



sanofi

Managed Access Programs (MAPs)

Physician

iEnvision EAP® 3.1 User Guide

Welcome to iEnvision MAPs!

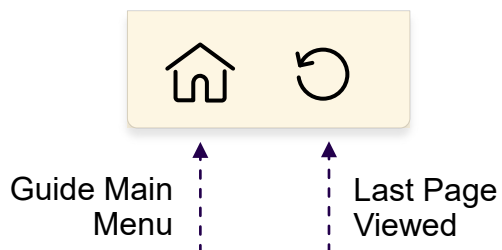
The MAPs platform serves as Sanofi's centralized tool for all MAP-related activities, designed to simplify and standardize the entire process, from the initial request creation to the final closure. By streamlining the approval process, this platform:

- ✓ Enhances compliance monitoring
- ✓ Ensures greater transparency
- ✓ Provides improved visibility of MAP initiatives across the entire Sanofi organization

This reference guide provides step-by-step instructions for tasks and activities Physicians may need to complete in the iEnvision system

USING THIS GUIDE

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



SUPPORT RESOURCES



To **access MAPs**, use the link below:
https://sanofi.envisionpharma.com/ienv_sanofi_qual/vision_tracker/portal/login.xhtml?pgm=PAA



To **request system access** or **training support**, contact a member of the Country Medical Team or email:
SanofiMAPRequests@sanofi.com



For **technical support**, contact the Envision Pharma Helpdesk
Email: helpdesk@envisionpharmasupport.com

If you are unable to access or receive email notifications from iEnvision due to firewall restrictions, please contact your Institution's IT Department to ensure the iEnvision domain/email is listed as an approved email

Guide Contents

01 | REGISTRATION AND ACCESS

- [Access MAPs](#)
- [New Account Registration](#)
- [Log in to MAPs](#)
- [Sanofi's Global Privacy Policy Agreement](#)
- [Navigation Overview](#)
- [Dashboard](#)
- [System Global Tools](#)
- [Workbench](#)
- [Locate Your Tasks on Your Workbench](#)
- [Context Bar and Menus](#)

02 | SUBMIT A NEW REQUEST

- [Migrated Records](#)
- [MAP Process Overview](#)
- [Create a New Request](#)
- [Program Selection](#)
- [Acknowledgement](#)
- [Decision Tree](#)
 - [Physician Eligibility](#)
 - [Patient Eligibility](#)
- [Request Overview](#)
- [General Information Node](#)
- [Personnel Node](#)
- [Sites Node](#)
- [Patient Details Node](#)
- [Patient Eligibility Node](#)
- [Submit the Request](#)

03 | PRIOR TO REQUEST APPROVAL

- [Additional Information Requested](#)
- [Withdraw Your Request](#)
- [Letter of Agreement \(LOA\)](#)

04 | ACTIVE REQUEST

- [Confirm Product Shipment Receipt](#)
- [Request Product Resupply or Status Update Request](#)
- [MAP Status Update Decision Tree](#)
 - [Resupply Criteria](#)
 - [Physician Criteria](#)
 - [Review Summary and Submit](#)

05 | REQUEST CLOSURE

- [Close the Request](#)
- [Support Resources](#)



01 | REGISTRATION AND ACCESS

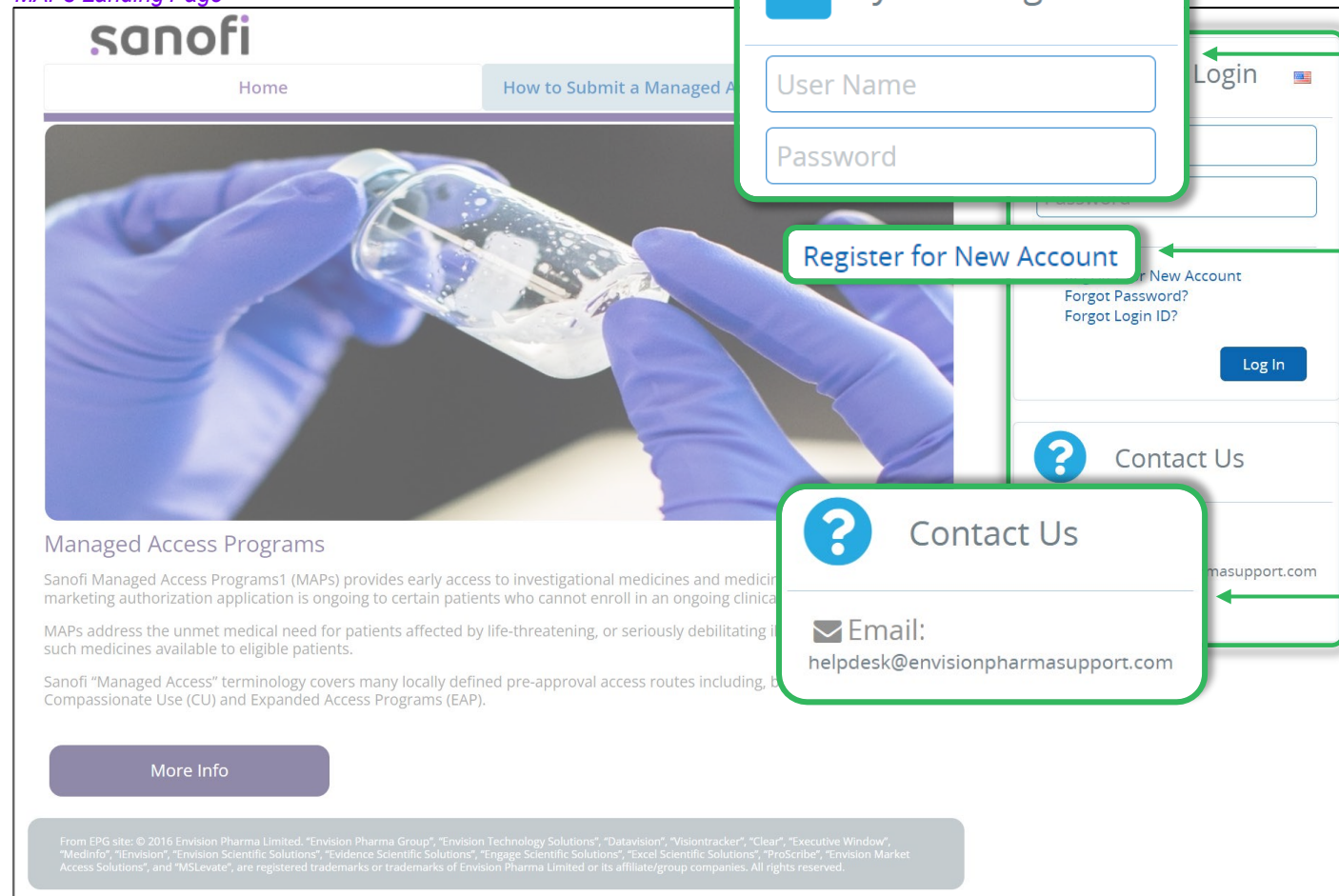
- [Access MAPs](#)
- [New Account Registration](#)
- [Log in to MAPs](#)
- [Sanofi's Global Privacy Policy Agreement](#)
- [Navigation Overview](#)
- [Dashboard](#)
- [System Global Tools](#)
- [Workbench](#)
- [Locate Your Tasks on Your Workbench](#)
- [Context Bar and Menus](#)

Access Managed Access Programs (MAPs)

For Managed Access Programs (MAPs) applications, navigate to the Sanofi MAPs landing page:

https://sanofi.envisionpharma.com/ienv_sanofi_qual/visiontracker/portal/login.xhtml?pgm=PAA

MAPs Landing Page



The screenshot shows the Sanofi MAPs Landing Page. The page features the Sanofi logo at the top left, a navigation bar with 'Home' and 'How to Submit a Managed Access Program', and a large image of a hand holding a vial. Below the image is the 'Managed Access Programs' section, which includes text about early access to investigational medicines and a 'More Info' button. On the right side of the page, there are three main sections: 'System Login', 'Register for New Account', and 'Contact Us'. Each section is highlighted with a green box and a callout line pointing to it. The 'System Login' box contains fields for 'User Name' and 'Password', and a 'Log In' button. The 'Register for New Account' box contains a link to 'Register for New Account'. The 'Contact Us' box contains an email address: 'helpdesk@envisionpharmasupport.com'.

APPLICANTS ALREADY HAVING ACCESS

Log into the Sanofi MAPs 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

HELPDESK SUPPORT

Support for login and technical inquiries

New Account Registration

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

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 MAPs Landing Page
2. On the Register for a New Account pop-up window, enter your **Email Address** and then click **Send** to open the **User Registration Form**

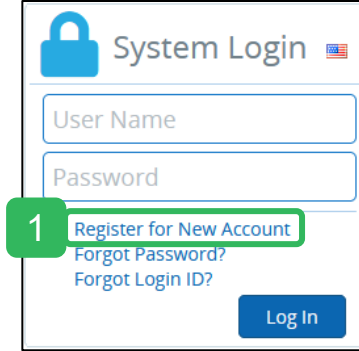
Note: Using an official organizational email address is preferred

3. Complete the **User Registration** form including:
 - a. All required fields marked with an asterisk (*), ie, **First Name**, **Last Name**, **Email Address**, and **Confirm Email**
 - b. Create a **Password** with a minimum of eight characters including at least one lowercase and one uppercase letter
 - c. Select two **Security Questions** from the respective drop-down menus and fill in their respective **Answer**
 - d. Check the **I agree to the Terms and Conditions** 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.

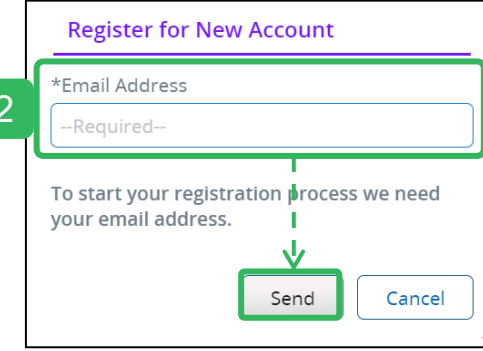
Supported Web Browsers: Google Chrome, Microsoft Edge, Apple Safari, Mozilla Firefox

MAPs System Login Screen



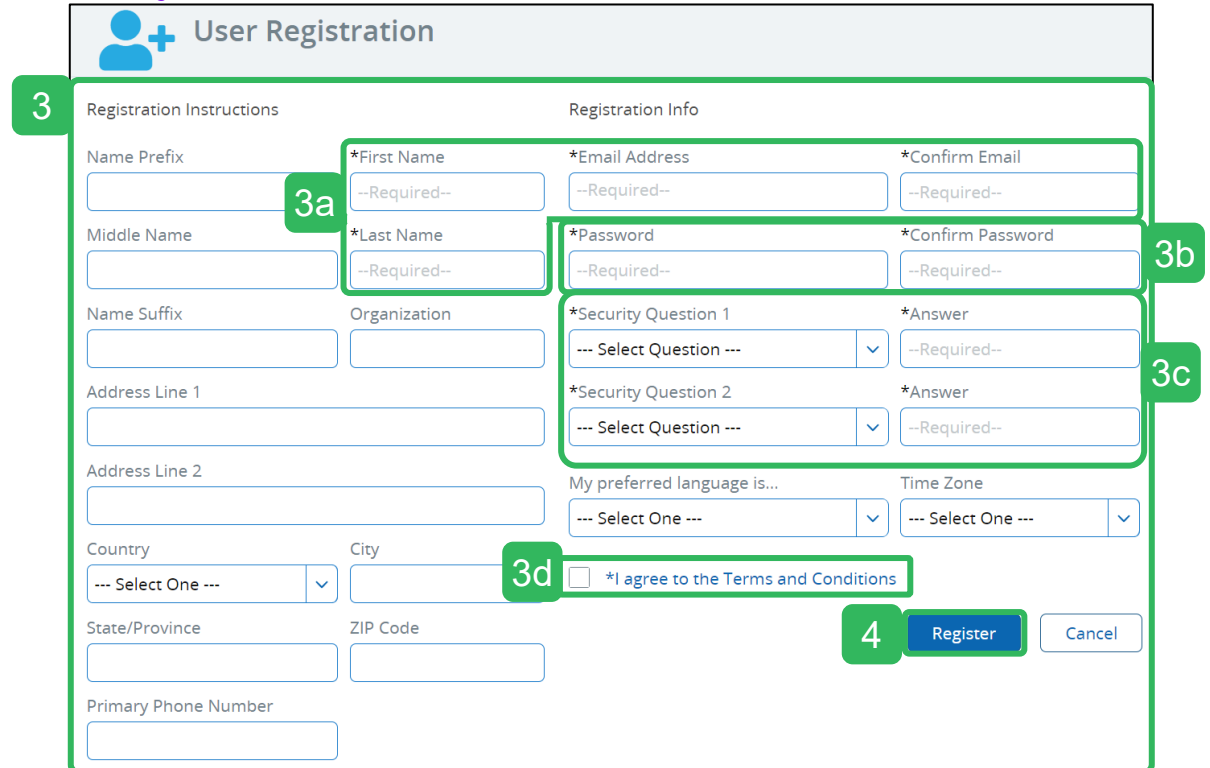
The login screen features a blue padlock icon and the text "System Login" with a small US flag. Below are input fields for "User Name" and "Password". A blue "Log In" button is at the bottom right. A green box labeled "1" highlights the "Register for New Account" link, which also includes links for "Forgot Password?" and "Forgot Login ID?".

Register for New Account Pop-Up Window



The pop-up window is titled "Register for New Account". It contains a text input field for "*Email Address" with a placeholder "--Required--". Below the field is the text "To start your registration process we need your email address." and a green "Send" button. A green box labeled "2" highlights the email address field. A "Cancel" button is at the bottom right.

User Registration Form



The registration form is titled "User Registration" and is divided into two main sections: "Registration Instructions" and "Registration Info".

Registration Instructions:

- Name Prefix (text input)
- Middle Name (text input)
- Name Suffix (text input)
- Address Line 1 (text input)
- Address Line 2 (text input)
- Country (dropdown menu)
- City (text input)
- State/Province (text input)
- ZIP Code (text input)
- Primary Phone Number (text input)

Registration Info:

- *First Name (text input, marked 3a)
- *Last Name (text input)
- *Email Address (text input, marked 3b)
- *Confirm Email (text input)
- *Password (text input, marked 3b)
- *Confirm Password (text input, marked 3b)
- *Security Question 1 (dropdown menu, marked 3c)
- *Answer (text input, marked 3c)
- *Security Question 2 (dropdown menu, marked 3c)
- *Answer (text input, marked 3c)
- My preferred language is... (dropdown menu)
- Time Zone (dropdown menu)
- *I agree to the Terms and Conditions (checkbox, marked 3d)

A green box labeled "4" highlights the "Register" button at the bottom right.

Log in to MAPs



Newly registered and returning applicants, log in to the system from the [Sanofi MAPs 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**)
Note: First-time users will need to answer two security questions as selected on the [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

MAPs System Login Screen

The screenshot shows the 'System Login' interface. At the top, there is a blue padlock icon and the text 'System Login' with a small US flag. Below this, there are two input fields: 'User Name' (callout 1) and 'Password' (callout 2). Below the password field, there are three links: 'Register for New Account', 'Forgot Password?', and 'Forgot Login ID?' (callout 4). At the bottom right, there is a blue 'Log In' button (callout 3).

Sanofi's Global Privacy Policy Agreement

When you first login to Sanofi MAPs, **Sanofi's Global Privacy Policy Agreement** will appear. You must read the statement and agree to it before being granted access to the MAPs system.

1. Click **Agree** to proceed and enter the system

Note: If you click **Disagree**, you will automatically be logged out and taken back to the login screen. If you login again, **you will not be able to continue past Sanofi's Global Privacy Policy Agreement unless you select Agree.**

Sanofi's Global Privacy Policy Statement

GDPR

Agreement

Physician Privacy Notice

Sanofi will collect and process or will have collected and processed certain identifying information about you, and, if needed, about the authorized signatory for the contract mentioned below ("**Personal Data**"). Such collection and processing are necessary to **(1) respond to your request** for the supply of a product under a Managed Access Program (MAP) of Sanofi (your Personal Data, and, if needed, that of the authorized signatory for the contract is then processed on the basis of the legitimate interests of Sanofi) and, if your request is approved, to **(2) establish a contract governing such supply** (your Personal Data and, if needed, that of the authorized signatory for the contract is then processed to prepare and perform this contract as, without such relevant Personal Data, this contract cannot be established and the supply of a product requested cannot occur) and to **(3) execute the MAP for its full duration** (in which case your Personal Data, and, if needed, that of the authorized signatory for the contract is then processed on the basis of performing the contract signed with Sanofi for the supply of the product. Throughout the duration of a MAP, Sanofi may collect and process your Personal Data which you would share when reporting safety information (if any), in order to **(4) comply with Sanofi's legal obligations** in this respect.

Personal Data collected for the above purposes will be processed, directly or on behalf of either (a) Sanofi Winthrop Industrie or (b) Sanofi-Aventis Recherche & Développement, located at 82 avenue Raspail, 94250, Gentilly, France and (c) as may be needed, local Sanofi affiliates responsible for the assessment of your request. Sanofi, its affiliates or service providers may access your data in order to manage the reporting of safety information, the assessment of your request and/or the supply of the product requested.

Personal Data collected will be processed and retained for a period of time sufficient to meet the four purposes listed above, in a confidential and secure way.

(1) Personal Data processed to respond to your supply request will be deleted 5 years after the closure of the relevant MAP in your country. Even if your request is not accepted, Sanofi must hold the data as it may be requested during a Health Authority inspection.

(2) Personal Data processed to establish a contract for the supply of the requested product will be deleted 10 years after the closure of the MAP in your country.

1

Agree

Disagree

Navigation Overview

When you login to MAPS as a Physician, the **EAP Applicant Dashboard** will be your default landing page allowing access to:

1. **Browser Buttons:** Use the back/forward buttons on your browser to move to/from a previous screen
2. **Navigation Menu:** Locate and access features that are available to you, such as your **Workbench**
3. **Global Tools:** Access your system support, bookmarks, notifications, and your user profile
4. **Navigation Trail:** See your current location within MAPs and how you got there
5. **Context Bar and Menus:** View your current screen location as well as access and progress your tasks
6. **Widgets:** Access specific information displayed in each one

The screenshot shows the Sanofi MAPs Dashboard interface. A green dashed line with numbered callouts (1-6) points to specific navigation elements:

- 1:** Browser navigation buttons (back, forward, home, search).
- 2:** A floating navigation menu containing 'Dashboard' and 'Workbench' options.
- 3:** Global tools icons (help, bookmarks, notifications, user profile, and a circular menu).
- 4:** The navigation trail showing the path 'Dashboard > EAP Applicant'.
- 5:** The context bar at the top of the main content area, displaying 'EAP Applicant' and buttons for 'Open' and 'Set as Default'.
- 6:** The main content area (widgets) which includes a date widget (Wednesday 18 SEP), a 'Welcome Physician' message, a 'Recent' table of applications, and a 'Start New' button.

Recent Applications Table:

Tracking Number	Program Name	Product	Status Group
24-MAP-000270	Test 8	OLIPUDASE ALFA [GZ402665]	Incomplete
TEMP-001266		OLIPUDASE ALFA [GZ402665]	Incomplete
TEMP-001261		CLOFARABINE [GZ393590]	Incomplete

Dashboard



The **Dashboard** is broken into specific widgets based on your system role including:

1. **Welcome:** View and open your current tasks
 - a. Click **Start New** to create a new Application
2. **Recent Documents:** Displays the last 20 records that you accessed; click any document to open it
3. Use the **Set as Default** button to make this your default landing page

EAP Applicant Dashboard

sanofi Expanded Access Program Portal

Dashboard > EAP Applicant

EAP Applicant

Open Set as Default

1

Wednesday 18 SEP

Welcome Physician

3 Incomplete Applications
1 Additional Information Requested
3 All My Requests

Last Login - 18 S 1a Start New

2

Recent

Tracking Number	Program Name	Product	Status Group
24-MAP-000270	Test 8	OLIPUDASE ALFA [GZ402665]	Incomplete
TEMP-001266		OLIPUDASE ALFA [GZ402665]	Incomplete
TEMP-001261		CLOFARABINE [GZ393590]	Incomplete

3

System Global Tools



Global Tools* display at the top right-hand corner of every screen and provide quick access to system support, bookmarks, notifications, and your user profile. Further details for each tool include:

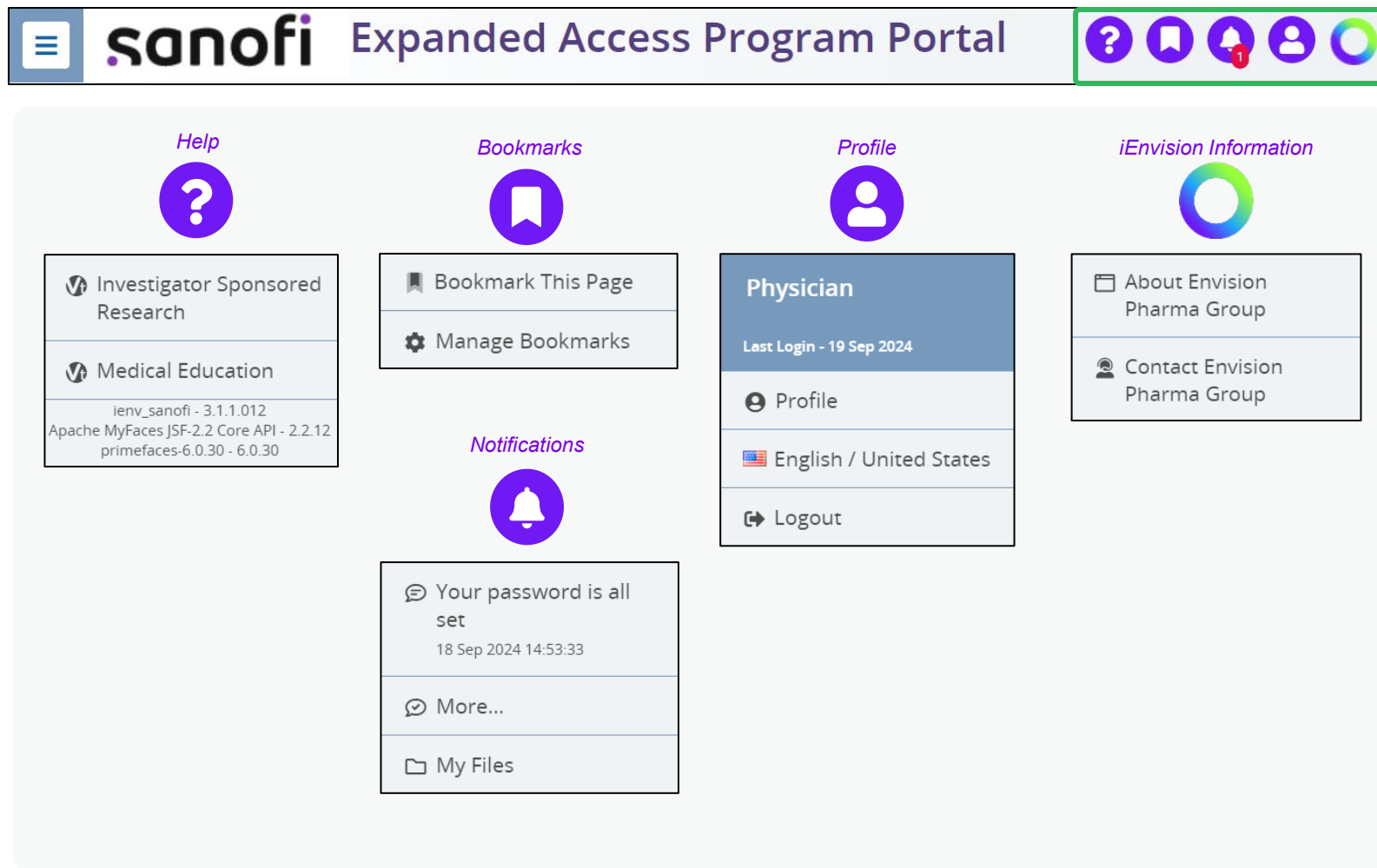
 **Help:** View a list of Frequently Asked Questions (FAQ), support documentation, and your current iEnvision version

 **Bookmarks:** Bookmark your current page and access and manage any saved iEnvision pages including **Dashboards** or **Workbenches**. This option is non-applicable to the Physician role.

 **Notifications:** View your system notifications including task requests and record updates

 **Profile:** Click **Profile** to update your local **Time Zone** and other information, preferred country and language, and **Logout**

 **iEnvision Information:** Learn more about the Envision Pharma Group and contact technical support



The screenshot shows the Sanofi Expanded Access Program Portal with a top navigation bar. On the right side of the bar, there is a 'Global Tools' menu highlighted with a green border, containing icons for Help, Bookmarks, Notifications, Profile, and iEnvision Information. Below the navigation bar, the main content area is divided into five sections:

- Help:** Includes links for 'Investigator Sponsored Research' and 'Medical Education', and displays system versions: 'ienv_sanofi - 3.1.1.012', 'Apache MyFaces JSF-2.2 Core API - 2.2.12', and 'primefaces-6.0.30 - 6.0.30'.
- Bookmarks:** Includes 'Bookmark This Page' and 'Manage Bookmarks'.
- Notifications:** Displays a notification: 'Your password is all set' dated '18 Sep 2024 14:53:33', along with 'More...' and 'My Files' links.
- Profile:** Shows the user role as 'Physician', 'Last Login - 19 Sep 2024', and options for 'Profile', 'English / United States', and 'Logout'.
- iEnvision Information:** Includes 'About Envision Pharma Group' and 'Contact Envision Pharma Group'.

*The content displayed within each of the Global Tools depends upon your role and system access and may not directly match the above screenshots

Your **Workbench** provides a high-level summary of your request records. The records are organized into groups based on the activity type (known as Task Groups).

To view your **Workbench** tasks:

1. From the **Navigation** menu, select **Workbench**
2. The active task group and total number of documents in the group are displayed on the **Context Bar**. Click the icon to search within the active task group.
3. Click the task card of a specific record to display a high-level summary on the right-hand side of the screen
4. Click the icon menu on record to open the record or to initiate document-related activities
5. The **View** menu enables you to change the layout of the display, sort your tasks by a specific status, and make this page your default page

Navigation Menu

Workbench – Additional Information Requested Task Group

Workbench > Expanded Access Program

24-MAP-000270

Physician, OE

Named Patient Program

Incomplete

Project Type: Named Patient Program

Therapeutic Area: Immunology

*Requested Indication: Acid Sphingomyelinase Deficiency (ASMD)

*Requested Product: OLIPUDASE ALFA [GZ402665]

Coordinator Comments: [empty]

Attachments:

Type	File Name	Posted Date
paa_researchrequest...	CV.docx	04 Oct 2024
paa_researchrequest...	CV.docx	04 Oct 2024

Open Details

Print

Submit Additional Information

Withdraw

Page Layout

Sort By

Make this my default

Open

View

Actions

Locate Your Tasks on Your Workbench

The active task group and number of documents in that group are listed on the **Context Bar** on your **Workbench**

1. In the example to the right, the **Additional Information Requested** task group is the active task group with one record
2. To change the task group, click the **Open** menu and then select one of the available options

Workbench

Workbench > Expanded Access Program

Additional Information Requested: 1 of 1 **1** **Open** View Actions

24-MAP-000270

 Physician, OE Incomplete

Named Patient Program

Project Type: Named Patient Program

Therapeutic Area: Immunology

*Requested Indication: Acid Sphingomyelinase Deficiency (ASMD)

*Requested Product: OLIPUDASE ALFA [GZ402665]

Coordinator Comments: [empty] [View All](#)

Attachments: [View All](#)

Type	File Name	Posted Date
paa_researchrequest....	CV.docx	04 Oct 2024 
paa_researchrequest....	CV.docx	04 Oct 2024 

Expanded Access Program

- Incomplete Applications [2]
- ✓ Additional Information Requested [1]

Context Bar and Menus

The **Context menus** on the **Context Bar** have varying availability and functionality based on your location in the system. The example below shows the **Context Bar** on the **Workbench**.

The general use of each **Context Menu** is described below:

1. **Open**: Use to open available task groups
2. **View**: Toggle between different views
3. **Actions**: Lists actions available based on your role and location in the system

Context Bar on the Workbench

Workbench > Expanded Access Program

Additional Information Requested: 1 of 1 ⁱ

24-MAP-000270 

 Physician, OE

Incomplete

Named Patient Program

Project Type

Named Patient Program

Therapeutic Area

Immunology

*Requested Indication

Acid Sphingomyelinase Deficiency (ASMD)

*Requested Product

OLIPUDASE ALFA [GZ402665]

1 10



02 | SUBMIT A NEW REQUEST

- [Migrated Records](#)
- [MAP Process Overview](#)
- [Create a New Request](#)
- [Program Selection](#)
- [Acknowledgement](#)
- [Decision Tree](#)
 - [Physician Eligibility](#)
 - [Patient Eligibility](#)
- [Request Overview](#)
- [General Information Node](#)
- [Personnel Node](#)
- [Sites Node](#)
- [Patient Details Node](#)
- [Patient Eligibility Node](#)
- [Submit the Request](#)

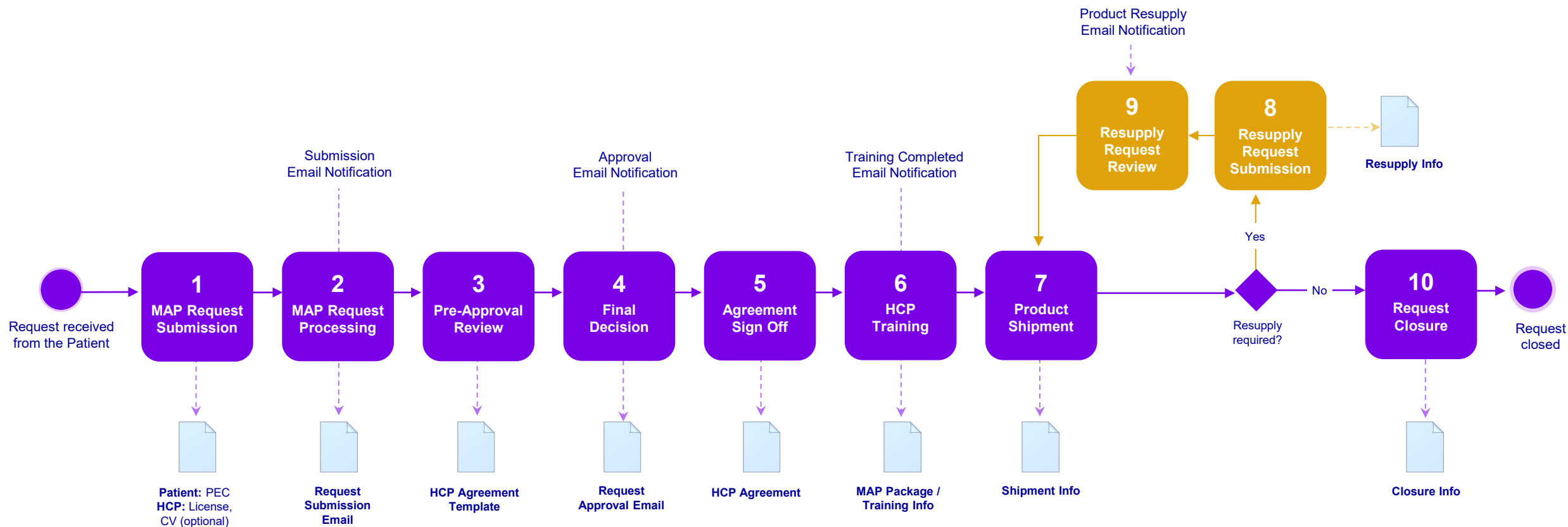
Migrated Records

If you already have a MAP patient application submitted through Clinigen Direct or Sanofi SmartSheet, you will see these patient applications migrated to iEnvision and visible on your **Dashboard Welcome** widget and **Workbench** under the **All My Requests** task group after logging in to the system

- Applications submitted or under review on or before January 10, 2025 will be migrated in March 2025
- It is recommended that you review the **Personnel** and **Site** nodes on your migrated records and update and complete the information, as necessary
- You will notice some blank fields on the other nodes, such as, **Patient Details** and **General Information**. You do not need to complete these fields.
- If you need to submit a status update for a migrated record, please refer to the steps on [Request Product Resupply or Status Update Request](#) and [Close the Request](#)

MAP Process Overview

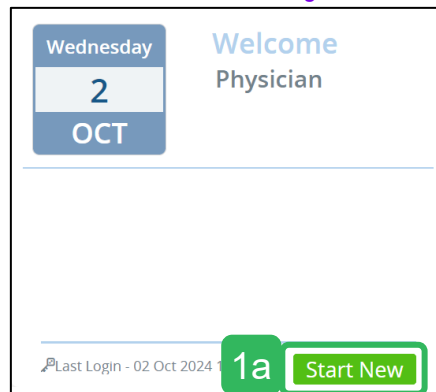
Below is an overview of the MAP process



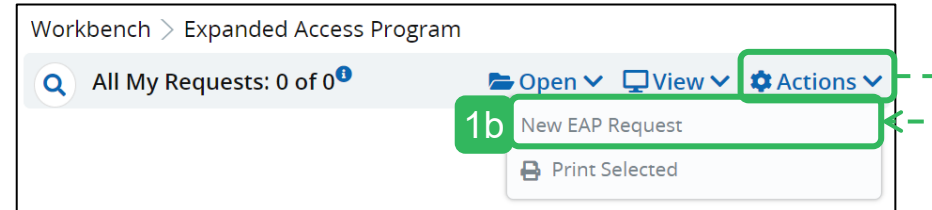
Create a New Request

- You can start a new MAP's EAP request from either your **Dashboard** or **Workbench**:
 - From your Dashboard**
On the **Welcome** widget of your **Dashboard**, click the **Start New** button
 - From your Workbench**
Click the **Actions** menu on your **Workbench** and select **New EAP Request**
- Regardless of which path you use to start your request, the **New Application Decision Tree** will open to show the first section of the request, **Product and Country**
- To complete the **Product and Country** section:
 - Select the investigational drug from the **Requested Product** drop-down menu
 - If you have another product, enter the text in the **If other product, please specify** field
 - Select the **Country** where the product is needed from the drop-down menu
 - Click **Next** to continue
- The **Review Summary** window will open; verify your **Product and Country** selections are correct
 - Click **Finish** if you are happy with your selections
 - Use the **Back** button to return to the **Product and Country** section if you need to alter your selections

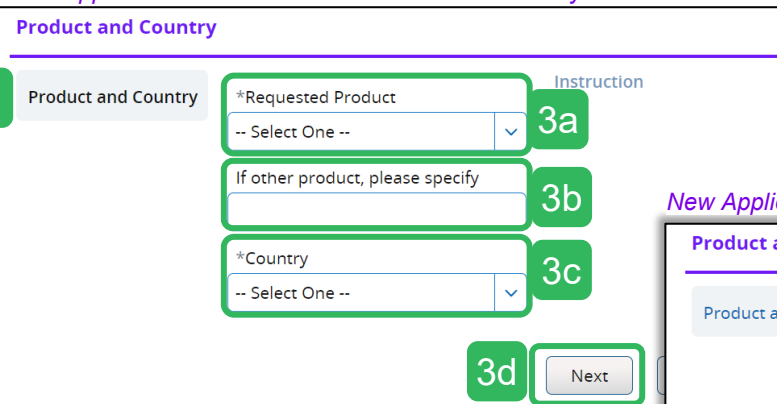
Dashboard – Welcome Widget



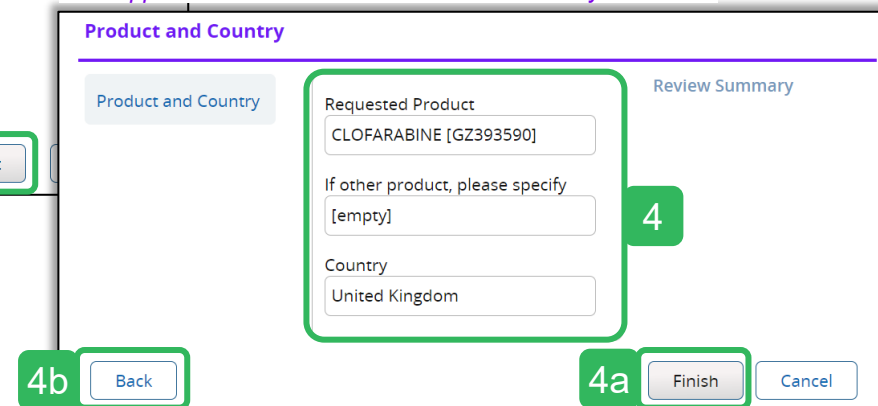
Workbench



New Application Decision Tree – Product and Country



New Application Decision Tree – Review Summary



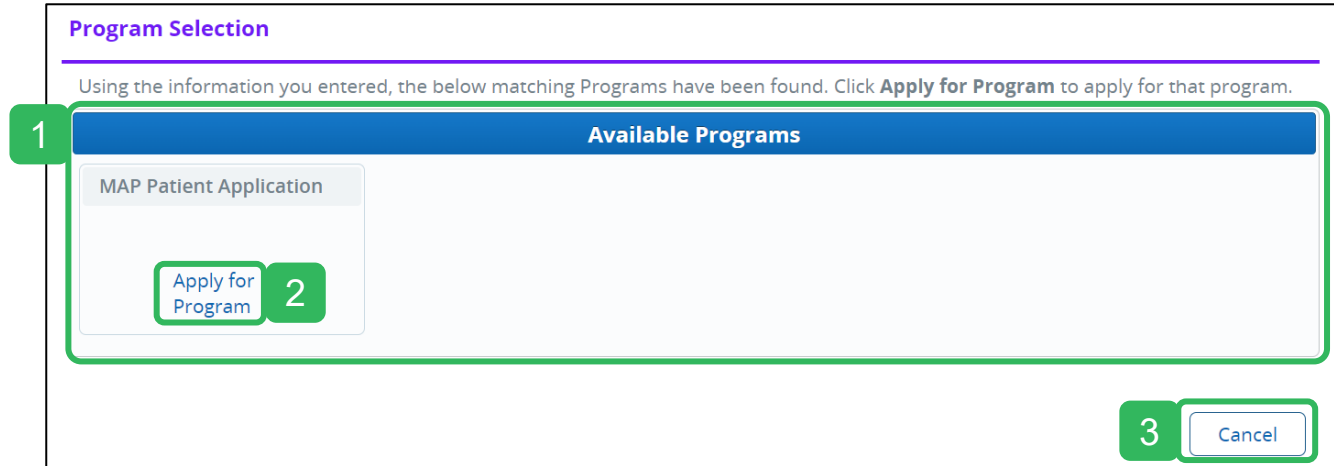
Program Selection

The next screen details the available Programs based on your previous **Product and Country** selections

To select your **Program**:

1. A collection of tiles for the **Available Programs** will appear in the box at the top of the screen based on the selections you have made on the [Decision Tree of the new EAP Request](#)
2. Click the blue **Apply for Program** link on the Program you would like to select
3. Click the **Cancel** button if none of the selections are applicable or to delete the request

Program Selection Window



The screenshot shows a 'Program Selection' window. At the top, a blue header bar contains the text 'Available Programs'. Below this, a light gray box displays 'MAP Patient Application'. Inside this box, there is a blue button labeled 'Apply for Program' and a green square with the number '2'. A green line highlights the entire 'Available Programs' section, with a green square containing the number '1' to its left. At the bottom right of the window, there is a green square with the number '3' next to a 'Cancel' button.

Program Selection

Using the information you entered, the below matching Programs have been found. Click **Apply for Program** to apply for that program.

Available Programs

MAP Patient Application

Apply for Program 2

3 Cancel

Acknowledgement



After you have selected the program to apply to, you will be required to accept the **Acknowledgement**

1. Review the statement
2. Check the **Acknowledged** box to confirm agreement and continue the application process

Acknowledgement

Dashboard > EAP Applicant > Acknowledgement (New Application)

Named Patient ... TEMP-001261 1 of 1 Physician Incomplete 02 Oct 2024 Save Actions

☒ Acknowledgement

☐ General Information

☐ Personnel

☐ Requesting Physician

☐ Sites

☐ Drug Shipment

☐ Patient Information

☐ Patient Details

☒ Patient Eligibility

☐ Resupply or Status Update Re...

☐ Physician Eligibility

☐ Documentation

☐ Regulatory

☐ General Attachments

1 **Acknowledgement**

Managed Access Request (MAP) - Principles and Conditions

In submitting this request, you acknowledge and consent to the following principles and agree to comply with the following conditions:

- Sanofi's processing of requests does not guarantee that access to the requested product will be provided, as this is dependent on the eligibility criteria set out as per Sanofi's standards, as well as on applicable local regulations. Patient eligibility is determined by Sanofi in accordance with Sanofi's established policies and procedures, including any local requirements, with requests considered on a case-by-case basis.
- You will provide timely response to all requests from Sanofi for additional information required to support your submitted request. Submitted requests will remain open for 30 calendar days at which time if requested additional information has not been provided to Sanofi, the request will be closed and you will be required to submit a new MAP request, if needed.
- Sanofi's Managed Access Programs are a temporary pathway and upon authorization of the requested product for the request use in your country, if treatment continuation is necessary, your patient is expected to transfer to a sustainable local access pathway as per local regulations and requirements.
- Sanofi reserves the right to review the conditions for the supply of the product at any time and in specific circumstances treatment may be discontinued.

The death of a Patient treated by a Sanofi product is also considered PV data and must also be reported to Sanofi.

"Product Complaint" shall mean any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, efficacy or performance of a product after it is released for distribution.

[MAP Patient Privacy Notice](#)

☒ *Acknowledged **2**

[General Information](#)

Decision Tree – Physician Eligibility

The **Physician Eligibility** decision tree section will open

1. Answer the questions using the drop-down menu options
2. Click **Next** to continue
3. The **Review Summary** window will appear allowing you to ensure that the selections you made are correct
 - a. Click **Finish** if you are happy with your selections
 - b. Use the **Back** button to return to the previous screen and alter your selections

New Application Decision Tree – Physician Eligibility

Physician Eligibility

1

*I confirm that I am a medically qualified and licensed physician in the country of request and the patient for whom I am filling the present request is currently under my care.

-- Select One --

*I confirm that the application will be completed accurately with the available information. ⓘ

-- Select One --

Instruction

As the licensed physician, you must confirm the eligibility criteria to be considered for approval.

You must understand Sanofi criteria for Managed Access Programs.

Together with patient, you must discuss and understand any potential risks associated with the treatment for this specific patient.

2

Next

Cancel

New Application Decision Tree – Review Summary

Physician Eligibility

3

I confirm that I am a medically qualified and licensed physician in the country of request and the patient for whom I am filling the present request is currently under my care.

Yes

I confirm that the application will be completed accurately with the available information.

Yes

Review Summary

Back

3b

3a

Finish

Cancel

Decision Tree – Patient Eligibility

The **Patient Eligibility** decision tree section will open

1. On the **General Patient Criteria** section, answer the questions using the drop-down menu options
2. Click **Next** to continue
3. The **Review Summary** window will appear allowing you to ensure that the selections you made are correct
 - a. Click **Finish** if you are happy with your selections
 - b. Click the **Back** button to return to the previous screen and alter your selections

New Application Decision Tree – Patient Eligibility

Patient Eligibility

General Patient Criteria

1

*Patient is affected by life-threatening or seriously debilitating illness, disease or condition.
-- Select One --

*Patient is not able to access the product for the requested use because it is either not yet authorized, or it is not commercially available in the patient's primary residence.
-- Select One --

*Patient has exhausted any other approved and/or satisfactory alternative treatment options (unmet medical need).
-- Select One --

*Patient is not currently receiving, or has not previously received treatment with the requested product.
-- Select One --

*Patient is not currently enrolled in a Sanofi sponsored trial. (note: for patients exiting a Sanofi sponsored trial, please refer to <https://www.sanofi.com/en/your-health/healthcare-professional-support/post-trial-access>)
-- Select One --

*Patient cannot enroll in any trial.
-- Select One --

*There is a favorable benefit risk profile for the requested use for this patient based on the most current scientific data available.
-- Select One --

Instruction

All of the information which is collected is necessary to process your request.

As the licensed physician, you have consulted with the patient to explore available alternate approved treatment options and clinical trials to determine whether this Managed Access Program is the only option.

The patient must meet all eligibility criteria to be considered. Please answer all criteria accurately by responding with "agree" or "disagree" to validate or invalidate the following statements, based on the knowledge you have to date.

2

Next **Cancel**

New Application Decision Tree – Review Summary

Patient Eligibility

General Patient Criteria

3

Patient is affected by life-threatening or seriously debilitating illness, disease or condition.
I Agree

Patient is not able to access the product for the requested use because it is either not yet authorized, or it is not commercially available in the patient's primary residence.
I Agree

Patient has exhausted any other approved and/or satisfactory alternative treatment options (unmet medical need).
I Agree

Review Summary

3a

Finish **Cancel**

3b

Back

Request Overview

Below is an overview of the parts of a Request

CONTEXT BAR

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

Note: The **TEMP** number will be replaced by the **Request ID Number** once it is submitted

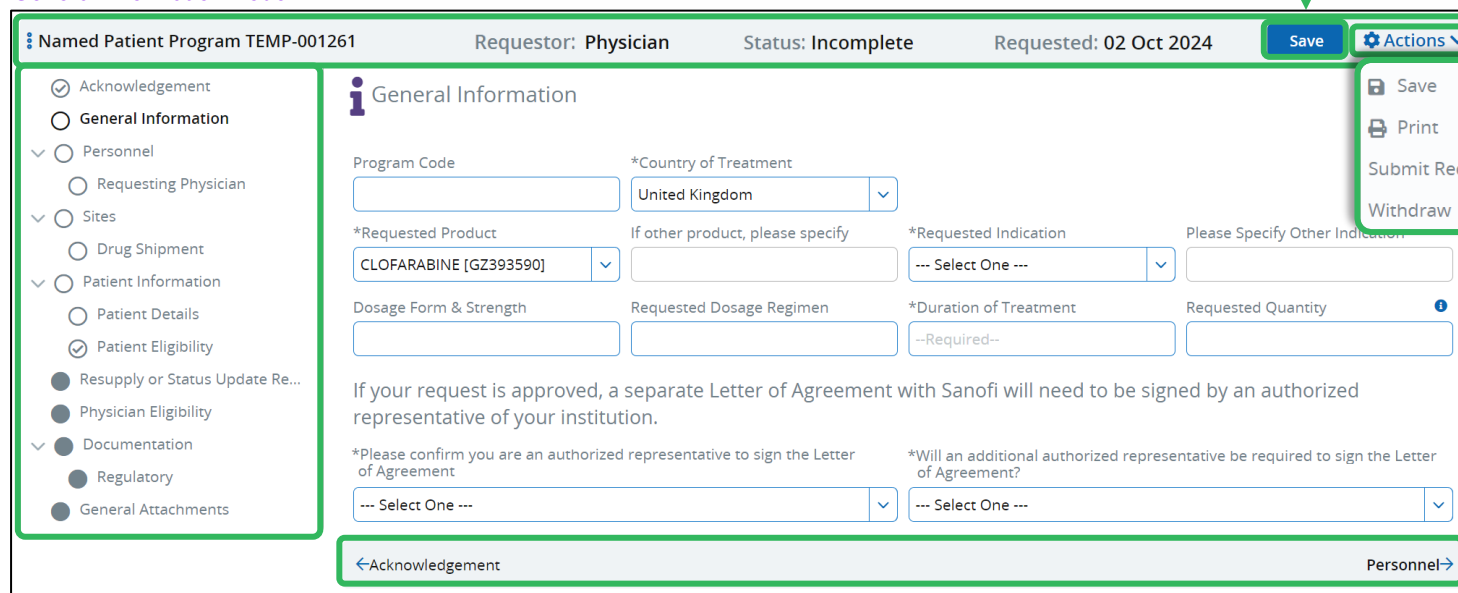
TABLE OF CONTENTS

The **Table of Contents** lists the nodes (sections) that make up a request. The node you are on appears in **bold**. Additional nodes become available as the application progresses. You will need to fill in the required fields in order to submit the application.

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 request

General Information Node



The screenshot shows the 'General Information Node' of a request form. At the top, a 'Context Bar' displays: 'Named Patient Program TEMP-001261', 'Requestor: Physician', 'Status: Incomplete', and 'Requested: 02 Oct 2024'. To the right of the status are 'Save' and 'Actions' buttons. The 'Actions' dropdown menu is open, showing options: 'Save', 'Print', 'Submit Request', and 'Withdraw'. On the left, a 'Table of Contents' sidebar lists nodes: 'Acknowledgement' (checked), 'General Information' (bold), 'Personnel' (expanded), 'Sites' (expanded), 'Patient Information' (expanded), 'Patient Details', 'Patient Eligibility' (checked), 'Resupply or Status Update Re...', 'Physician Eligibility', 'Documentation' (expanded), 'Regulatory', and 'General Attachments'. The main form area is titled 'General Information' and contains fields for: 'Program Code', '*Country of Treatment' (United Kingdom), '*Requested Product' (CLOFARABINE [GZ393590]), 'If other product, please specify', '*Requested Indication' (--- Select One ---), 'Please Specify Other Indication', 'Dosage Form & Strength', 'Requested Dosage Regimen', '*Duration of Treatment' (--Required--), and 'Requested Quantity'. Below these fields is a note: 'If your request is approved, a separate Letter of Agreement with Sanofi will need to be signed by an authorized representative of your institution.' At the bottom, there are two confirmation questions: '*Please confirm you are an authorized representative to sign the Letter of Agreement' and '*Will an additional authorized representative be required to sign the Letter of Agreement?', both with '--- Select One ---' dropdowns. At the very bottom, navigation buttons for '< Acknowledgement' and 'Personnel >' are visible.

SAVE BUTTON

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

ACTIONS MENU

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

NAVIGATION BAR

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 (*)

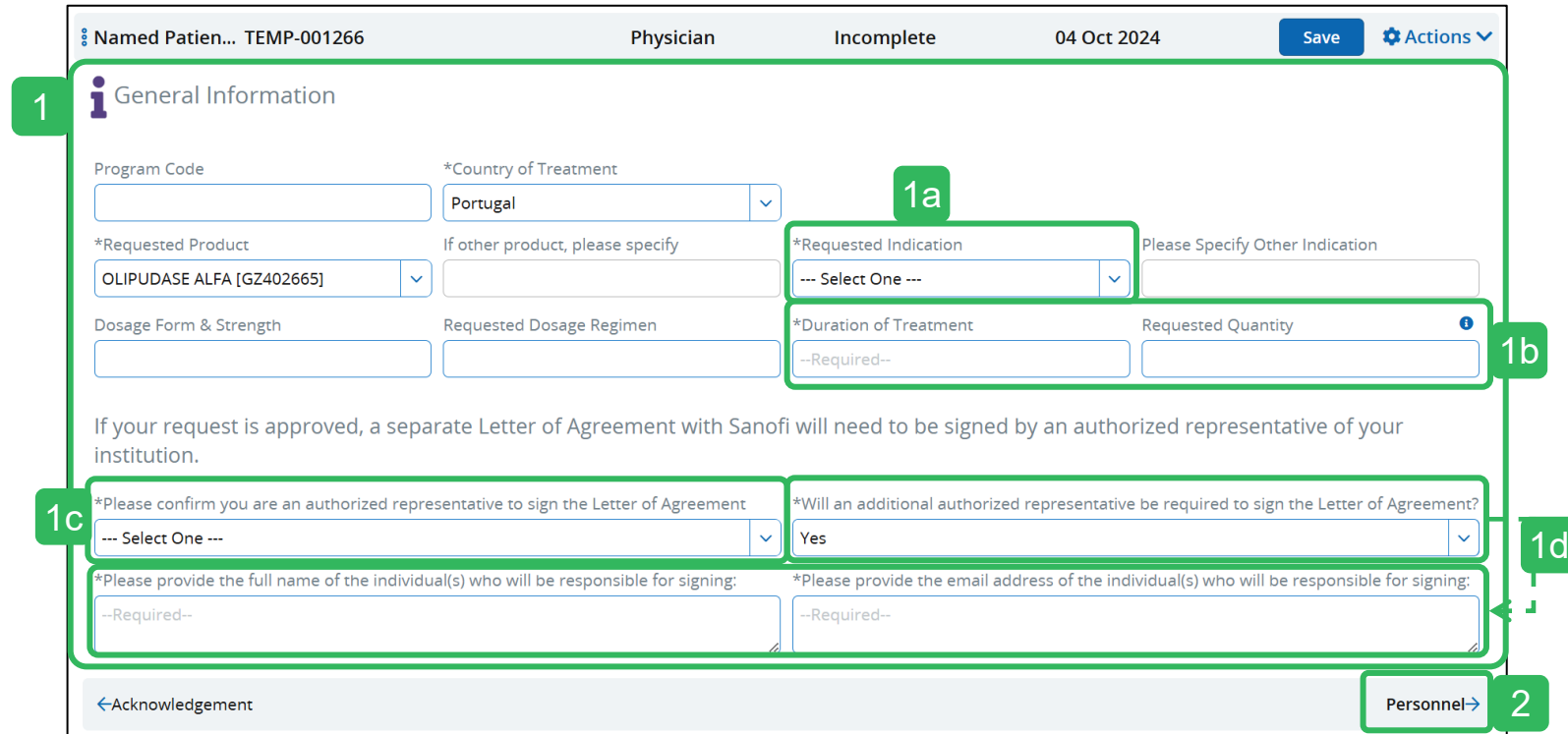
General Information Node

The **General Information** node is the next 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 (*)
 - a. **Requested Indication**
 - b. **Duration of Treatment**
 - c. **Please confirm you are an authorized representative to sign the Letter of Agreement**
 - d. **Will an additional authorized representative be required to sign the [Letter of Agreement](#)?**
 - If your answer to this question is **Yes**, two additional fields will appear: **Please Provide the full name of the individual(s) who will be authorized for signing** and **Please provide the email address of the individual(s) who will be authorized for signing**. Enter the required names and email addresses in the appropriate boxes.

2. When all mandatory fields are completed, click **Personnel** to continue to the next node

General Information Node



The screenshot shows the 'General Information' form within a patient record. The header bar includes patient details (Named Patient... TEMP-001266), role (Physician), status (Incomplete), date (04 Oct 2024), and buttons for 'Save' and 'Actions'. The form is titled 'General Information' and contains several input fields and dropdown menus. Green boxes and numbers highlight specific sections: '1' for the entire form, '1a' for the 'Requested Indication' dropdown, '1b' for the 'Duration of Treatment' and 'Requested Quantity' fields, '1c' for the 'Please confirm you are an authorized representative...' dropdown, '1d' for the 'Will an additional authorized representative...' dropdown, and '2' for the 'Personnel' button at the bottom right. The form also includes a section for 'Please provide the full name of the individual(s) who will be responsible for signing' and 'Please provide the email address of the individual(s) who will be responsible for signing'.

Named Patient... TEMP-001266 Physician Incomplete 04 Oct 2024 Save Actions

1 General Information

Program Code *Country of Treatment Portugal

*Requested Product OLIPUDASE ALFA [GZ402665] If other product, please specify

*Requested Indication --- Select One --- Please Specify Other Indication

Dosage Form & Strength Requested Dosage Regimen

*Duration of Treatment --Required-- Requested Quantity

If your request is approved, a separate Letter of Agreement with Sanofi will need to be signed by an authorized representative of your institution.

1c *Please confirm you are an authorized representative to sign the Letter of Agreement --- Select One ---

*Will an additional authorized representative be required to sign the Letter of Agreement? Yes

*Please provide the full name of the individual(s) who will be responsible for signing: --Required--

*Please provide the email address of the individual(s) who will be responsible for signing: --Required--

← Acknowledgement Personnel → **2**

*The Letter of Agreement (LOA) sets out the terms and conditions applicable to the unsolicited request received under Sanofi Managed Access Program and must be signed and agreed to by all parties before Sanofi can provide access to the requested product

Personnel Node

The **Personnel** node is where you are required to enter all information on project personnel. At a minimum, the *Requesting Physician* must be entered, as the first entry.

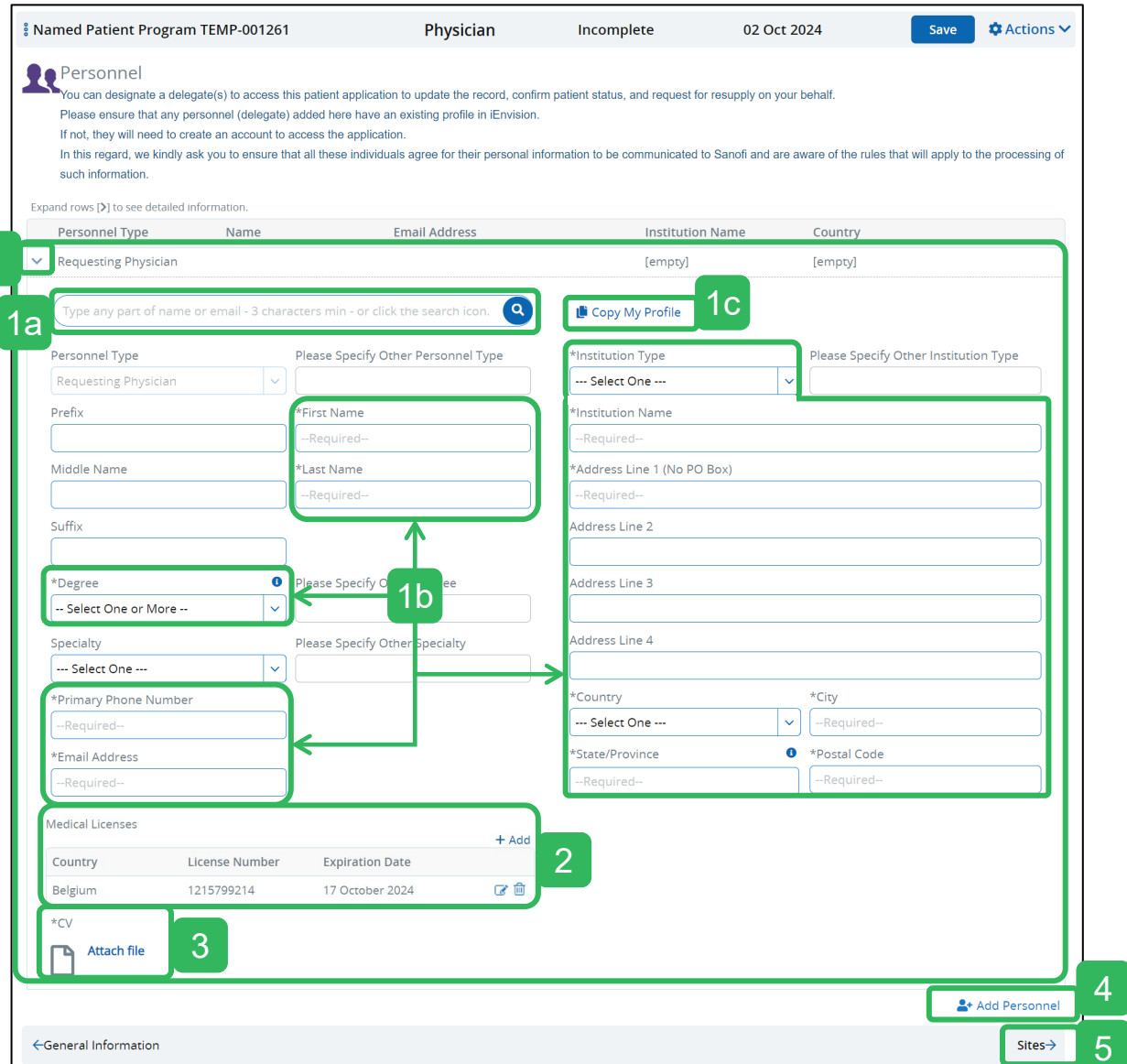
To enter the individual information:

- 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 (*)
 - 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
- For Medical Doctors, you will need to fill in the **Medical Licenses** table before you are able to submit your application for approval
- In the **CV** field, use the **Attach file** link to upload a copy of the Curriculum Vitae for the Requesting Physician to the record
- Click  **Add Personnel** to add another **Personnel**, ie, a delegate, and follow steps 1 and 2 to fill in their details. You will also have to select the appropriate value for **Personnel Type**.

Note: If you add a Delegate to the **Personnel Node**, they will receive all notifications and have access to the record in order to perform any necessary actions, if needed. The Delegate must have an active iEnvision account.

- Click **Sites** to continue to the next node

Personnel Node



The screenshot shows the 'Personnel Node' form for a 'Named Patient Program TEMP-001261' under the 'Physician' role, which is 'Incomplete' as of '02 Oct 2024'. The form includes a 'Personnel' section with instructions and a table for 'Personnel Type'.

Personnel Table:

Personnel Type	Name	Email Address	Institution Name	Country
Requesting Physician	[empty]	[empty]	[empty]	[empty]

Form Fields and Annotations:

- 1:** Expand the row you would like to work on.
- 1a:** Search field: 'Type any part of name or email - 3 characters min - or click the search icon.'
- 1b:** 'Copy My Profile' button.
- 1c:** 'Copy My Profile' button (repeated).
- 2:** 'Medical Licenses' table with columns: Country, License Number, Expiration Date. Row: Belgium, 1215799214, 17 October 2024.
- 3:** 'CV' field with 'Attach file' link.
- 4:** 'Add Personnel' button.
- 5:** 'Sites' button.

Sites Node

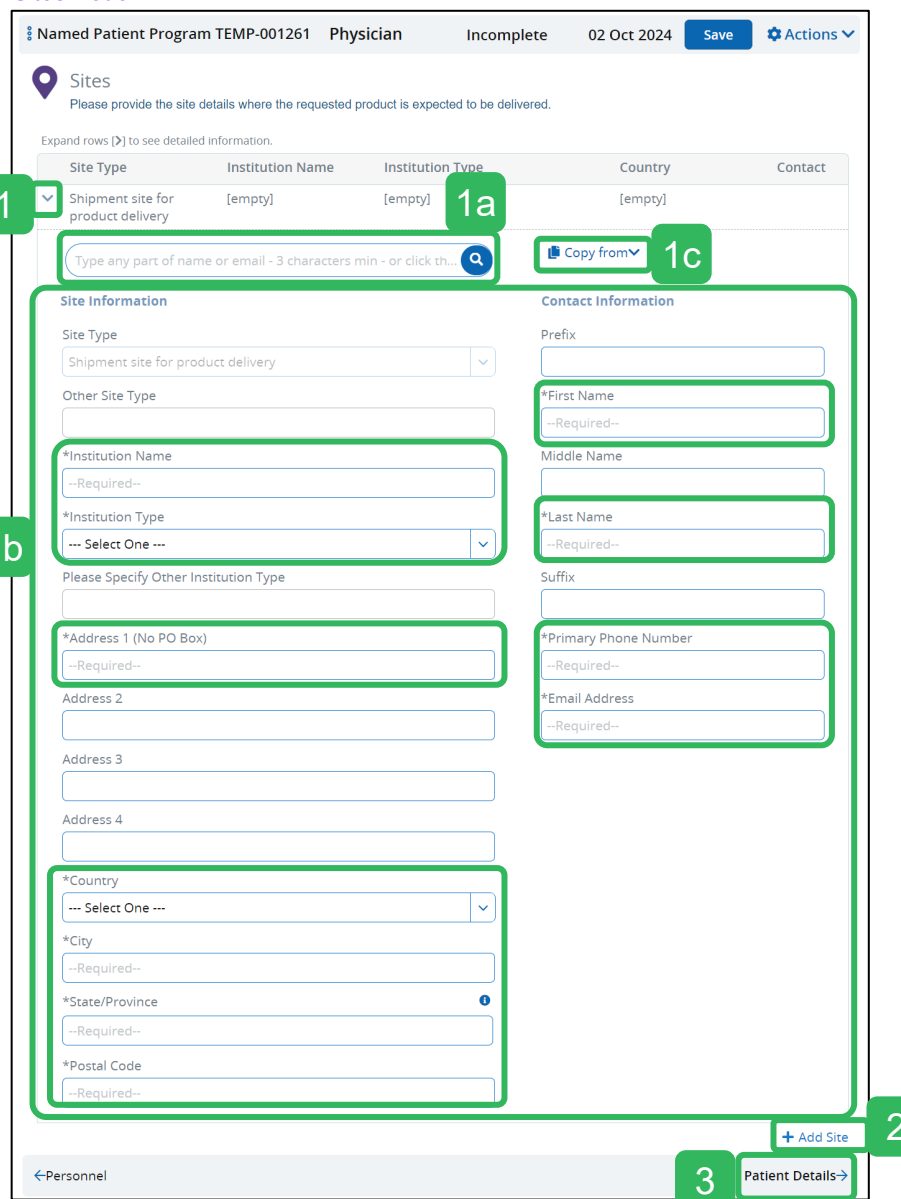
The **Sites** node is where you are required to enter all information regarding the delivery site for the product. Additionally, you can enter in other delivery sites as needed.

For the information on the primary shipment site:

- Expand the **Shipment site for product delivery** 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 (*)
 - 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 storage sites, if applicable
- Click **Patient Details** to continue to the next node

Note: Make sure to select the **Site Type** when adding additional sites

Sites Node



The screenshot shows the 'Sites Node' form for a 'Named Patient Program TEMP-001261' under the 'Physician' tab. The form is marked as 'Incomplete' and dated '02 Oct 2024'. It features a 'Save' button and an 'Actions' dropdown menu.

The main section is titled 'Sites' and includes a sub-header: 'Please provide the site details where the requested product is expected to be delivered.' Below this, there is a table with columns: 'Site Type', 'Institution Name', 'Institution Type', 'Country', and 'Contact'. The first row is 'Shipment site for product delivery', which is expanded to show a detailed form.

The expanded form is divided into two main sections: 'Site Information' and 'Contact Information'. The 'Site Information' section includes fields for 'Site Type' (a dropdown menu), 'Other Site Type', '*Institution Name' (required), '*Institution Type' (required, with a 'Select One' dropdown), 'Please Specify Other Institution Type', '*Address 1 (No PO Box)' (required), 'Address 2', 'Address 3', 'Address 4', '*Country' (required, with a 'Select One' dropdown), '*City' (required), '*State/Province' (required), and '*Postal Code' (required). The 'Contact Information' section includes fields for 'Prefix', '*First Name' (required), 'Middle Name', '*Last Name' (required), 'Suffix', '*Primary Phone Number' (required), and '*Email Address' (required).

Numbered callouts highlight specific features:

- 1**: A green box around the 'Shipment site for product delivery' row in the table.
- 1a**: A green box around the search field in the expanded form.
- 1b**: A green box around the 'Site Information' section of the expanded form.
- 1c**: A green box around the 'Copy from' button in the expanded form.
- 2**: A green box around the '+ Add Site' button at the bottom right of the form.
- 3**: A green box around the 'Patient Details' button at the bottom right of the form.

Patient Details Node



Provide the required patient information on the **Patient Details** node by filling in the required fields (*) and any other relevant fields

1. Fill in the following required fields:

- **Year and Month of Birth**
- **Patient Program Age Group**
- **Gender assigned at birth**
- **Body Weight (in Kgs)**
- **Height (in cm)**
- **Have all available approved therapies as appropriate for this indication been exhausted?**
- **Is the patient currently pregnant, lactating or expecting to become pregnant during treatment?**
- **Scientific Rationale for Use**
- **History of Diagnosis and Current Extent of Disease**
- **Relevant Medical History (including Co-morbidities and Recent Hospitalizations)**
- **History of Prior Treatment and Outcomes Received**
- **Relevant Laboratory or Diagnostic Findings**; If the answer is **Yes**, you will need to specify in the field below
- **Date of Last Evaluation**
- **Allergies to medications**; If the answer is **Yes**, you will need to list which medications in the field that appears
- **All Current Ongoing Medications and Indications for Use**

2. When all fields are completed to the best of your knowledge, click **Patient Eligibility** to continue

Patient Details Node

Named Patient Program TEMP-001261 Physician Incomplete 02 Oct 2024 Save Actions

Patient Details
Please do not include any patient identifiers (e.g., patient name, initials, address or contact details etc.) in any of the open fields in this section.

1

*Year of Birth --Required-- *Month of Birth --- Select One --- *Patient Program Age Group Not applicable or specified *Gender assigned at birth --- Select One --- *Body Weight (In Kgs) --Required-- *Height (in cm) --Required--

*Have all available approved therapies as appropriate for this indication been exhausted? --- Select One --- *Is the patient currently pregnant, lactating or expecting to become pregnant during treatment? --- Select One ---

*Scientific Rationale for Use *History of Diagnosis and Current Extent of Disease

*Relevant Medical History (including Co-morbidities and Recent Hospitalizations)

*History of Prior Treatment and Outcomes Received *Relevant Laboratory or Diagnostic Findings

Date of Diagnosis Date Of Last Evaluation --Required--

*All Current Ongoing Medications and Indications for Use

Other Relevant Information to Help Evaluate the Request

*Allergies to medications? --- Select One ---

*Which medication(s) and what type of reaction? --Required--

2 Patient Eligibility

Patient Eligibility Node

Provide the following details on the **Patient Eligibility** node:

1. Answer the question **Does the patient meet this program specific Patient Eligibility Criteria (PEC)?**
 - a. If the answer was **No**, enter text for the **Please describe which criteria are not met**
2. Use the **Save** button to save your updates to this node

Patient Eligibility Node

Named Patient Program TEMP-001261
Physician
Incomplete
04 Oct 2023

2

Save

Actions

Patient Eligibility

Please download the following PEC file.
Once reviewed, please respond to its contents using the fields below.

[Click here to download a new PEC form](#)

PEC Form


Attach file

1

*Does the patient meet this program specific Patient Eligibility Criteria?

--- Select One ---

1a

Please describe which criteria are not met

Patient Eligibility

General Patient Criteria

Patient is affected by life-threatening or seriously debilitating illness, disease or condition.
I Agree

Patient is not able to access the product for the requested use because it is either not yet authorized, or it is not commercially available in the patient's primary residence.
I Agree

Patient has exhausted any other approved and/or satisfactory alternative treatment options (unmet medical need).
I Agree

Patient is not currently receiving, or has not previously received treatment with the requested product.
I Agree

Patient is not currently enrolled in a Sanofi sponsored trial.

(note: for patients exiting a Sanofi sponsored trial, please refer to <https://www.sanofi.com/en/your-health/healthcare-professional-support/post-trial-access>)
I Agree

Patient cannot enroll in any trial.
I Agree

There is a favorable benefit risk profile for the requested use for this patient based on the most current scientific data available.
I Agree

← Patient Details

Resupply or Status Update Request →

Submit the Request



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

To submit the Request:

1. Check that all required information has been entered. Completed sections will be indicated with a ✓ checkmark.
2. From the **Actions** menu, select **Submit Request**
Note: If there are required fields that must be completed in order to submit your request, 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 **Pending Approval Decision**

Submitted Request Context Bar

Named Patient Program 24-MAP-000270 Physician Pending Approval Decision 04 Oct 2024 Save Actions

General Information Node

Named Patient Program TEMP-001261 Physician Incomplete 04 Oct 2024 Save Actions

1

- ✓ Acknowledgement
- ✓ General Information
- ✓ Personnel
 - ✓ Gillespie, Physician*
 - ✓ Delegate, Physician
- ✓ Sites
 - ✓ Medical Hospital UK*
- ✓ Patient Information
 - ✓ Patient Details
 - ✓ Patient Eligibility
 - Resupply or Status Update Re...
 - Physician Eligibility
- Documentation
 - Regulatory
 - General Attachments

2

General Information

Program Code *Country of Treatment

*Requested Product If other product, please specify *Requested Indication Please Specify Other Indication

Dosage Form & Strength Requested Dosage Regimen *Duration of Treatment Requested Quantity

If your request is approved, a separate Letter of Agreement with Sanofi will need to be signed by an authorized representative of your institution.

*Please confirm you are an authorized representative to sign the ... *Will an additional authorized representative be required to sign t...

← Acknowledgement Personnel →

Save Print Submit Request Withdraw



03 | PRIOR TO REQUEST APPROVAL

- [Additional Information Requested](#)
- [Withdraw Your Request](#)
- [Letter of Agreement \(LOA\)](#)

Additional Information Requested



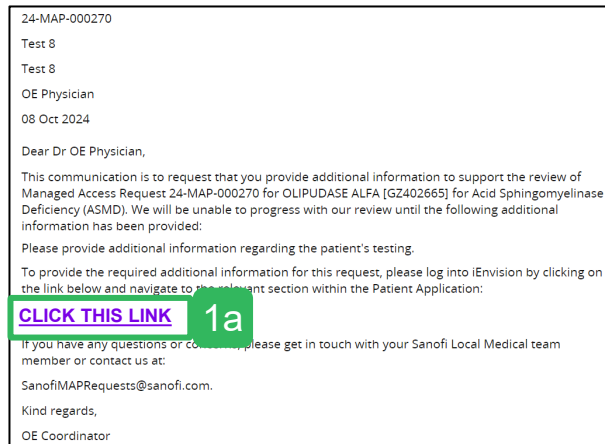
After your application has been submitted and throughout the lifecycle of the request, you may be asked to provide **Additional Information** to support your request

Note: The Physician can edit any part of the application as relevant to provide additional information as well as upload any attachments, as necessary, at this time

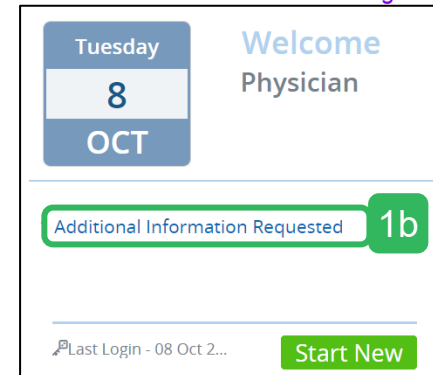
To respond to a request for additional information:

- You will be notified by both email and a system notification that there is a request for additional information. To access the application:
 - Click the link in the notification email
 - OR
 - Click the **Additional Information Requested** link in the **Welcome** widget on your **Dashboard**
- 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 sections
 - If the window is closed, you can open it by clicking the **i** icon in the **Context Bar** or by using the **Addtl. Info Requested** option on the **Actions** menu
- After you have completed your updates, resubmit your application by selecting **Submit Additional Information** from the **Actions** menu

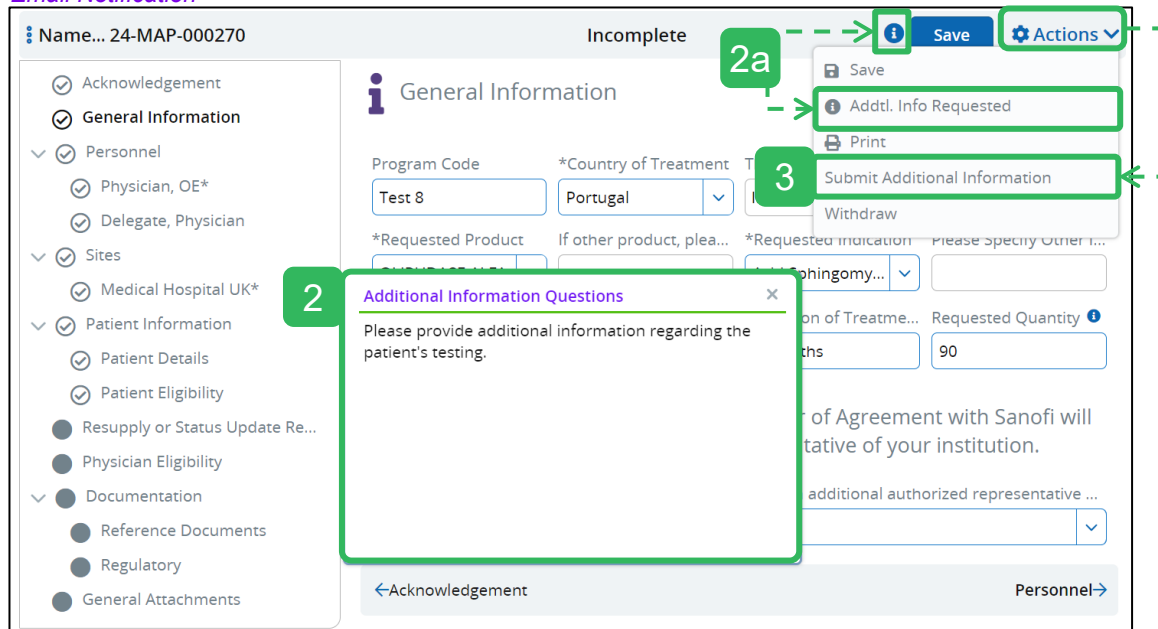
Email Notification



MAPs Dashboard – Welcome Widget



Email Notification



If during the time period after the submission of your Request to before the **Active Patient** status, you would like to withdraw your request, you can choose to mark it as **Withdrawn** and close it out

1. From the **Actions** menu, select **Withdraw**

2. The **Withdraw Notification Window** will open. Make any changes to the **CC**, **Subject**, and **email body** (here is where you can indicate the reason for Withdrawal in the notification), if necessary

3. Click the **Submit** button to send the notification

4. The **Status** on the context bar will update to **Closed**

Withdraw

Copy Attachments From EAP Named Patient Request Include Global Attachment(s) Upload Attachments

No Attachments

▼ Header Information

*To
"Gillespie, Michelle Local Medical" <MichelleLocalMedical@sanofi.com>; "Gillespie, Michelle Coordinator" <MichelleCoordinator@sanofi.com>; "Physician, Delegate" <delphys@email.com>; "Gillespie, Michelle Physician" <MichellePhysician@sanofi.com>;

CC
"Physician, Delegate" <delphys@email.com>

*Subject
Sanofi Managed Access Request 24-MAP-000187 for OLIPUDASE ALFA [GZ402665] is Withdrawn

The E-mail below will be sent to all persons listed. Please change it if necessary. Please know that if you go back and edit the set up, you will have to redo this notification changes.

Sans Serif Normal B I U S A x² x₂ H L Table Link Image Text

24-MAP-000187
Test 8
Test 8
Michelle Physician Gillespie

Context Bar

Named... TEMP-001367 **Closed** Actions

24-MAP-000187 for OLIPUDASE ALFA [GZ402665] for Acid Sphingomyelinase Deficiency (ASMD) has been received and the request will no longer be progressed.

☐ Do not send a notification **Submit** Cancel

Letter of Agreement (LOA)

The Letter of Agreement (LOA) sets out the terms and conditions applicable to the unsolicited request received under the Sanofi Managed Access Program and must be signed and agreed to by all parties before Sanofi can provide access to the requested product

Once your application has been reviewed and you have received a decision of Approved, the LOA process will be initiated

1. You will receive the following communications:
 - a. An email requiring you to sign the **LOA** and send it back to the Coordinator
 - b. A **LOA required** notification in your **Welcome** widget

Once you have signed the LOA and the process has been completed, the Coordinator will be notified and your application will enter the **Project Setup** status

Approval Email

1a

24-MAP-000270
Test 8
Test 8
OE Physician
10 Oct 2024

Medical Hospital UK

Dear Dr OE Physician,
We are pleased to notify you that the Managed Access Request 24-MAP-000270 has been approved as follows for this initial supply:

Program Indication: Test 8

Product: OLIPUDASE ALFA [GZ402665]

Dosage and Formulation: 4 MG/1 ML VIAL X 1

Approved Quantity (units): 300

Approved Duration (in days): 120

Dosage Regimen: 3x a day

You will soon receive a separate email (through Adobe Sign) with the Letter of Agreement for this request which will require an electronic signature. Once Sanofi has received a fully signed copy of the Letter of Agreement, we will provide you with the Managed Access Program Treatment Package for this request.

To be directed to this request, please log into iEnvision by clicking on the link below:

If you have any questions or concerns, please get in touch with your Sanofi Local Medical team member or contact us at:

SanofiMAPRequests@sanofi.com.

Kind regards,
OE Coordinator

Welcome Widget

Thursday
10
OCT

Welcome
Physician

1 LOA Required
1b

Last Login - 10 Oct 2...
Start New



04 | ACTIVE REQUEST

- [Confirm Product Shipment Receipt](#)
- [Request Product Resupply or Status Update Request](#)
- [MAP Status Update Decision Tree](#)
 - [Resupply Criteria](#)
 - [Physician Criteria](#)
 - [Review Summary and Submit](#)

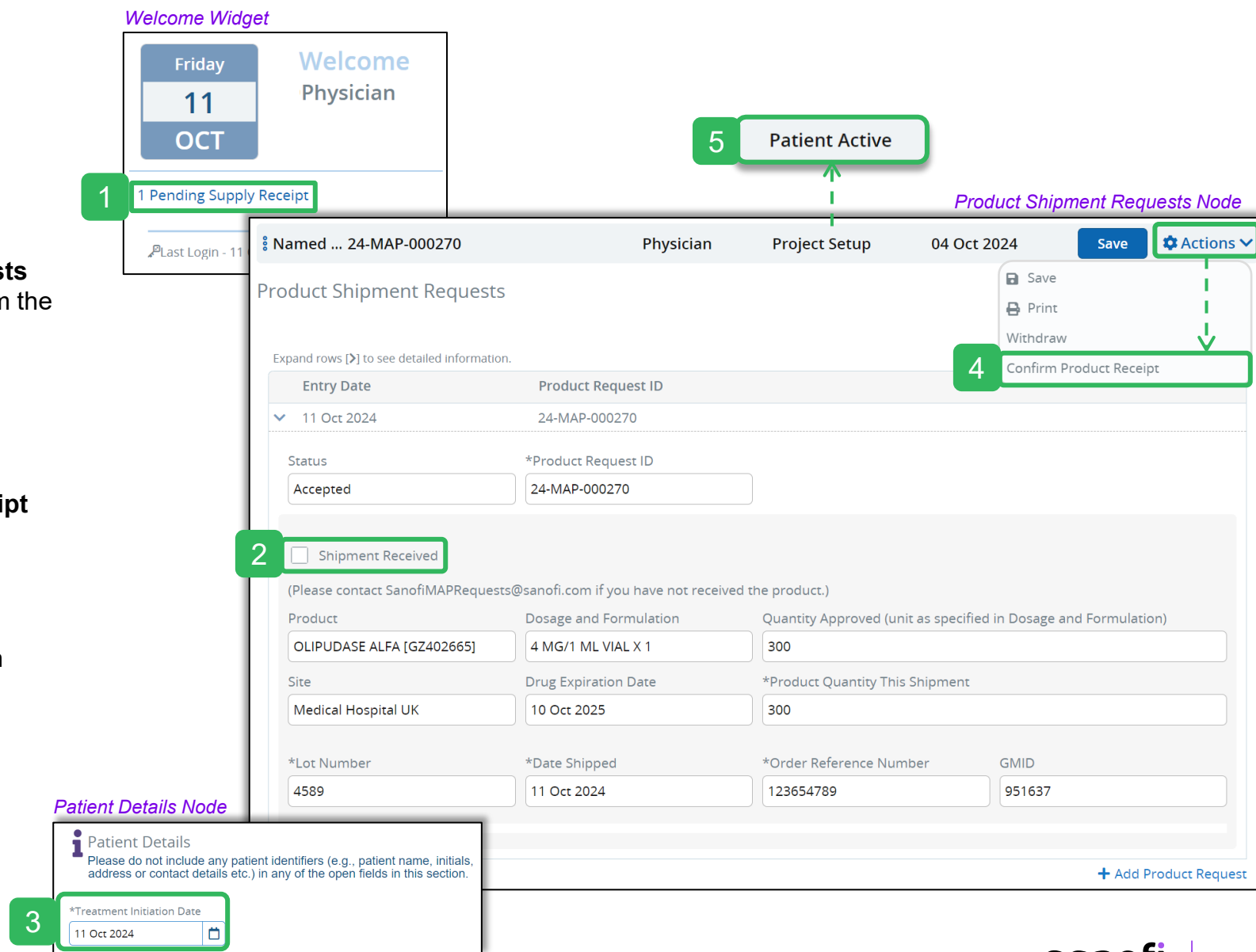
Confirm Product Shipment Receipt

When a product has been shipped, you will receive a notification

To confirm receipt of your product shipment:

1. Click the **Pending Supply Receipt** link on the **Welcome** widget
2. The request will open to the **Product Shipment Requests** node. Click the **Shipment Received** checkbox to confirm the receipt of the product shipment.
3. On the **Patient Details** node, be sure to update the **Treatment Initiation Date** if you are confirming the initial supply
4. From the **Actions** menu, select **Confirm Product Receipt**
5. The **Status** will update to **Patient Active**

Note: If you added a Delegate to the **Personnel** node, they will receive all notifications and have access to the record in order to perform any necessary actions, if needed



Welcome Widget

Friday
11
OCT

Welcome
Physician

1 Pending Supply Receipt

5 Patient Active

Product Shipment Requests Node

Named ... 24-MAP-000270 Physician Project Setup 04 Oct 2024 Save Actions

Product Shipment Requests

Expand rows [P] to see detailed information.

Entry Date	Product Request ID
11 Oct 2024	24-MAP-000270

Status: Accepted *Product Request ID: 24-MAP-000270

2 ☐ Shipment Received

(Please contact SanofiMAPRequests@sanofi.com if you have not received the product.)

Product	Dosage and Formulation	Quantity Approved (unit as specified in Dosage and Formulation)
OLIPUDASE ALFA [GZ402665]	4 MG/1 ML VIAL X 1	300

Site	Drug Expiration Date	*Product Quantity This Shipment
Medical Hospital UK	10 Oct 2025	300

*Lot Number	*Date Shipped	*Order Reference Number	GMID
4589	11 Oct 2024	123654789	951637

4 Confirm Product Receipt

Patient Details Node

Patient Details
Please do not include any patient identifiers (e.g., patient name, initials, address or contact details etc.) in any of the open fields in this section.

3 *Treatment Initiation Date
11 Oct 2024

+ Add Product Request

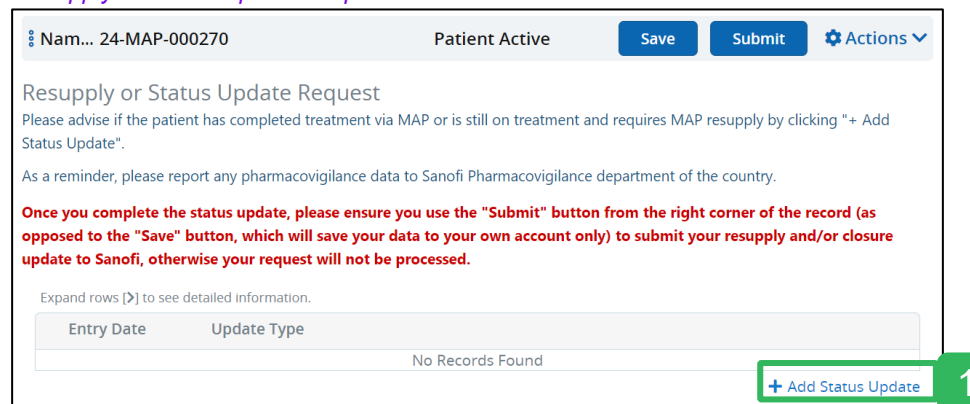
Request Product Resupply or Status Update Request

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

1. On the **Resupply or Status Update Request** node, click the **Add Status Update** link on the table
2. The **EAP Status update – Closure or Resupply** decision tree will open. For the **Update Type** section, answer the question, **Would you like to request treatment continuation for your patient via Sanofi MAP?**
 - If your answer is **No**, the patient no longer requires treatment via Sanofi MAP, then you will begin the process of [ending the request](#)
 - If your answer is **Yes**, I would like to request resupply for this patient, then you will continue to the [Resupply Criteria](#) section
3. Click **Next** to continue to the next section

Note: If you added a Delegate to the **Personnel Node**, they will receive all notifications and have access to the record in order to perform any necessary actions, if needed

Resupply or Status Update Request



Nam... 24-MAP-000270 Patient Active Save Submit Actions

Resupply or Status Update Request

Please advise if the patient has completed treatment via MAP or is still on treatment and requires MAP resupply by clicking "+ Add Status Update".

As a reminder, please report any pharmacovigilance data to Sanofi Pharmacovigilance department of the country.

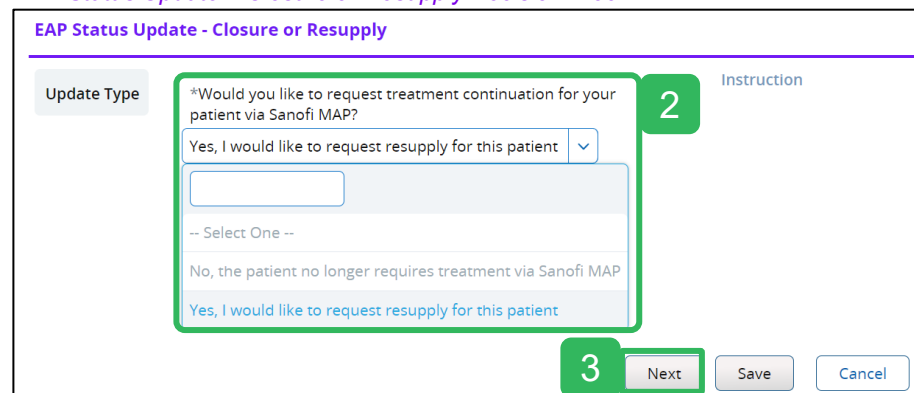
Once you complete the status update, please ensure you use the "Submit" button from the right corner of the record (as opposed to the "Save" button, which will save your data to your own account only) to submit your resupply and/or closure update to Sanofi, otherwise your request will not be processed.

Expand rows [X] to see detailed information.

Entry Date	Update Type
No Records Found	

+ Add Status Update 1

EAP Status Update – Closure or Resupply Decision Tree



EAP Status Update - Closure or Resupply

Update Type

*Would you like to request treatment continuation for your patient via Sanofi MAP?

Yes, I would like to request resupply for this patient

-- Select One --

No, the patient no longer requires treatment via Sanofi MAP

Yes, I would like to request resupply for this patient

Instruction

2

3 Next Save Cancel

MAP Status Update Decision Tree – Resupply Criteria

If you selected **Yes**, I would like to request resupply for **this patient** to the question, **Would you like to request treatment continuation for your patient via Sanofi MAP?**, then you will continue to the **Resupply Criteria** section

1. Use the drop-down menu to answer the question, **Does the patient continue to meet all the MAP criteria specified in the initial request?**
2. If there is a change in dosage, enter the information in the **Dosage Regimen (specify if different than the approved initial request)** field
3. Enter the **Duration for each supply request (in days)**
4. Enter the amount of product you are requesting in the **Requested Quantity for the defined duration of treatment to be supplied in intervals (please specify unit)** field
5. If you have any product leftover from the previous shipment, enter the amount in the **Remaining Quantity (please specify unit)** field
6. Confirm or update the deliver site in the **Please confirm the shipment site for product delivery. Note: If you need to change the delivery site, please edit the site details in the "Site" node and select "Shipment site for product delivery" as the "Site Type"** field
7. Click **Next** to continue to the **Physician Criteria** section

EAP Status Update – Closure or Resupply Decision Tree – Resupply Criteria Section

EAP Status Update - Closure or Resupply

Update Type

Resupply Criteria

1 *Does the patient continue to meet all the MAP criteria specified in the initial request?

-- Select One --

2 Dosage Regimen (specify if different than the approved initial request)

3 Duration for each supply request (in days)

4 *Requested Quantity for the defined duration of treatment to be supplied in intervals (please specify unit)

5 *Remaining Quantity (please specify unit)

6 *Please confirm the shipment site for product delivery. Note: If you need to change the delivery site, please edit the site details in the "Site" node and select "Shipment site for product delivery" as the "Site Type".

7

Instruction

All of the information which is collected is necessary to process your request.

As the licensed physician, you have consulted with the patient to explore available alternate approved treatment options and clinical trials to determine whether this Managed Access Program is the only option.

The patient must meet all eligibility criteria to be considered. Please answer all criteria accurately by responding with "agree" or "disagree" to validate or invalidate the following statements, based on the knowledge you have to date.

Back

Next Save Cancel

MAP Status Update Decision Tree – Physician Criteria

The **Physician Criteria** section of the Decision Tree is next

8. Use the drop-down menu to answer the field
Physician still meets all criteria previously provided
9. Click **Next** to continue to the **Review Summary** section

EAP Status Update – Closure or Resupply Decision Tree – Physician Criteria Section

Update Type

Resupply Criteria

Physician Criteria

*Physician still meets all criteria previously provided

-- Select One --

8

Instruction
As the licensed physician, you must confirm the eligibility criteria to be considered for approval.

You must understand Sanofi criteria for Managed Access Programs.

Together with patient, you must discuss and understand any potential risks associated with the treatment for this specific patient.

9

Next

Save

Cancel

MAP Status Update Decision Tree – Review Summary and Submit

The **Review Summary** section of the Decision Tree is next

10. The **Review Summary** will appear allowing you to review all your selection
11. If you need to make edits to your selections, click the **Back** button or use the **section links** to return to a section
12. Click the **Finish** button to end the Decision Tree and return to the request record
13. To complete the request, use the **Submit** button or select **Submit Status Update** from the **Actions** menu
14. The **Status** will update to **Status Update Submitted** and the Coordinator will receive notification of the request

If your request is approved, you will need to confirm receipt of the additional product shipment when it arrives. You will receive a notification with this request. Refer to [Confirm Product Shipment Receipt](#) for further instructions on completing this task.

EAP Status Update – Closure or Resupply Decision Tree – Review Summary

EAP Status Update - Closure or Resupply

Update Type
Resupply Criteria
Physician Criteria

10 Would you like to request treatment continuation for your patient via Sanofi MAP?
Yes, I would like to request resupply for this patient

Does the patient continue to meet all the MAP criteria specified in the initial request?
Yes

Dosage Regimen (specify if different than the approved initial request)
[empty]

Duration for each supply request (in days)
90

Requested Quantity for the defined duration of treatment to be supplied

11 Back

12 Finish Cancel

Review Summary

Resupply or Status Update Request Node

13

Nam... 24-MAP-000270 Patient Active Save Submit Actions

Resupply or Status Update Request

Please advise if the patient has completed treatment via MAP or is still on treatment and "+ Add Status Update".

As a reminder, please report any pharmacovigilance data to Sanofi Pharmacovigilance department.

Once you complete the status update, please ensure you use the "Submit" button from the right corner of the record (as opposed to the "Save" button, which will save your data to your own account only) to submit your resupply and/or closure update to Sanofi, otherwise your request will not be processed.

Save Print Submit Status Update

Context Bar

24-MAP-000270 14 Status Update Submitted Save Actions



05 | REQUEST CLOSURE

- [Close the Request](#)
- [Support Resources](#)

Close the Request (1 of 3)



You can close out your request when your project is in the **Patient Active Status**

To complete the request to end treatment:

1. On the **Resupply or Status Update Request** node, click the **Add Status Update** link on the table
2. The **EAP Status Update – Closure or Resupply** decision tree will open. On the **Update Type** section, answer the question, **Would you like to request treatment continuation for your patient via Sanofi MAP?** using the option **No, the patient no longer requires treatment via Sanofi MAP**
3. Click **Next** to continue to the **Closeout Information** section

Resupply or Status Update Request

Nam... 24-MAP-000270 Patient Active Save Submit Actions

Resupply or Status Update Request

Please advise if the patient has completed treatment via MAP or is still on treatment and requires MAP resupply by clicking "+ Add Status Update".

As a reminder, please report any pharmacovigilance data to Sanofi Pharmacovigilance department of the country.

Once you complete the status update, please ensure you use the "Submit" button from the right corner of the record (as opposed to the "Save" button, which will save your data to your own account only) to submit your resupply and/or closure update to Sanofi, otherwise your request will not be processed.

Expand rows (X) to see detailed information.

Entry Date	Update Type
No Records Found	

+ Add Status Update 1

EAP Status Update – Closure or Resupply Decision Tree

EAP Status Update - Closure or Resupply

Update Type

*Would you like to request treatment continuation for your patient via Sanofi MAP?

Yes, I would like to request resupply for this patient

-- Select One --

No, the patient no longer requires treatment via Sanofi MAP

Yes, I would like to request resupply for this patient

Next Save Cancel

2 3

Close the Request (2 of 3)



4. On the **Closeout Information** section, use the Calendar menu to choose a date for **Treatment Discontinuation Date via MAP**
5. Use the drop-down menu options to answer the question **Do you have any remaining drug supply?**
 - a. If your answer is **Yes**, you will need to answer the pop-up field **The drug supply provided within the scope of Managed Access Program is only for the MAP patient approved for treatment and must not be used for other purposes. Please advise the action you will take for the remaining stock.**
 - b. If your answer is **Destroy remaining drug supply** to 5a, you will need to answer the pop-up field **If you have remaining drug supply, you are required to upload a drug destruction certificate or provide details. Please select how you would like to provide documentation of the destruction.**
 - c. If your answer is **Upload Destruction Certification obtained by a certified organization attesting the destruction** to 5b, you will need to check off the box acknowledging the statement **After finishing this Status Update form, please add the following attachment to this Status Update entry, then use the "Submit Status Update" action: Destruction Certification obtained by a certified organization attesting the destruction.**
6. Click **Next** to continue to the **Review Summary** section

EAP Status Update – Closure or Resupply Decision Tree

EAP Status Update - Closure or Resupply

Update Type
Closeout Information

*Treatment Discontinuation Date via MAP
18 Oct 2024

*Do you have any remaining drug supply?
Yes

The drug supply provided within the scope of Managed Access Program is only for the MAP patient approved for treatment and must not be used for other purposes. Please advise the action you will take for the remaining stock.
Destroy remaining drug supply

If you have remaining drug supply, you are required to upload a drug destruction certificate or provide details. Please select how you would like to provide documentation of the destruction.
Upload Destruction Certification obtained by a certified organization attesting the destruction

☒ After finishing this Status Update form, please add the following attachment to this Status Update entry, then use the "Submit Status Update" action: Destruction Certification obtained by a certified organization attesting the destruction

Back Next Save Cancel

Close the Request (3 of 3)



The **Review Summary** section of the **Decision Tree** is next

7. The **Review Summary** will appear allowing you to review all your selection
8. If you need to make edits to your selections, click the **Back** button or use the **section links** to return to a section
9. Click the **Finish** button to end the **Decision Tree** and return to the request record
10. If you checked off the box for 2c, be sure to upload your **Product Supply Destruction Certificate** on the **Resupply or Status Update Request** node
11. To complete the request, use the **Submit** button or select **Submit Status Update** from the **Actions** menu
12. The **Status** will update to **Status Update Submitted** and the Coordinator will receive notification of the request

When the Coordinator has closed out the request on his/her side, you will receive a notification, the **Status** will update to **Closed**, and you will no longer be able to update the record

EAP Status Update – Closure or Resupply Decision Tree – Review Summary

EAP Status Update - Closure or Resupply

Update Type
Closeout Information

Would you like to request treatment continuation for your patient via Sanofi MAP?
No, the patient no longer requires treatment via Sanofi MAP

Treatment Discontinuation Date via MAP
18 Oct 2024

Do you have any remaining drug supply?
Yes

The drug supply provided within the scope of Managed Access Program is only for the MAP patient approved for treatment and must not be used for other purposes. Please advise the action you will take for the remaining stock.
Destroy remaining drug supply

If you have remaining drug supply, you are required to upload a drug destruction certificate or provide details. Please select how you would like to provide documentation of the destruction.
Upload Destruction Certification obtained by a certified organization attesting the destruction

After finishing this Status Update form, please add the following attachment to this Status Update entry, then use the "Submit Status Update" action:
Destruction Certification obtained by a certified organization attesting the destruction
Yes

Back **Finish** **Cancel**

Resupply or Status Update Request Node

24-MAP-000270 Physician Patient Active 04 Oct 2024 **Save** **Submit** **Actions**

Resupply or Status Update Request
Please advise if the patient has completed treatment via MAP or is still on treatment and requires MAP resupply by clicking "+ Add Status Update"

As a reminder, please report any pharmacovigilance data to Sanofi Pharmacovigilance department of the country.

Once you complete the status update, please ensure you use the "Submit" button from the right corner of the record (as opposed to the data to your own account only) to submit your resupply and/or closure update to Sanofi, otherwise your request will not be processed.

Expand rows [X] to see detailed information.

Entry Date	Update Type
17 Oct 2024	No, the patient no longer r...

24-MAP-000 **Status Update Submitted** **Save** **Actions**

Update Type
No, the patient no longer requires treatment via Sanofi MAP

***Product Supply Destruction Certificate**
Remove Replace
Destruction Certificate.docx
17 Oct 2024 11:53:35



iENVISION MAPs PHYSICIAN SUPPORT RESOURCES



To **access MAPs**, use the link below:

https://sanofi.envisionpharma.com/ienv_sanofi_qual/visiontracker/portal/login.xhtml?pgm=PAA



To **request system access** or **training support**,
a member of the Country Medical Team or email:

SanofiMAPRequests@sanofi.com



For **technical support**, contact the Envision Pharma Helpdesk

Email: helpdesk@envisionpharmasupport.com

