

## MSD INVESTIGATOR STUDIES PROGRAM (MISP)

# Applicant Guide

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iEnvision® 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

*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\\_mrkvisiontracker/portal/login.xhtml?pgm=ISR](https://mrk.envisionpharma.com/ienv_mrkvisiontracker/portal/login.xhtml?pgm=ISR)



For general MISP questions, or to request system access support, please contact: [vt\\_support@msd.com](mailto: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](mailto:helpdesk@envisionpharmasupport.com)

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# 01 | MISP Portal and Registration

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# MISP Portal Overview

## 1. NEW ACCOUNT REGISTRATION



### 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](mailto:helpdesk@envisionpharmasupport.com)

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

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

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**

**System Login**

User Name

Password

**1** Register for New Account  
Forgot Password?  
Forgot Login ID?

Log In

**2** **User Registration**

Registration Instructions

Registration Info

Name Prefix	*First Name	*Email Address	*Confirm Email
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Middle Name	*Last Name	*Password	*Confirm Password
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Name Suffix	Organization	*Security Question 1	*Answer
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Address Line 1		*Security Question 2	*Answer
<input type="text"/>		<input type="text"/>	<input type="text"/>
Address Line 2		*Security Question 3	*Answer
<input type="text"/>		<input type="text"/>	<input type="text"/>
Country	City	My preferred language is...	Time Zone
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
State/Province	ZIP Code	<b>2a</b> <input type="checkbox"/> *I agree to the Terms and Conditions	
<input type="text"/>	<input type="text"/>	<b>2b</b> Register Cancel	
Primary Phone Number	<input type="text"/>		

# 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>](#)

2 System Login

User Name  
Password

3 Register for New Account  
Forgot Login ID?  
**Log In**

4 Contact Us

Email: vt\_support@msd.com  
Envision Pharma Helpdesk:  
helpdesk@envisionpharmasupport.com

## 02 | Completing a New Application

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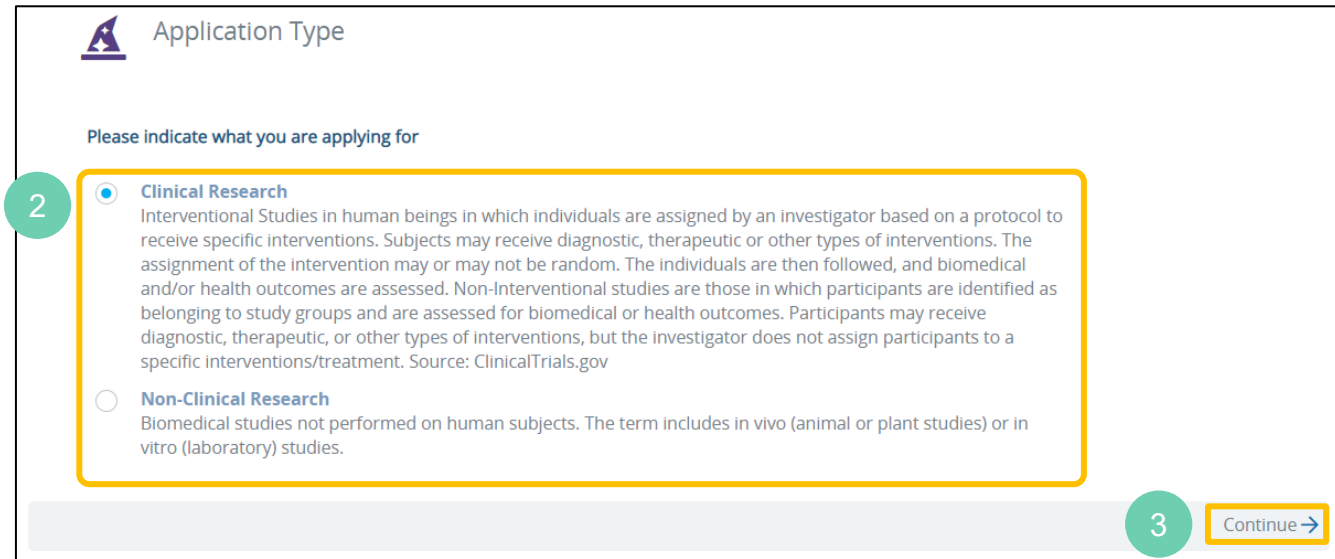
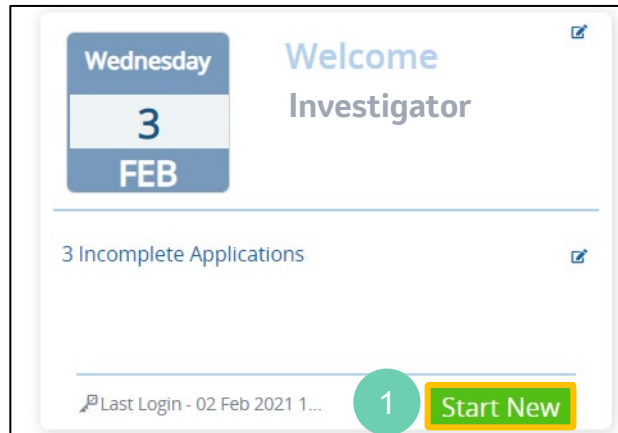


# Starting a New Application

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

 Acknowledgement

**1**

Merck & Co., Inc., Kenilworth, NJ, USA, which has a tradename of MSD outside of the U.S. and Canada ("MSD"), is committed to ensuring your personal information is handled in accordance with all applicable data privacy laws and the MSD's internal policies and procedures.

The personal information that you provide above, and on ongoing basis, will be processed by MSD specifically for the purposes of the management of the Investigator Studies Program ("MISP"). In this sense, you agree to MSD's collection, use, and disclosure of personal information about you, such as contact information, professional credentials, profiling, Conflict of Interest checks based on conflict of interest laws and Foreign Corrupt Practice Act (FCPA) requirements only to the extent necessary to verify the appropriateness of the MISP grant, and, to the extent necessary, tax identification number to process payments, and additional activities required for the management of the MISP.

You further agree to MSD's processing of personal information about you to invite you to participate in other MSD scientific programs and to keep track of MSD's interactions with you both online and offline, to ensure compliance, and to remember your professional preferences.

Consistent with the purposes described in the MISP, personal information about you provided to MSD may be transmitted to our subsidiaries and to companies globally that provide services on our behalf and in accordance with our instructions. It also may be transmitted to qualified experts to help evaluate your proposals. This may include sending your personal information to countries having laws less protective of your personal information. Any party handling information on behalf of MSD is required to process your Personal information in accordance with the same privacy standards as MSD.

Should you at any time wish to access, amend, correct or delete the personal information you provide to MSD, you can exercise your rights by contacting your Scientific Leadership & Research Manager at: <http://engagezone.msd.com/contacts.php>

If you would like to know more about MSD's privacy policy, please go to <http://www.msd.com/privacy/>

By clicking on the following button, you expressly consent to the processing of your personal information as described in this Notice.

**2**  \*Acknowledged

**3** [General Information →](#)

# Application Screen Overview



Use the **Navigation** menu to navigate across the MSD platform

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

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

The screenshot shows the MSD MISP Portal interface. At the top left is a navigation menu icon. The header includes the MSD logo and 'MISP Portal'. A global tools bar contains icons for help, notifications, profile, and refresh. The breadcrumb trail reads 'Dashboard > MISP Applicant > General Information (New Application)'. The context bar shows 'Clinical ... TEMP-00529', '1 of 1', 'Applicant', 'Incomplete', and '15 Apr 2021'. A table of contents on the left lists nodes: Acknowledgement (checked), General Information (bold), Personnel (checked), Primary Investigator, Sites, Primary Site, Study Information (checked), Proposal, Protocol, Planned Publications, and Attachments. The main form area is titled 'General Information' and contains fields for Submission Type (Protocol), Study Title, Short Title, Concurring RDMA, T/A to be Studied, and Areas of Interest. An actions menu on the right includes Save, Copy Record, Print, and Submit. A bottom navigation bar shows '← Acknowledgement' and 'Personnel →'. A callout box points to an information icon in the Submission Type field, stating: 'Throughout the system, click on the **i** icon to see further details regarding a field'.

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

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

# General Information Node

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

- 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](#)

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

- 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**

# Personnel Node



- Add the **Primary Investigator** information on the **Personnel** node using one of the following three options:
  - Search** for a Primary Investigator, enter three or more characters in the search field, then click the **Q** icon for additional options  
*OR*
  - Complete all required fields the Primary Investigator information manually  
*OR*
  - If you are one of the key personnel, you can click **Copy My Profile** to populate the fields with your information
- Click **+ Add Personnel** to add additional key personnel such as the Grant Administrator, Drug Supply Contact and Study Coordinator as appropriate

## Personnel

Expand rows [ > ] to see detailed information.

Personnel Type	Name	Email Address	Institution Name	Country																
▼ Primary Investigator																				
<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="border: 1px solid #ccc; padding: 5px; width: 60%;">           1a <input type="text" value="Type any part of name or email - 3 characters min - or click the search icon."/> <span style="font-size: 1.2em; color: #0070c0;">Q</span> </div> <div style="border: 1px solid #ccc; padding: 5px; width: 30%;">           1c <span style="font-size: 1.2em; color: #0070c0;">Q</span> Copy My Profile         </div> </div>																				
<div style="border: 1px solid #ccc; padding: 5px;"> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; padding: 5px;">Personnel Type <input type="text" value="Primary Investigator"/></td> <td style="width: 25%; padding: 5px;">Please Specify Other Personnel Type <input type="text"/></td> <td style="width: 25%; padding: 5px;">*Institution Type --- Select One ---</td> <td style="width: 25%; padding: 5px;">Please Specify Other Institution Type <input type="text"/></td> </tr> <tr> <td style="padding: 5px;">Prefix <input type="text"/></td> <td style="padding: 5px;">*First Name --Required--</td> <td colspan="2" style="padding: 5px;">*Institution Name --Required--</td> </tr> <tr> <td style="padding: 5px;">*Middle Name --Required--</td> <td style="padding: 5px;">*Last Name --Required--</td> <td colspan="2" style="padding: 5px;">*Address Line 1 (No PO Box) --Required--</td> </tr> <tr> <td style="padding: 5px;">Suffix <input type="text"/></td> <td style="padding: 5px;">HCP Identification Number <input type="text"/></td> <td colspan="2" style="padding: 5px;">Address Line 2 <input type="text"/></td> </tr> </table> </div>					Personnel Type <input type="text" value="Primary Investigator"/>	Please Specify Other Personnel Type <input type="text"/>	*Institution Type --- Select One ---	Please Specify Other Institution Type <input type="text"/>	Prefix <input type="text"/>	*First Name --Required--	*Institution Name --Required--		*Middle Name --Required--	*Last Name --Required--	*Address Line 1 (No PO Box) --Required--		Suffix <input type="text"/>	HCP Identification Number <input type="text"/>	Address Line 2 <input type="text"/>	
Personnel Type <input type="text" value="Primary Investigator"/>	Please Specify Other Personnel Type <input type="text"/>	*Institution Type --- Select One ---	Please Specify Other Institution Type <input type="text"/>																	
Prefix <input type="text"/>	*First Name --Required--	*Institution Name --Required--																		
*Middle Name --Required--	*Last Name --Required--	*Address Line 1 (No PO Box) --Required--																		
Suffix <input type="text"/>	HCP Identification Number <input type="text"/>	Address Line 2 <input type="text"/>																		
				2 <span style="font-size: 1.2em; color: #0070c0;">+</span> Add Personnel																

# 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)

Sites

Expand rows [ > ] to see detailed information.

Site Type	Institution Name	Institution Type	Country	Contact
Primary Site				

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

1c Copy from

**Site Information**

Site Type: Primary Site

\*Institution Name: --Required--

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

Please Specify Other Institution Type:

Website:

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

Address 2:

\*Country: --- Select One ---

\*City: --Required--

\*State/Province: --Required--

\*Postal Code: --Required--

**Contact Information**

Prefix:

Middle Name:

Suffix:

\*First Name: --Required--

\*Last Name: --Required--

\*Primary Phone Number: --Required--

Fax Number:

\*Email Address: --Required--

2 + Add Site

← Personnel Proposal →

# 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**
5. **Background, Significance of Selected Topic, Preliminary Data**

ONCOLOGY ONLY

ONCOLOGY ONLY





The screenshot shows a web form titled "Proposal" with a light blue header and a white body. The form is divided into several sections, each highlighted with a yellow border and a numbered callout (1-5) in a green circle. Section 1 is the top metadata section with dropdowns for Study Type, Trial Design, and Study Phase, and input fields for Number of Patients, Age Demographic, Enrollment Duration, Treatment Duration, Length of Study, Visits Per Patient, Contract Execution, and Study End. Section 2 is "Diversity and Inclusion" with a rich text editor. Section 3 is "Patient Engagement" with a rich text editor. Section 4 is "Hypothesis" with a rich text editor. Section 5 is "Background, Significance of Selected Topic, Preliminary Data" with a rich text editor. At the bottom, there are navigation links for "Sites" and "Scientific Summary".

# Scientific Summary Node

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

ONCOLOGY ONLY

Scientific Summary
2

\*Objectives

--Required--

\*Inclusion Criteria

--Required--

\*Treatment Plan

--Required--


\*Population

--Required--

\*Primary Endpoints

Primary Endpoints

Study Design

 Attach file

\*Study Design/Clinical Plan

--Required--

\*Exclusion Criteria

--Required--

\*Statistical Plan

--Required--

\*Collateral Research

--Required--

1
3

4
5

6
7

8
9

10

# 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**

**Budget Template Instructions**

Click on the link to download the template, and open the workbook in Microsoft Excel. All costs must be entered into either the Direct or Indirect table, and have one of the appropriate categories.

[Download Budget Template](#)

**Budget Submission Instructions**

Enter all amounts in the currency you have specified. When complete, upload the template using the link. Values will be extracted from the template, and moved to the table.

[Upload and Extract](#)

**Budget Submission Instructions**

Enter the local currency you wish to be paid in. Budget summary below displays direct and overhead subtotals calculated from your budget entries. Please enter the overhead percentage applied by your site. Total Project Costs will be reflected below. Please enter the amount you are requesting as part of this application for support.

*Type	*Category	*Amount ()	Description
Direct Costs	Miscellaneous Fees		

**\*Requested Currency:**

--- Select One ---

**Budget Summary**

Direct Costs	0.00
*Overhead %	--Required--
Total Direct Costs w...	0.00
Total Indirect Costs	0.00
Total Project Costs	0.00
*Amount Requested ()	--Required--

**\*List other sources of funding (grants, additional supporters, etc.)**

--Required--

← Scientific Summary
Requested Product →

# 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 Template can be found on [MISP Portal](#)

**Protocol**

When complete, then navigate to Actions and choose 'Submit Protocol' to submit your Protocol

1

Please attach a copy of the protocol that aligns with this submission.

\*Protocol

Attach file

2

Please attach a copy of the final budget that aligns with the attached protocol.

Protocol Budget

Attach file

3

**Budget Summary**

\*Requested Currency  \*ForEx Rate


\*Estimated Budget (  ) \*Amount Requested (  )

\*List other sources of funding (grants, additional supporters, etc.)  ⓘ

←Oncology Analysis
Requested Product→

# 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**

1 of 6 | Requestor: Applicant | Status: Incomplete | Requested: 10 Mar 2021 | Actions

**Requested Product**

Expand rows [ > ] to see detailed information.

Product	Formulation	Dosage	Quantity	
MK-0217 (alendronate sodium)	Capsules	10mg	1,000	

\*Product: MK-0217 (alendronate sodium) | \*Formulation: Capsules | \*Dosage: 10mg | \*Quantity: 1,000 | \*Quantity of Placebo Drug: 100

Comments

+ Add Product

← Requested Funding | Planned Publications →

# 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**

The screenshot illustrates the process of adding a planned publication through the 'Planned Publications' node. It is divided into two main sections: the main interface and two search dialog boxes.

**Main Interface (Planned Publications):** Shows a table with columns for 'Journal/Congress', 'Publication Type', and 'Anticipated Date'. A '+ Add Journal/Congress' button is highlighted with a green circle '1'. Below the table, there are navigation options: '< Requested Product' and 'Attachments >'. The table currently displays 'No Line Items Found'.


**Search Dialog 1 (Left):** Titled 'Search Target Name', it contains a dropdown to 'Select the type of target' with radio buttons for 'Journal' (selected) and 'Congress'. Below this is a search input field with the placeholder 'Enter the name or abbreviation of your desired target'. A 'Search' button is highlighted with a green circle '4'. Other buttons include 'Clear' and 'Cancel'.

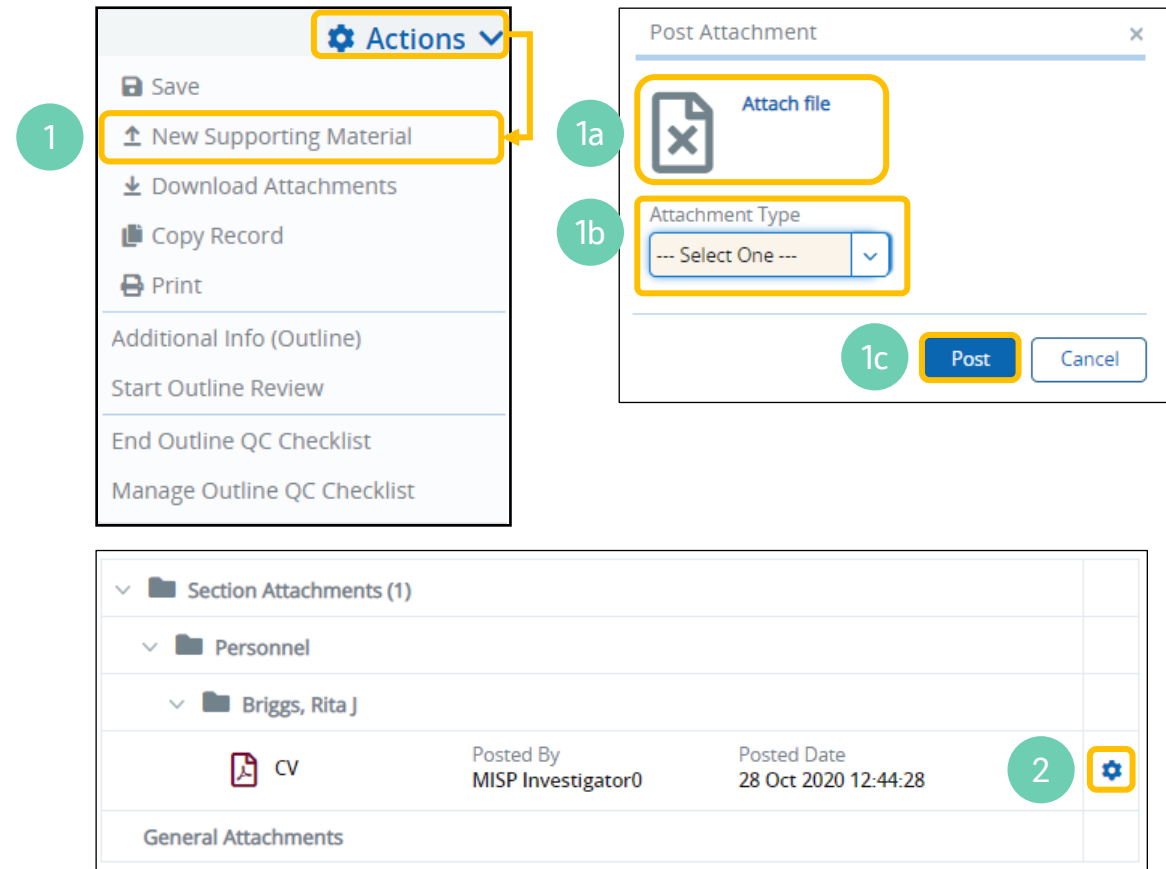
**Search Dialog 2 (Right):** Also titled 'Search Target Name', it shows the search results for 'new england'. The 'Journal' radio button is selected. A search result is displayed: 'N Engl J Med' with a detailed view 'New England Journal of Medicine' and an information icon 'i'. A green circle '5' highlights this result. At the bottom, there is an 'Add' button highlighted with a green circle '6'. A note at the bottom of the dialog says: 'If you did not find your target, please click [here](#) to add it manually.'

# 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



The screenshot illustrates the process of adding a new attachment. On the left, the 'Actions' menu is open, with 'New Supporting Material' highlighted. On the right, the 'Post Attachment' dialog is shown, with 'Attach file' selected, 'Attachment Type' set to '--- Select One ---', and the 'Post' button highlighted. Below these, a table shows the 'Attachments' node with a folder structure: 'Section Attachments (1)', 'Personnel', and 'Briggs, Rita J'. Under 'Briggs, Rita J', there is an attachment named 'CV' with a gear icon next to it, indicating it can be managed. The 'Posted By' is 'MISP Investigator0' and the 'Posted Date' is '28 Oct 2020 12:44:28'.

Attachment Name	Posted By	Posted Date	Actions
CV	MISP Investigator0	28 Oct 2020 12:44:28	

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

The screenshot shows the application submission interface. The top bar displays the application ID 'Clinical Research TEMP-000477', the page number '1 of 2', the requestor 'ApplicantKD', the status 'Incomplete', and the request date '03 Feb 2021'. The left sidebar shows a list of nodes: Acknowledgement, General Information, Personnel, Bonney, Lucia J\*, Study Information, Concept Summary, and Attachments. The main content area shows the 'General Information' section with fields for '\*Submission Type' (set to 'Concept Summary') and '\*Study Title' (set to 'Lorem Ipsum Dolor'). The right sidebar shows the 'Actions' menu with options: Save, Copy Record, Print, and Submit. A yellow box highlights the 'Submit' button, and a yellow arrow points to it from the 'Actions' menu. A green circle with the number '1' is next to the sidebar, and a green circle with the number '2' is next to the 'Submit' button.

1

2

3

Clinical Research 110057

1 of 2

Requestor: ApplicantKD

Status: Concept Summary Evaluation

## 03 | Post Submission Activities

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# Providing Additional Information

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

- You can access a Request for Additional Information by either:
  - Clicking the link in the notification email
  - OR
  - Clicking the **Additional Information Requested** task on the **Welcome** panel
- View the **Additional Information Questions** window; you can open the window if it is closed by clicking the **i** icon in the context bar
- Provide the requested additional information
- Select the **Actions** menu and then select **Submit Additional Information**

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

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

Dear MISP Applicant,

This communication is to inform you that the regulatory information associated with "Clinical Study Funding and Product Support" has been received. Additional information is needed in order to adequately review this request.

*Can you add an updated IRB/EC on the Regulatory node?*

Please log into iEnvision by clicking on the link below to complete your update.

[Link to MISP Portal](#)

Saturday  
 27  
 MAR

Welcome  
 MISP Applicant

1 Additional Information Requested

Last Login - 26 Mar ... [Start New](#)

1 of 8 | Applicant | Active Project | 27 Mar 2021 | Actions

**Regulatory Update**  
 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	IRB/EC Approval Date	IRB/EC Expiration Date	Regulatory Approval Date
27 Mar 2021	22 Apr 2021	22 Apr 2022	

\*IRB/EC Approval Date: 22 Apr 2021

\*IRB/EC Expiration Date: 22 Apr 2022

\*Institutional IRB/EC Number: 12345

\*IRB/EC Approval Document: [Post New Version](#)  
 IRB-EC Approval Documen...  
 27 Mar 2021 22:07:10

Regulatory Authorization: [Post New Version](#)  
 Regulatory Authorization...  
 27 Mar 2021 22:07:10

\*Public Database Registration Number: 12345

\*Registration Posted Date: 27 Mar 2021

\*Location of Registration: ABC XYZ

[+ Add Regulatory Update](#)

Actions

- Save
- Copy Record
- Print
- Submit Additional Info**
- Create Amendment
- Request Cancellation

# Submitting Regulatory Information

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

- You can access Regulatory Information requests by either:
  - Clicking the link in the notification email
  - OR
  - Clicking the **Regulatory Information Requested** task on the **Welcome** panel
- Click Regulatory Node
- Provide the information on the **Regulatory** node, required fields are notated with and asterisk (\*)
- 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.

1a [Link to MISP Portal](#)

Saturday  
27  
MAR

Welcome  
MISP Applicant

1b 1 Regulatory Information Requested

Last Login - 26 Mar 2... [Start New](#)

2

- Application
  - Summary
  - Acknowledgement
  - General Information
  - Personnel
  - Sites
  - Study Information
    - Proposal
    - Oncology Analysis
    - Protocol
    - Requested Product
    - Planned Publications
    - Attachments

3

Regulatory

Expand rows [ > ] to see detailed information.

Entry Date	IRB/EC Approval Date	IRB/EC Expiration Date	Reg. #	Actions
27 Mar 2021				<ul style="list-style-type: none"> <li>Save</li> <li>Copy Record</li> <li>Print</li> <li>Submit Regulatory</li> <li>Withdraw</li> </ul>

4

\*IRB/EC Approval Date  
--Required--

\*IRB/EC Expiration Date  
--Required--

\*Institutional IRB/EC Number  
--Required--

\*IRB/EC Approval Document [Attach file](#)

Regulatory Authorization [Attach file](#)

Regulatory Approval Type  
--- Select One ---

Regulatory Approval Date  
--Required--

Regulatory Authorization IND/EudraCT Number  
--Required--

\*Public Database Registration Number  
--Required--

\*Registration Posted Date  
--Required--

\*Location of Registration  
--Required--

+ Add Regulatory Update

# 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

1

2

2a

2b

1 Milestone Update Due

Start New

Last Login - 26 Mar 2...

- >  Application
- ∨  Project Management
- ∨  Project Status Updates
  - Milestone Updates
  - Product Management
  - Invoices
  - Publications
  - Regulatory Update
- >  Personnel
- Amendments

Milestone Updates

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	Target Enrollment	Last Reported Enrollment	Updated Number of Subjects

+ Add No Change Milestone Update + Add Milestone Update

← Attachments Invoices →

# 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'**

**Milestone Updates**  
Please provide any updates to your planned publications at this time as well. When complete, then navigate to Actions and choose 'Provide Project Update' to submit your Project Status Update.

Expand rows [>] to see detailed information.

Entry Date	Target Enrollment	Last Reported Enrollment	Updated Number of Subjects
08 Nov 2022	100	0	

\*Target Enrollment: 100  
Last Reported Enrollment: 0  
Number of Evaluable Subjects Enroll...: 0  
Updated Number of Active Subjects on ...:

Milestone	Current Plan Date	Updated Plan Date	Actual
Date First Patient is Enrolled	01 Nov 2022		<input type="checkbox"/>
Date Enrollment is Complete	01 Nov 2023		<input type="checkbox"/>
Date First Patient Visit is Complete	01 Nov 2023		<input type="checkbox"/>
Date all Patient Visits are Complete	01 Nov 2024		<input type="checkbox"/>
Final Deliverable Received Date	31 Mar 2025		<input type="checkbox"/>

\*Have any SAEs occurred since your last update?  
--- Select One ---

If Yes, I confirm the SAE has been reported to the company  
--- Select One ---

Study Progress

**Actions** menu:  
Save  
Copy Record  
Print  
Provide Project Update  
Create Amendment  
Request Cancellation

# 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, use 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

Expand rows [D] to see detailed information.

Entry Date	Milestone Reached	Payment Amount - loc...	Status	Paid Am...
23 Mar 2026	---		Submitted	

Milestone Reached 1

Payment Amount - local currency 2

Attach Invoice, If Required 3

This check box is not used and can be left blank. 4

Comments from Approver to Submitter

Comments

Status 6

Decision Date

Paid Amount

Paid Date [empty]

Reference [empty]

**Actions**

Save 5b

View Changes

Copy Record

Print

Run Debarment Check

Needs Meeting

Provide Project Update 5a

Create Amendment

Request Project Closure Info

Place On Hold

Request Study Cancellation

Terminate

Generate DV Document(s)

Retrieve DV Document Info

Delegate My Role

Start Publication Review

View All Feedback

History

Workflow Execution Log

Delete

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'

1 of 8 ▾

Applicant Active Project 27 Mar 2021

2 Actions ▾

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

Planned Publications

Journal/Congress	Publication Type	Anticipated
New England Journal of Medicine	Manuscript	01 Mar 2022

1 Actual Publications

Expand rows [ > ] to see detailed information.

Entry ...	Journal/Congress	Publication Type	Publication Date	Status
<a href="#">+ Add Journal/Congress</a>				

# 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'**

The top screenshot shows the 'General Information' page for an active project. The 'Actions' menu is open, and 'Create Amendment' is highlighted. The 'Submission Type' is set to 'Protocol'.

The bottom screenshot shows the 'Amendments' page. The 'Actions' menu is open, and 'Submit Amendment' is highlighted. The table below shows one amendment:

Amendment Number	Status	Additional Amou...	Additional Amc
#1 - 28 Mar 2021	New		

The form fields for the amendment are as follows:

- \*Description of change: --Required--
- \*Reason: -- Select One or More --
- Additional Amount Requested: [empty]
- IRB/EC Approval Date: [empty]
- \*Status: New
- Decision Date: [empty]
- Additional Amount Approved: [empty]

Total Amendment Approved: USD 0.00

# 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**

- You can access Project Closure Information requests by either:
  - Clicking the link in the notification email
  - OR
  - Clicking the **Project Closure** task on the **Welcome** panel

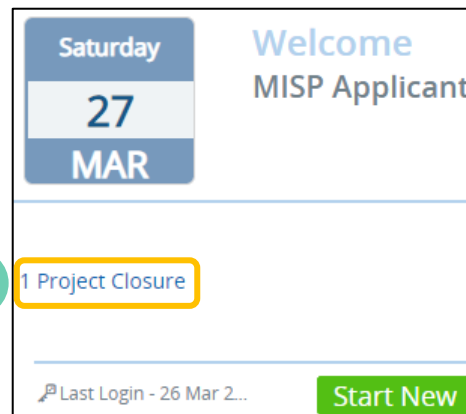
1a

Tracking Number : 110061  
 Study Title: Clinical Study Funding and Product Support  
 Investigator: MISP Applicant  
 26 Mar 2021  
 Dear MISP Applicant,  
 This communication is to inform you that your study Clinical Study Funding and Product Support requires closure information.  
 Please log into iEnvision with the web address below to provide your update.

[Link to MISP Portal](#)

1b

1 Project Closure



- 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**

- Select the **Actions** menu and then select **Submit Project Closure**

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

2

3

Submit Project Closure

# 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](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](mailto:vt_support@msd.com)



For technical support, contact the Envision Pharma Helpdesk:

US: +1860-266-4944 UK & EU: +44 1403-322095

Email: [helpdesk@envisionpharmasupport.com](mailto:helpdesk@envisionpharmasupport.com)

