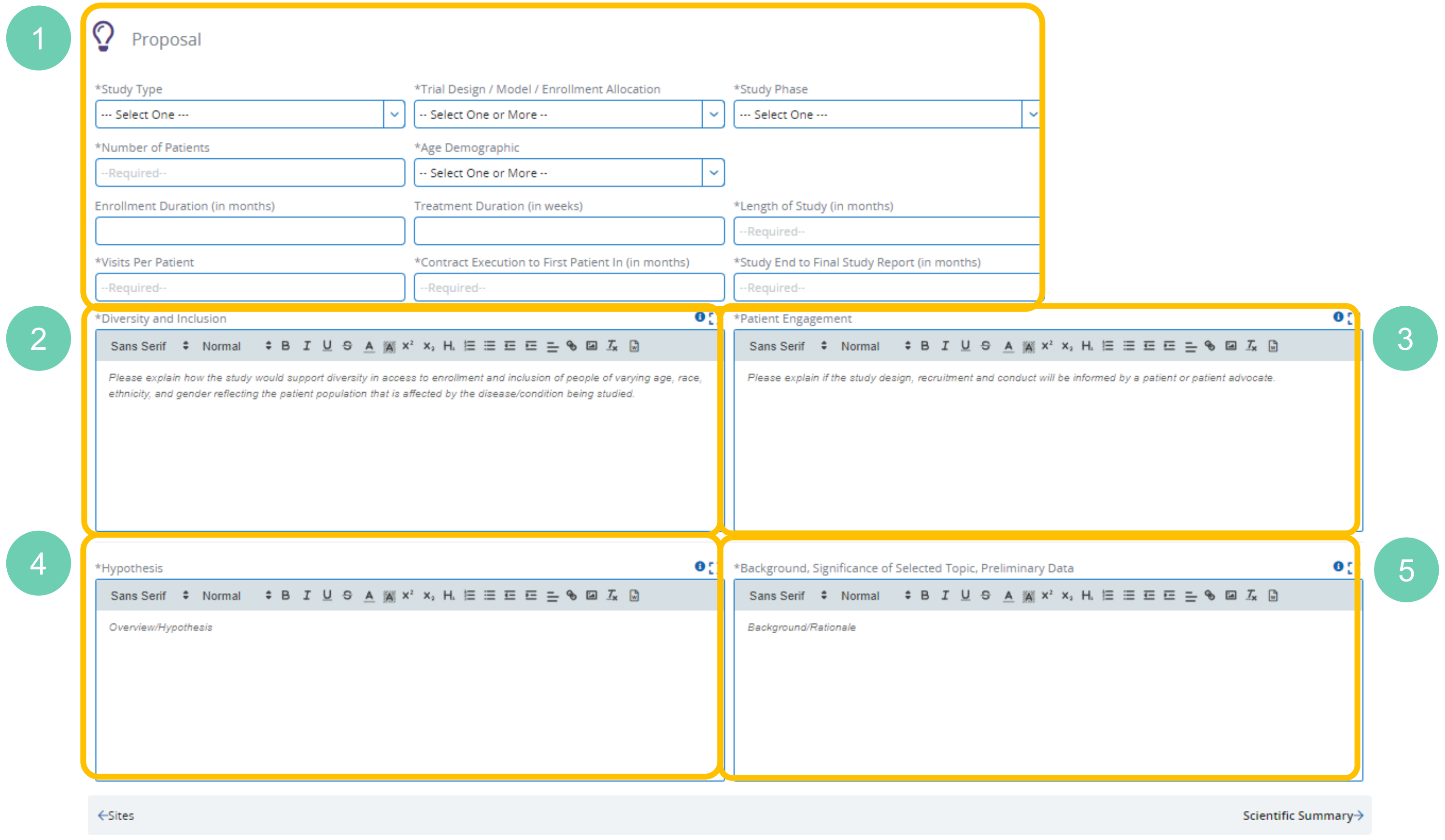
Proposal Node

Add the mandatory information on the **Proposal** node including:

1. The proposed study timing and design
   - This top section is for ALL study submissions
2. **Diversity and Inclusion**
   - This top section is for ALL study submissions
3. **Patient Engagement**
   - This top section is for ALL study submissions
4. **Hypothesis**

   ONCOLOGY ONLY
5. **Background, Significance of Selected Topic, Preliminary Data**

   ONCOLOGY ONLY

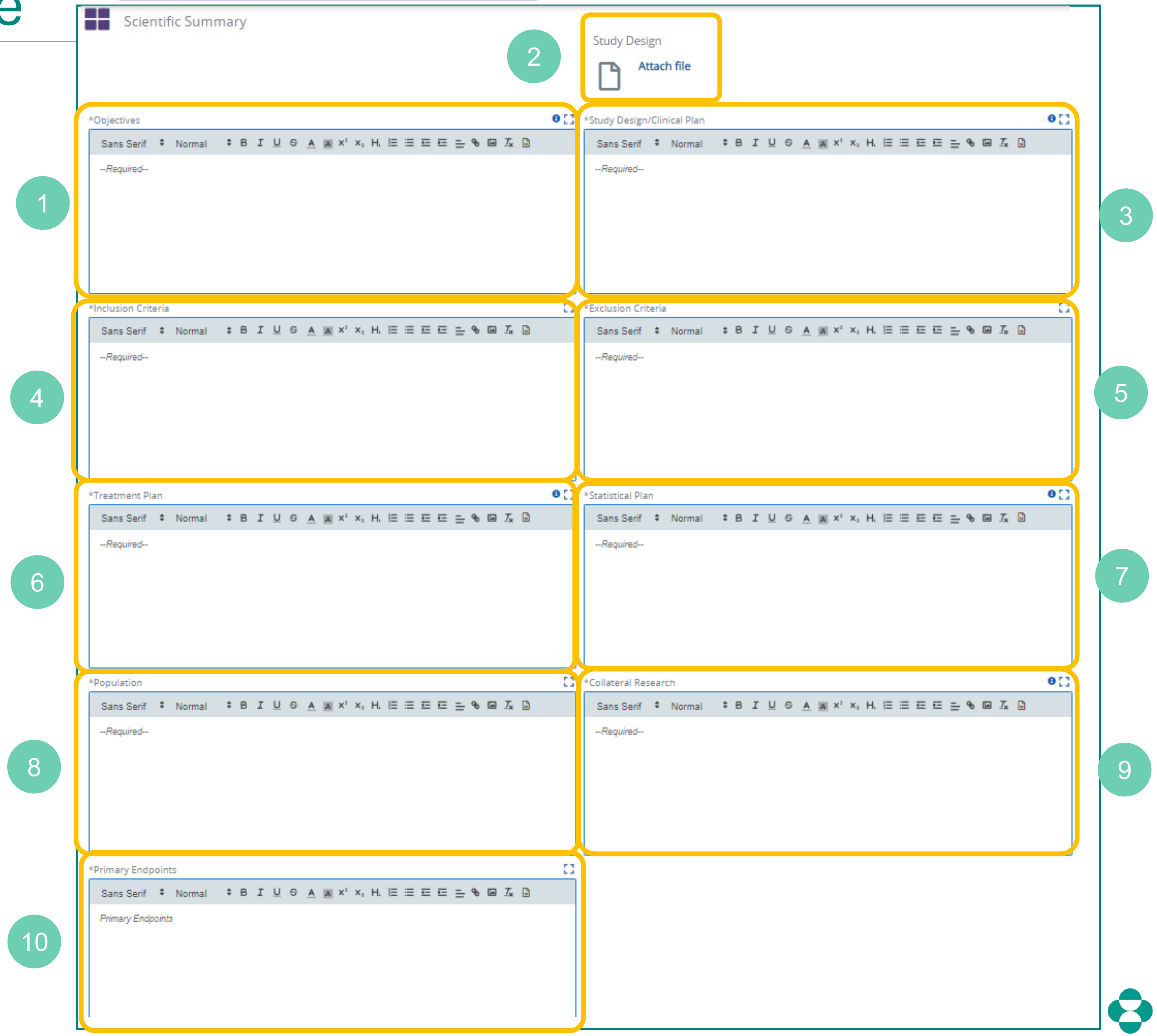


Scientific Summary Node

ONCOLOGY ONLY

Provide the required study details on the **Scientific Summary** node including:

1. **Objectives**
2. **Study Design**
   – Attachment
3. **Study Design/Clinical Plan**
4. **Inclusion Criteria**
5. **Exclusion Criteria**
6. **Treatment Plan**
7. **Statistical Plan**
8. **Population**
9. **Collateral Research**
10. **Primary Endpoints**



Requested Funding Node

ONCOLOGY ONLY

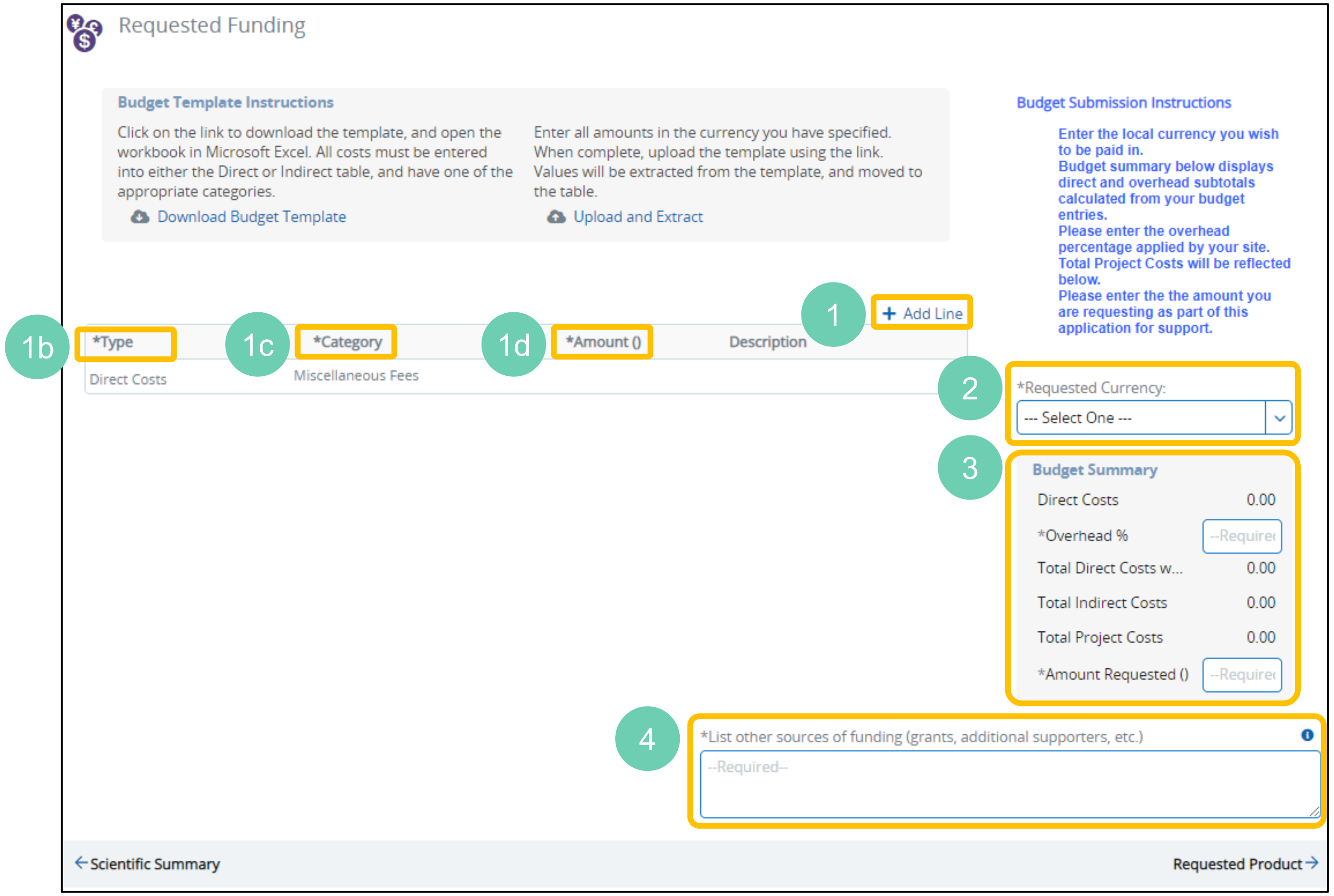
If you are requesting funding, you will be required to complete the **Requested Funding** node

1. Provide your Requested Funding information by **Manually** entering the enter entire study costs as **'Direct Costs' (1b) , 'Miscellaneous' (1c) and 'Amount' (1d)**

2. Select your **Requested Currency**

3. The **Budget Summary** will auto-populate based on the information you have provided

4. Finally, **List other sources of funding**



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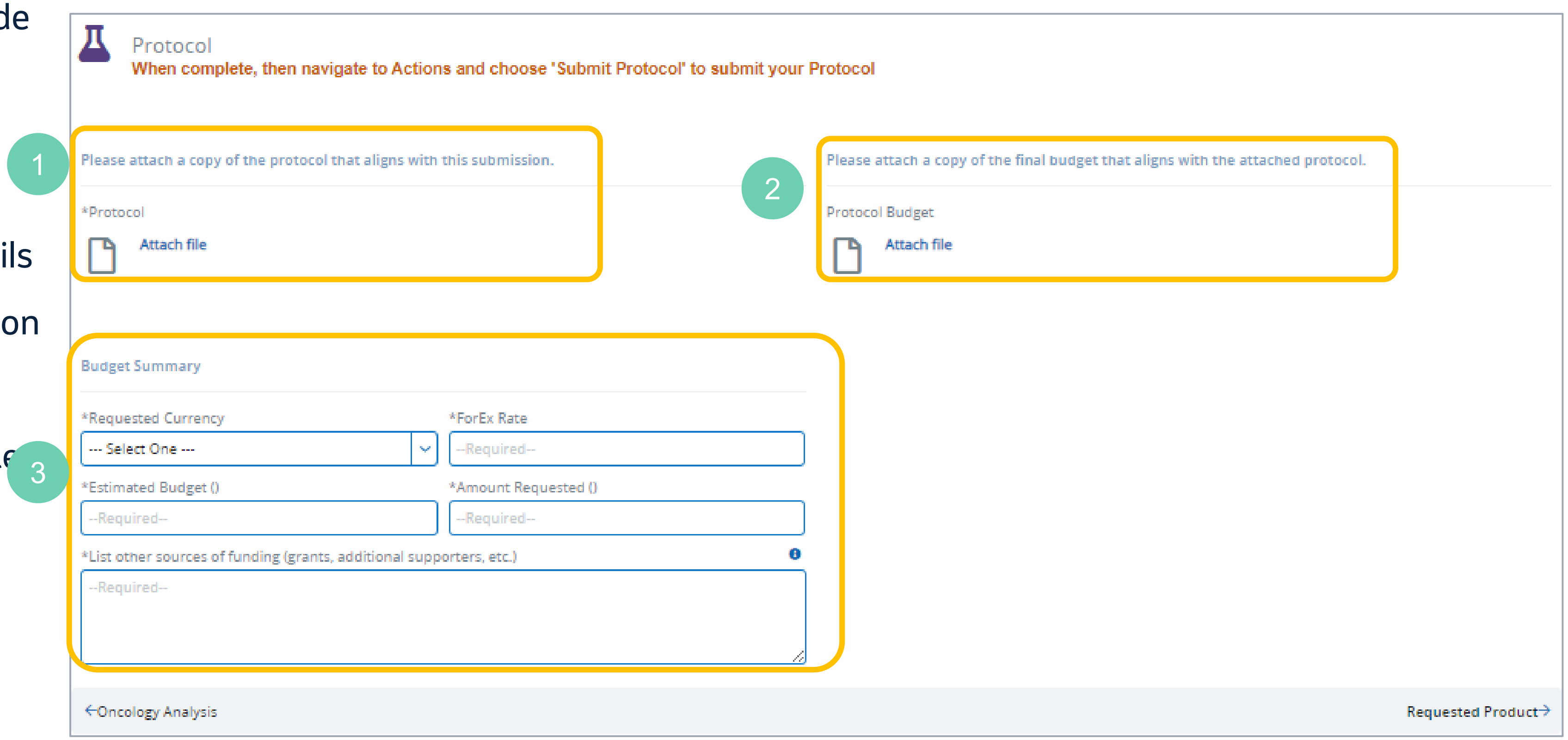
Protocol Node

Provide the details on the Protocol node including:

1. A copy of the **Protocol**
2. A copy of the **Protocol Budget**
3. Enter your **Budget Summary** details
   - ForEx Rate at date of submission
   - Enter 1 for USD Currency

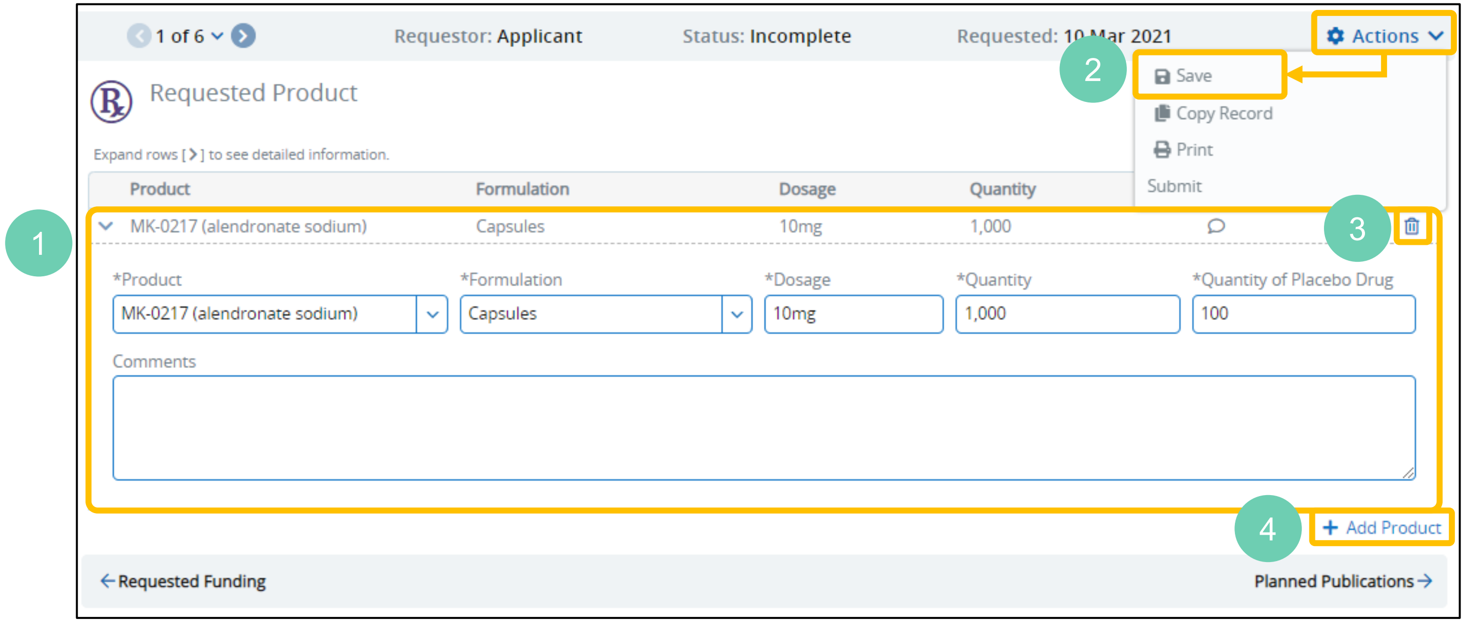
Protocol and Protocol Budget Templates can be found on [MISP Portal]



Requested Product Node

If you are requesting product, you will be required to complete the **Requested Product** node

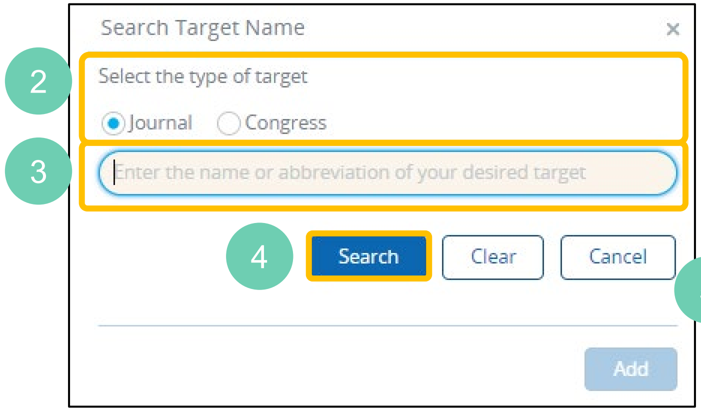
1. Populate the required fields
2. From the **Actions** menu, select **Save**
3. To delete a product from the table, click the 🗑 icon
4. To add requests for additional products and/or materials, select **+ Add Product**

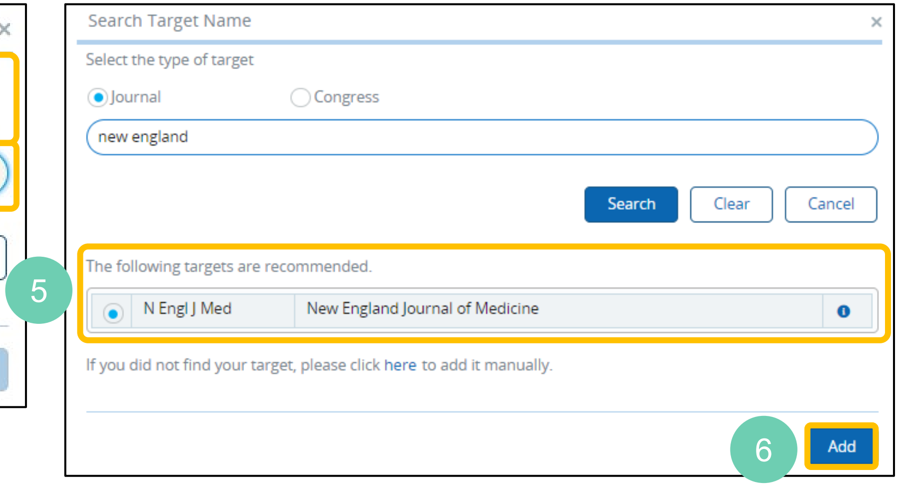


Planned Publications Node

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

1. Select **+ Add Journal/Congress**
2. Select the **type of target** (Journal or Congress)
3. Search for the target
   - Enter at least three characters within the search field
   - If searching for a congress, you will have the option to set a timeframe to narrow your search results
4. Click **Search**
5. Select the desired target from the search results
   Note: Click the ℹ icon to view a detailed summary of the target, including the website, T/As, and submission timeline
6. Confirm the target information is correct, then select **Add**



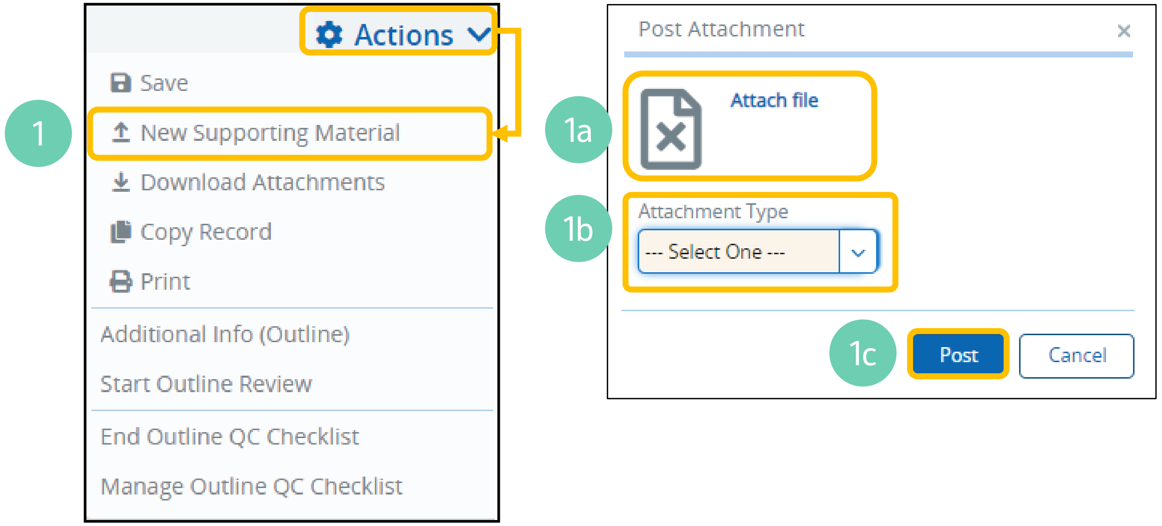


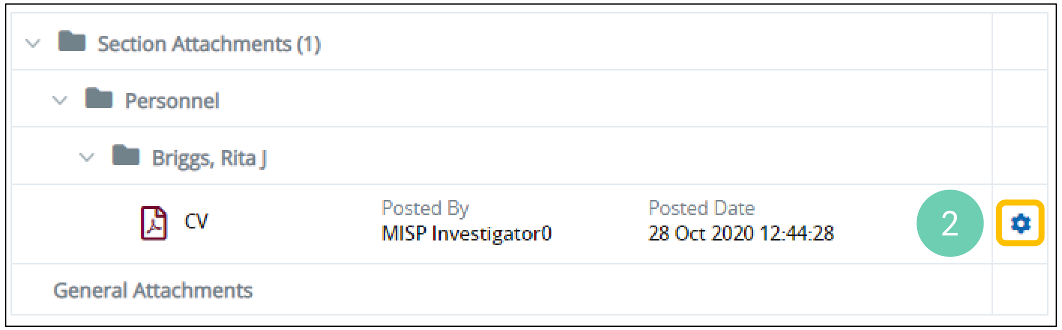
Attachments Node

Any documents associated with the application are stored in the Attachments node. Use the Attachments node to store project documentation such as tax information, letters of request, and additional documents.

There is also an option to upload additional documentation:

1. From the **Actions** menu select **New Supporting Material**
   a. Select **Attach file** and upload your documentation
   b. Next, select the **General Attachment Type**
   c. Click **Post** to add the document to the Attachments node
2. From the **Attachments** node you can select the ⚙ icon of an existing attachment to choose whether to **Remove**, **Replace**, or **View** the attachment





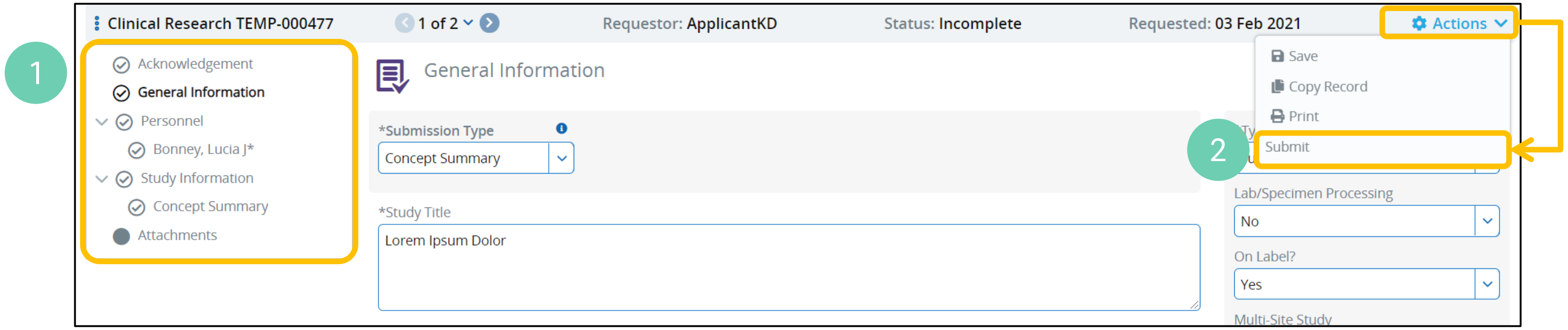
Oncology Proposal submissions require ‘Feasibility Sheet’ to be uploaded here

Submitting The Application

When all the required information has been entered submit the application for review and approval:

1. Check that all required information has been entered, completed nodes will be indicated with a checkmark
2. Select the **Actions** menu and then **Submit**
   – If there are **required fields that must be completed** in order to submit, they will be highlighted in red, and the node will be marked with an ⚠ icon
3. Your project will be assigned a Tracking Number and the Status will be updated to **Concept Summary Evaluation, Proposal Evaluation or Protocol Evaluation**

   You will be notified if the Scientific Leadership & Research Manager requires additional information and/or when a review decision has been made



03 | Post Submission Activities

- [Study Nodes]
- [Providing Additional Information]
- [Submitting Regulatory Information]
- [Submitting a Milestone Update]
- [Submitting Publication Information]
- [Submitting an Amendment]
- [Submitting the Project Closure Information]

Providing Additional Information

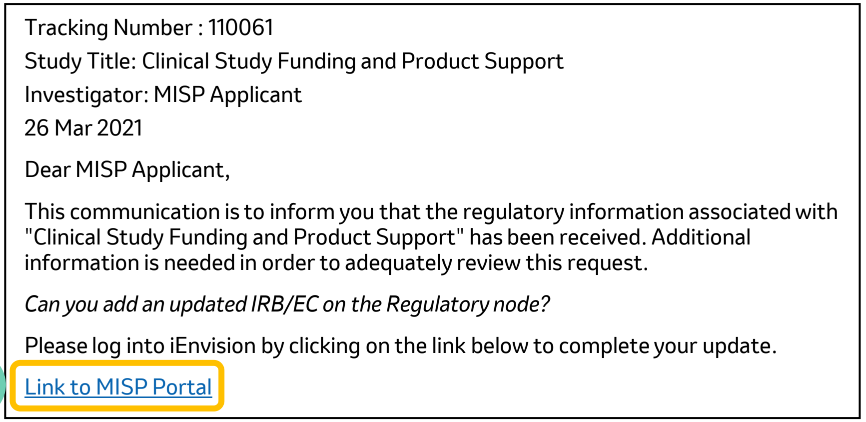
You may be asked to provide **Additional Information** after the application has been submitted

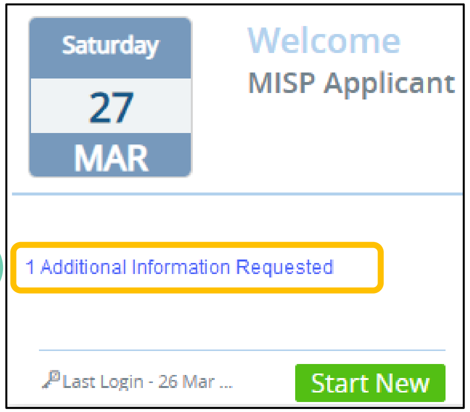
1. You can access a Request for Additional Information by either:
   a. Clicking the link in the notification email

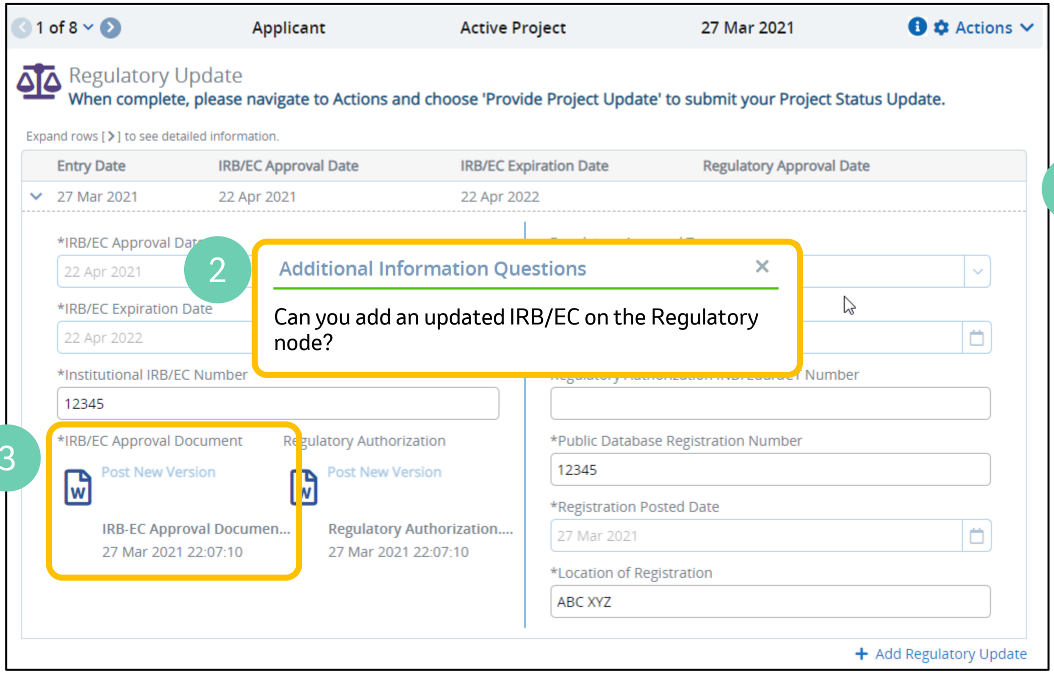
   OR

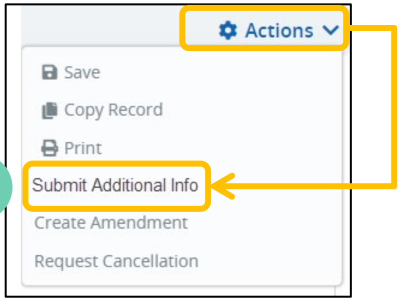
   b. Clicking the **Additional Information Requested** task on the **Welcome** panel
2. View the **Additional Information Questions** window; you can open the window if it is closed by clicking the ℹ icon in the context bar
3. Provide the requested additional information
4. Select the **Actions** menu and then select **Submit Additional Information**

Submission is not complete until you select 'Submit Additional Info'









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Submitting Regulatory Information

After your protocol is **APPROVED**, you will be asked to provide regulatory information

1. You can access Regulatory Information requests by either:
   a. Clicking the link in the notification email
   OR
   b. Clicking the **Regulatory Information Requested** task on the **Welcome** panel
2. Click Regulatory Node
3. Provide the information on the **Regulatory** node, required fields are notated with and asterisk (*)
4. Select the **Actions** menu and then select **Submit Regulatory**

Submission is not complete until you select 'Submit Regulatory'


Tracking Number : 110061
Study Title: Clinical Study Funding and Product Support
Investigator: MISP Applicant
26 Mar 2021

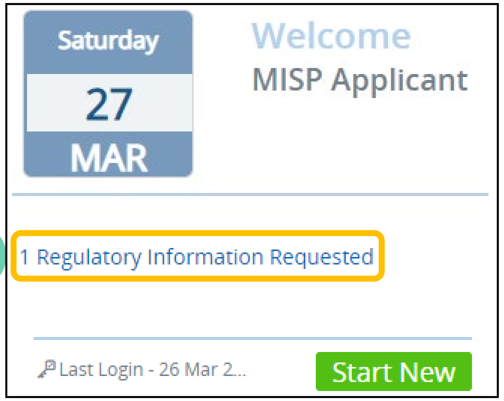
Dear MISP Applicant,

Thank you for the opportunity to review your proposal entitled, " Study Funding and Product Support".

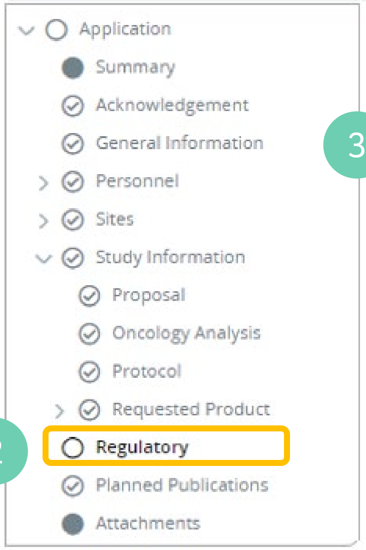
The Review Committee has approved your protocol and determined that you may proceed to submission of regulatory information. As a next step, please provide regulatory information as required.

Link to MISP Portal

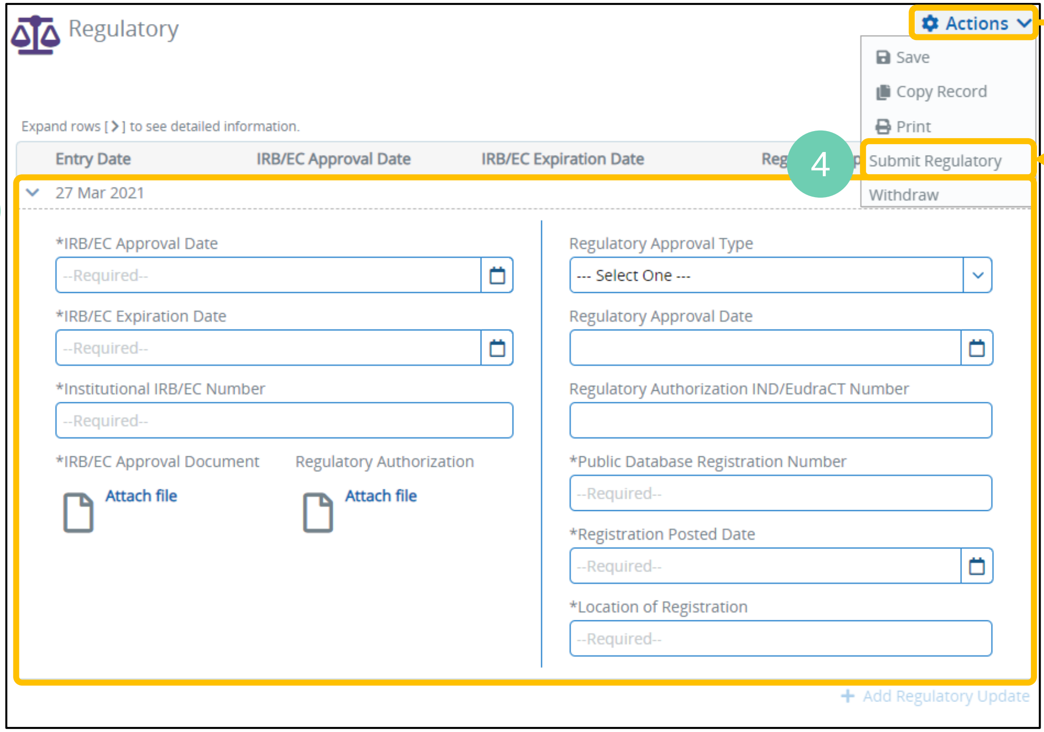
1a



1b



2



3

4

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Submitting a Milestone Update (page 1 of 2)

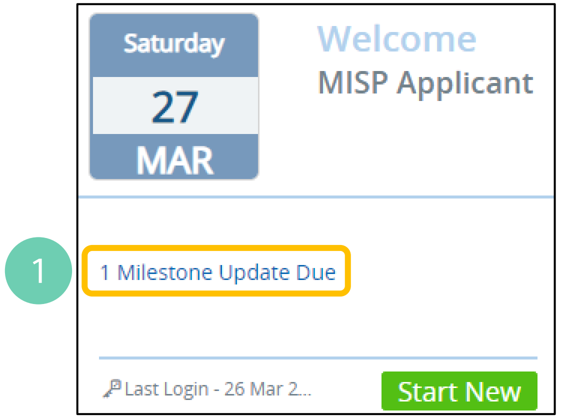
You will be notified when your active project requires an update

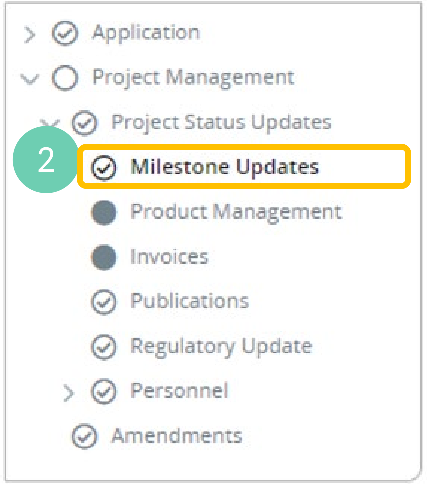
1. You can access Milestone Update requests by clicking the **Milestone Update Due** task on the **Welcome** panel

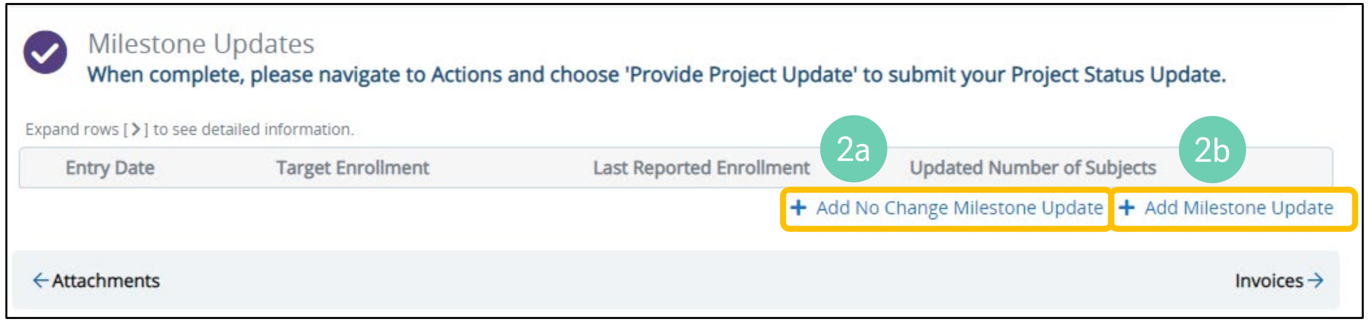
2. From the Milestone Updates node select either:
   a. **+ Add No Change Milestone Update** if there are no changes to report

      OR

   b. **+ Add Milestone Update** to provide an update on one of the scheduled milestone







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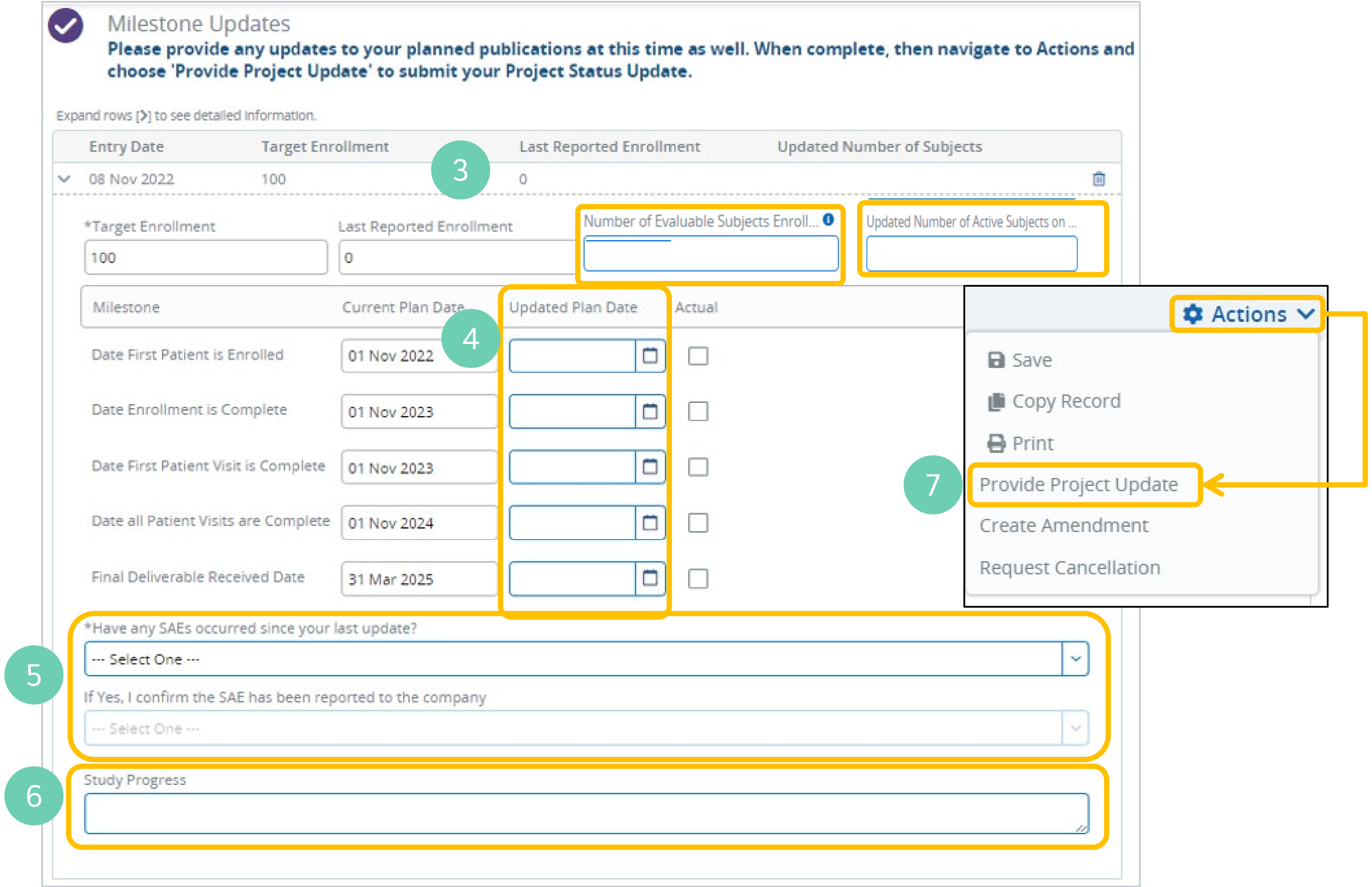
ADDITIONAL INFO | REGULATORY | MILESTONES | INVOICING | PUBLICATION INFO | AMENDMENTS | PROJECT CLOSE

Submitting a Milestone Update (page 2 of 2)

3. Enter any **Subject Updates**, as applicable
   - Number of Evaluable Subjects Enrolled
     - Evaluable is defined as all subjects whose data can be used in the final analysis data set
   - Updated Number of Active Subjects on Treatment
4. Reforecast **Updated Plan Date** items, as needed
   - Actual is marked when completed
5. Answer the question, **Have any SAEs occurred since your last update?**
6. Note any **Study Progress**
7. Once all the Milestone Updates have been completed, select the **Actions** menu and the select **Provide Project Update**

Submission is not complete until you select 'Provide Project Update'



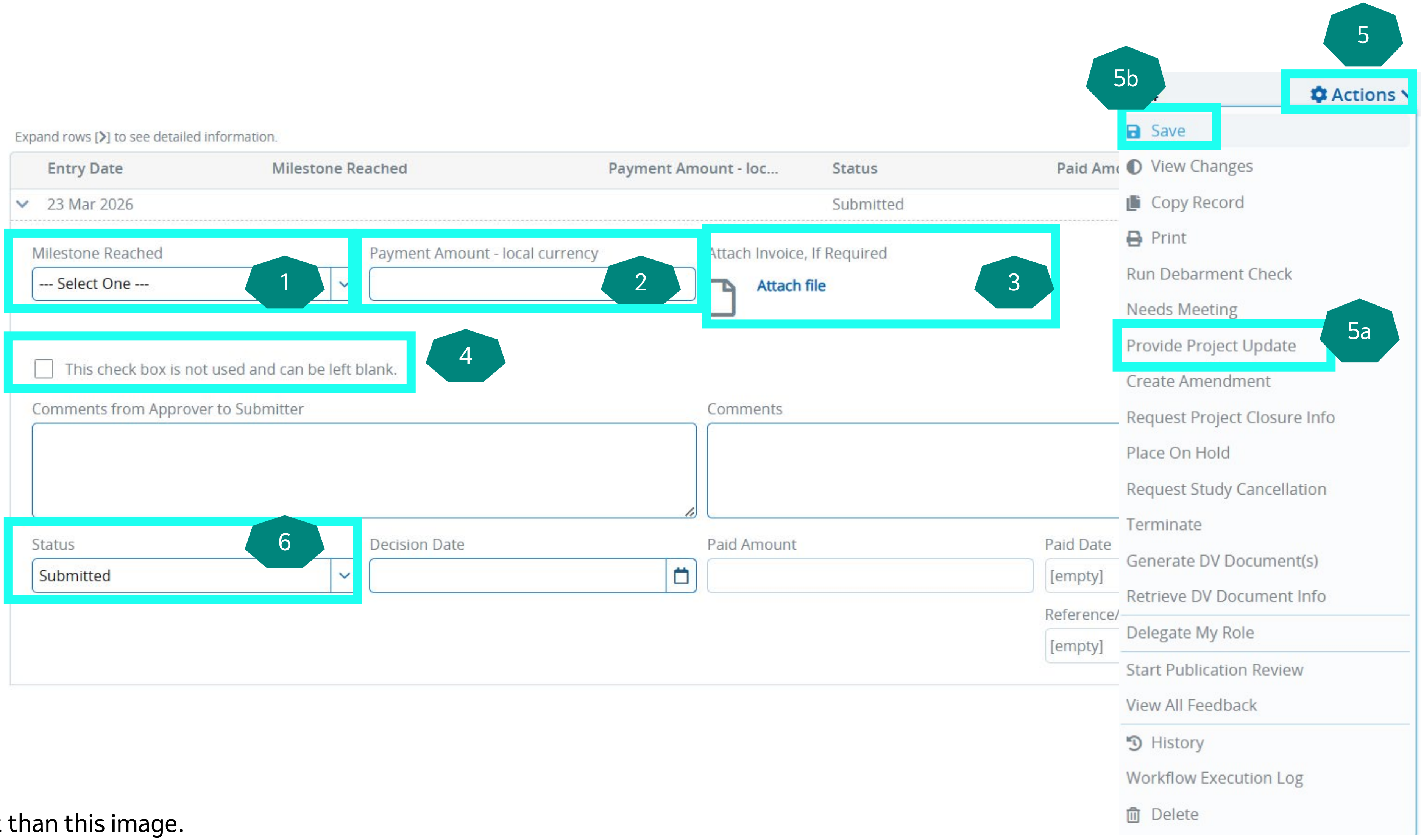
Completing the Payment Request Node

Directions to complete Payment Requests:

1. Select milestone reached
2. Entry is optional. If you choose to complete this field, user your local currency or follow the amount outlined in your contract.
3. Attach invoice if required
4. You may leave this box unchecked; attestation is not required.
5. In the Actions Drop Down:

5a. Select *Provide Project Update*
5b. Then select: *Save*

6. Confirm that the Status reads: Submitted; then exit



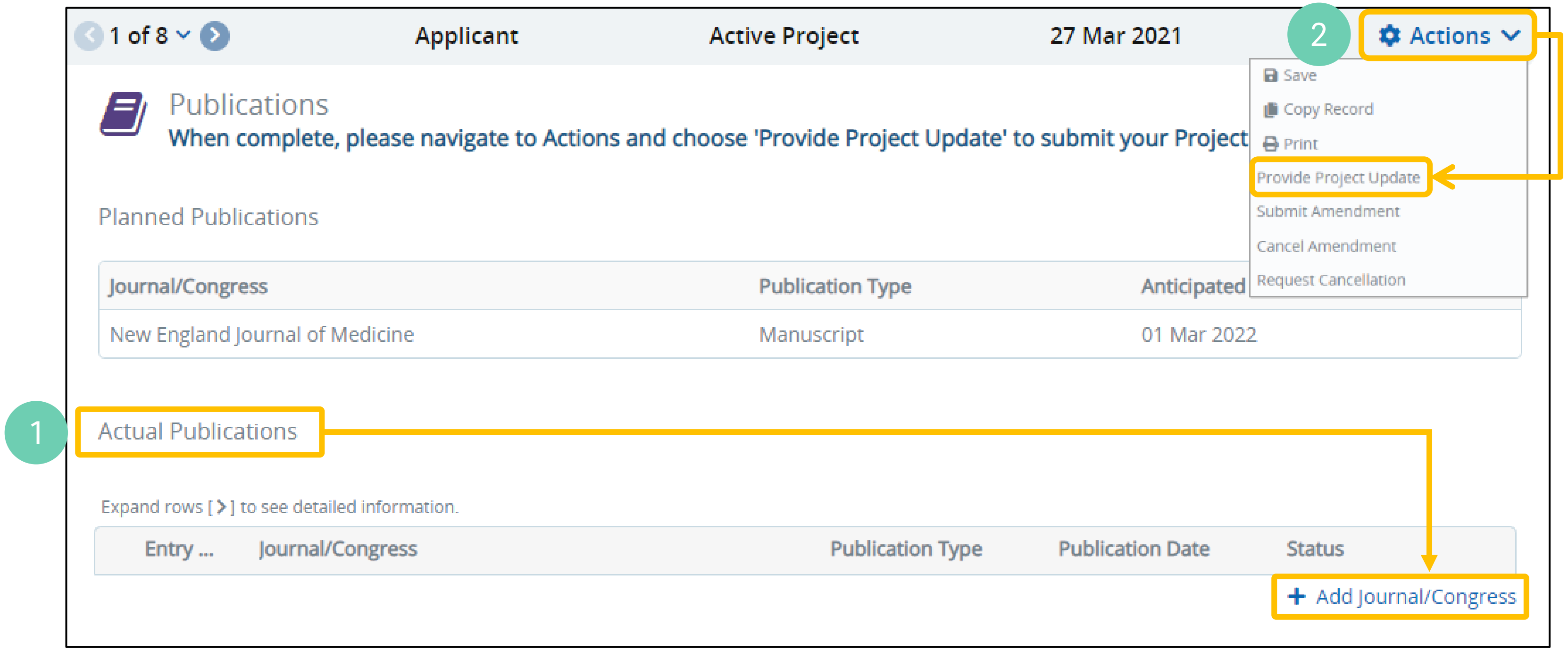
Your screen may look slightly different than this image.

Submitting Publication Information

While the project is active, update the **Publications** node with any draft publications

1. Under **Actual Publications**, click **+ Add Journal/Congress**
   For more information on adding a journal/congress click here
2. Once you have added all your Actual Publications, select the **Actions** menu and then select **Provide Project Update**

Submission is not complete until you select 'Provide Project Update'

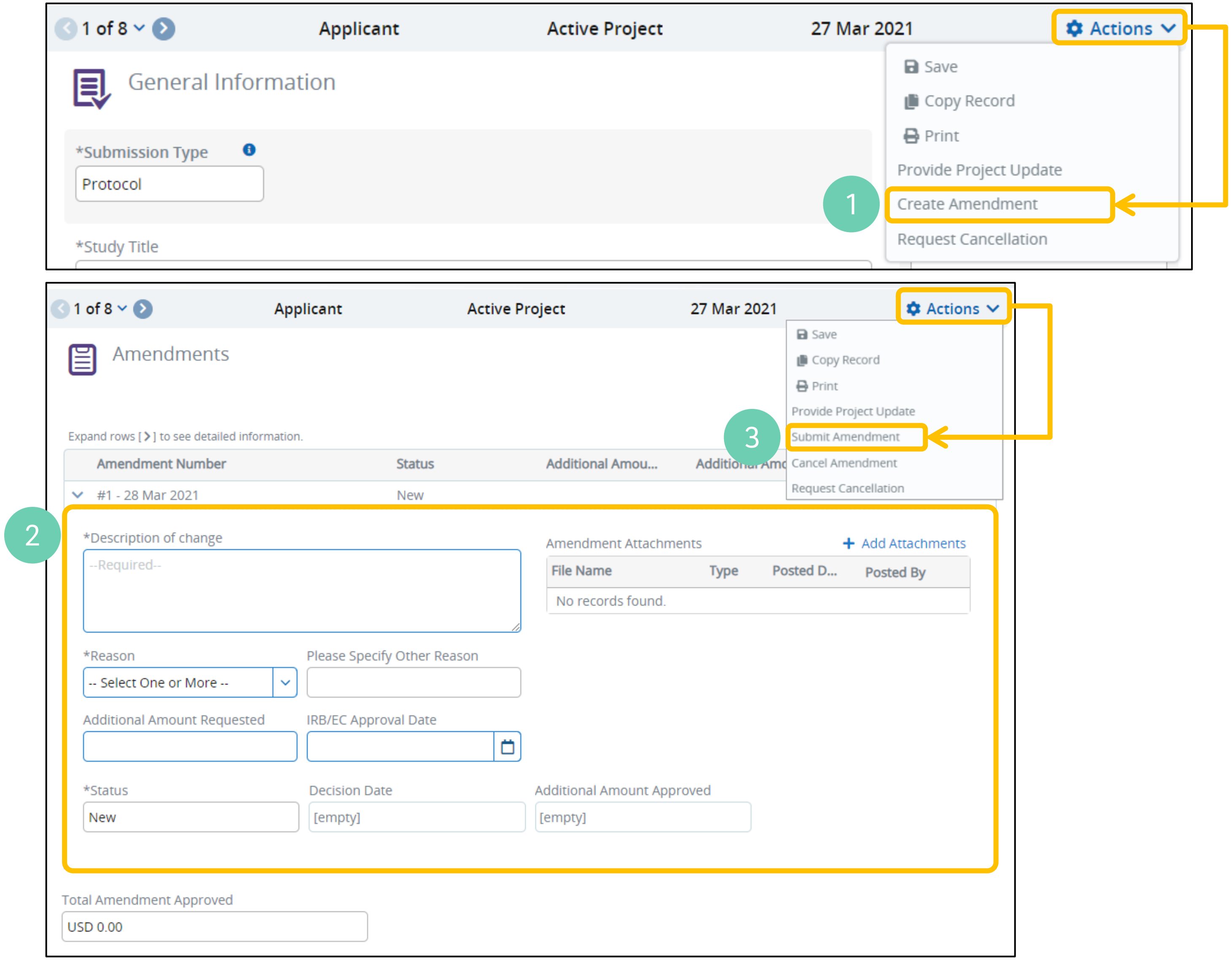


Submitting an Amendment

To request an **Amendment** on an active project such as an additional funding request or an administrative change:

1. From the **Actions** menu and then select **Create Amendment**
2. On the **Amendments** node provide the following information:
   - ✓ **Description of change** (required)
   - ✓ **Reason** (required)
   - ✓ **Specify Reason** if set to Other
   - ✓ **IRB/EC Approval Date**
   - ✓ Add any **Amendment Attachments**
3. Once you have provided the Amendment details, select the **Actions** menu and then select **Submit Amendment**

Submission is not complete until you select ‘Submit Amendment’



Submitting the Project Closure Information

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

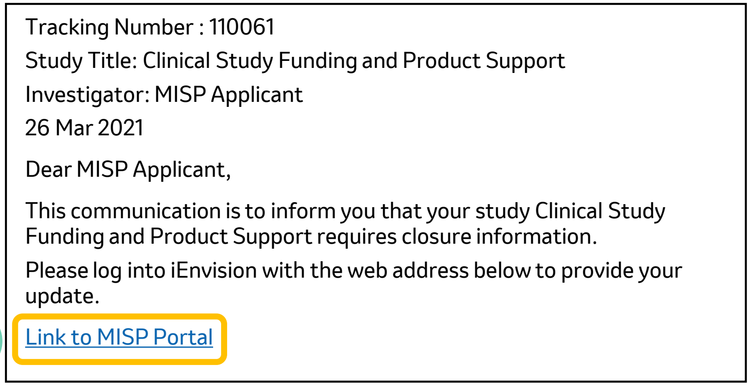
1. You can access Project Closure Information requests by either:
   a. Clicking the link in the notification email

   OR

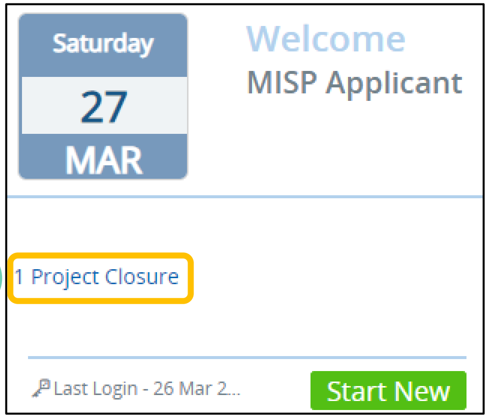
   b. Clicking the **Project Closure** task on the **Welcome** panel
2. Complete the fields on the **Project Closure** node including:
   - ✓ Attach the **Final Study Report** (required)
   - ✓ Answer the question, **Was There Unused product/Material?** (required)
   - ✓ Provide the **Date Results Published on Public Registry** (required)
   - ✓ **Attach a copy of the Drug Description Certificate**
   - ✓ Provide any **Closure Notes**
3. Select the **Actions** menu and then select **Submit Project Closure**

Submission is not complete until you select 'Provide Project Update'

1a

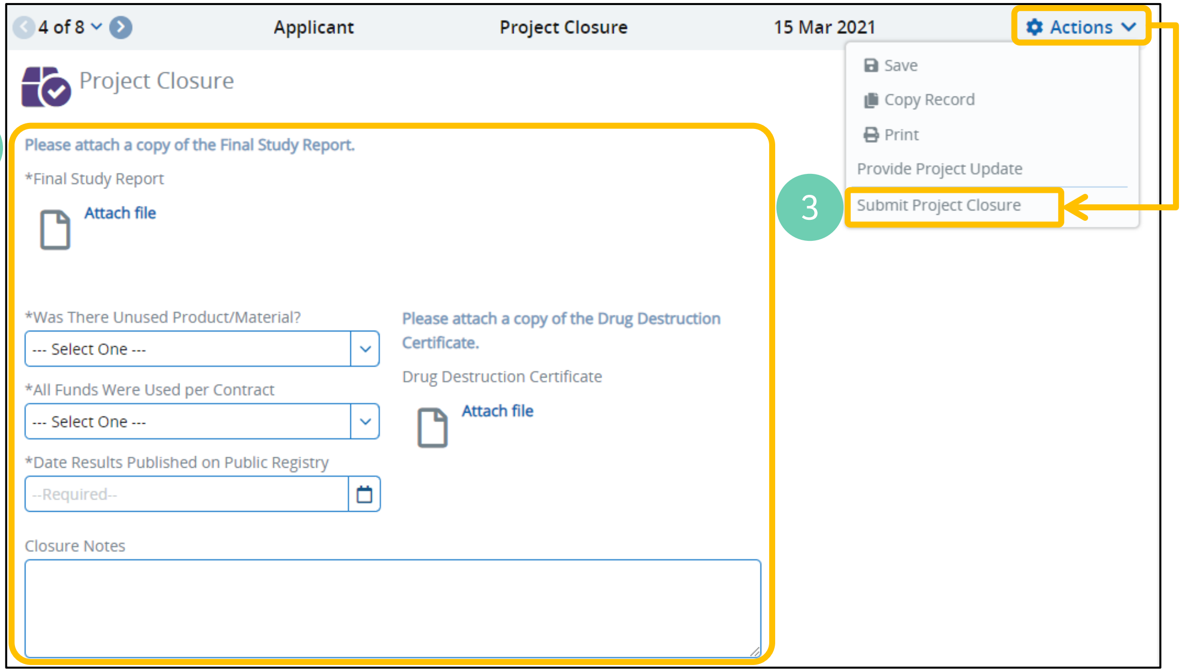


1b



2

3



MISP PORTAL / REGISTRATION
NEW MISP APPLICATIONS
POST SUBMISSION ACTIVITIES

Definitions: Status Groups and Steps

1. Incomplete
   - Submission in process; yet to be submitted
2. Proposal Evaluation ONCOLOGY ONLY
   - Proposal Submitted
   - Proposal Under Review
   - Additional Proposal Info Needed
   - Proposal Additional Info Submitted
   - Proposal Committee Meeting
3. Protocol Evaluation
   - Protocol Submitted
   - Protocol Under Review
   - Additional Protocol Info Needed
   - Protocol Additional Info Submitted
   - Protocol Committee Meeting
4. Project Setup
   - Project Setup
   - QC Check for Regulatory/Contract
   - Additional Regulatory Info Needed
   - Additional Regulatory Info Submitted
5. Active Project
   - Unsubmitted Amendment
   - Amendment Submitted
   - Amendment Under Review
   - Additional Amendment Info Needed
   - Amendment Addl Info Submitted
   - Amendment Committee Meeting
   - Amendment Setup
   - Cancellation Requested
   - On Hold – Active
6. Project Closure
   - Open for Project Closure
   - Project Closure Submitted
7. Closed Successfully
8. Closed Unsuccessfully

Support Resources

To access MISP, click the link below:
https://mrk.envisionpharma.com/ienv_mrk/visiontracker/portal/login.xhtml?pgm=ISR

For general MISP questions, or to request system access:
Email: vt_support@msd.com

For technical support, contact the Envision Pharma Helpdesk:
US: +1 860-266-4944 UK & EU: +44 1403-322095
Email: helpdesk@envisionpharmasupport.com