

Guidance for Reporting of PV Data Using the Updated PV Data Reporting Tools Effective 9 March 2026

This guidance is applicable to Internal Staff and Services Providers working in Patient Programs, Market Research, Digital Properties, and General Services to which PV Requirements apply

PV Data can be reported using the Individual Safety Information (ISI) Collection & Documentation Forms **or** using the PV Portal.

I. PV Data reporting when using the forms:

Internal staff and Services Providers who were using forms to report PV Data before March 9th, 2026 are required to continue to report PV Data using forms, unless otherwise instructed by Sanofi PV.

From March 9 onward, the two forms to be used are:

Solicited Individual Safety Information (ISI) Collection & Documentation Form_V 2.0_ 9 Mar 2026 (**Solicited ISI form**)

Spontaneous Individual Safety Information (ISI) Collection & Documentation Form_V 2.0_ 9 Mar 2026 (**Spontaneous ISI form** – Spontaneous is also referred to as Unsolicited)

Unless otherwise instructed by Sanofi PSPV,

-the SOLICITED ISI form is to be used to report PV data collected in Patient Programs and Market Research

-the SPONTANEOUS (UNSOLICITED) ISI form is to be used to report PV data collected in Digital Properties and in General Services

Send the completed form via email to PV-ARTEMIS-SANOFI@IQVIA.COM or if agreed with Sanofi Country PSPV team to the Sanofi Country PSPV generic mailbox as per the PV Contact List available in the PV Resources Toolbox.

If your email signature contains a logo, the logo needs to be removed before sending the email.

You will receive an acknowledgement of receipt containing a unique INBOX ID, and the subject line of your initial submission.

1. Acknowledgements of receipt must be kept on file.
2. If you do not receive an acknowledgement of receipt, the report should be resent as soon as possible and no later than one (1) business day.

II. PV Data reporting when using Sanofi PV Artemis Portal (PV Portal):

Internal staff and Service Providers who were using the PV Portal to report PV Data before March 9th, 2026 are required to continue to report PV Data via the PV Portal unless otherwise instructed by Sanofi PSPV.

The link to the PV Portal remains unchanged: [Sanofi PV Artemis Portal](#).

At the time of the first report, Portal users must:

Self register to create an account (“sign up”) and then access the PV Portal with the “sign in” option

or

request to be added to their POP account if this type of account is set for their group

Note: All existing accounts will remain active in the new PV Portal version.

Main advantages of registering to the PV Portal

As contact information is provided at time of registration, this contact information (including e-mail address used for acknowledgement of receipt, name, address, etc.) will be auto-populated in the Contact Details section of the PV Portal for every subsequent report of safety information.

Registered users have access to a dashboard where they can see and retrieve the reports they previously submitted via the PV Portal and they are able to add incoming follow-up data in existing registered cases.

For corrections to a previously submitted report, registered users can retrieve the report in the dashboard and correct the data as needed.

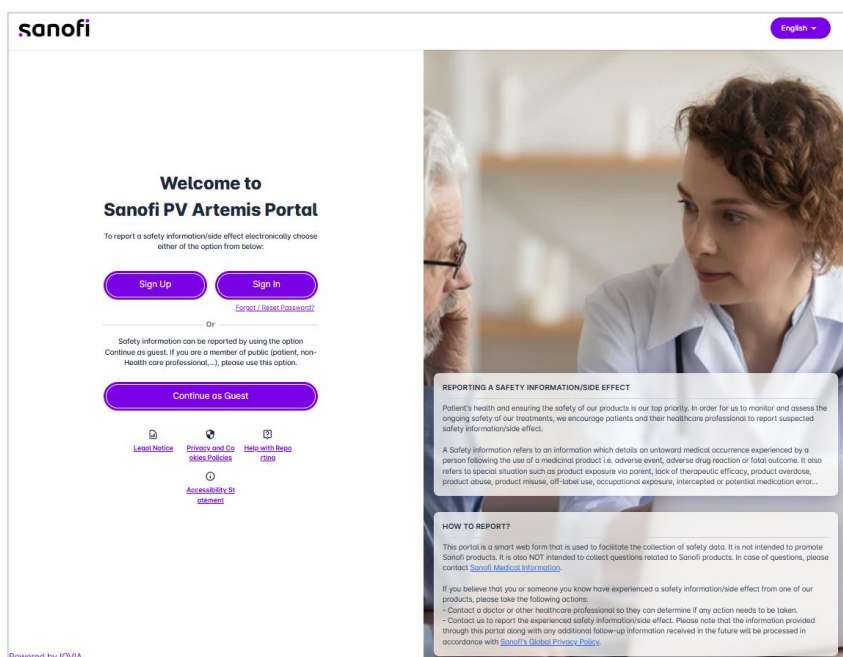
In the "Patient" section, go to the field "Please describe all information associated to the reported safety information/side effect (all signs and symptoms, possible causes and progression)", add the statement: "Correction to previously submitted report" along with details of the correction (e.g., "Correction to previously submitted report – Revised the unique patient ID"). Submit the report.

The PV Portal fields titles are available in English, French, and a few other languages but individual fields can be completed in any language.

For registration to the PV Portal please follow the instructions:

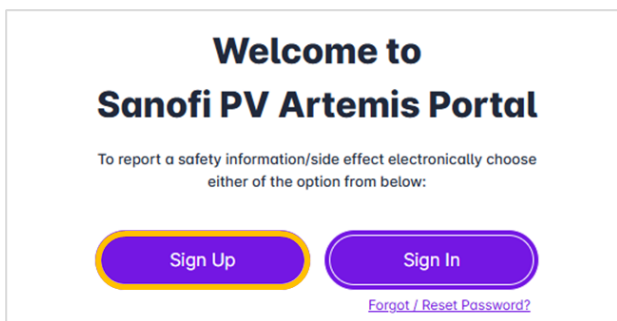
How to register:

1. Follow the link to the PV Portal.

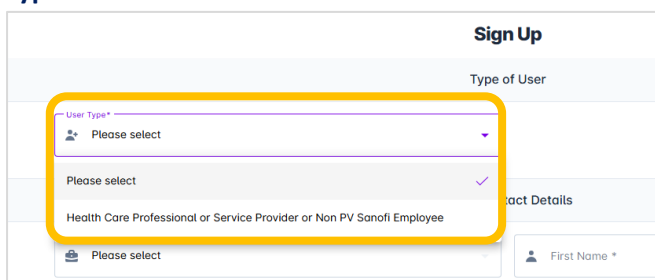


The screenshot shows the Sanofi PV Artemis Portal registration page. The page is titled "Welcome to Sanofi PV Artemis Portal" and includes a "Sign Up" button, a "Sign In" button, and a "Continue as Guest" button. There are also links for "Level Notice", "Privacy and Cookies Policies", "Help with Reporting", and "Accessibility Statement". The page is powered by IQVIA. On the right side, there is a section titled "REPORTING A SAFETY INFORMATION/SIDE EFFECT" which explains the purpose of the portal and provides instructions on how to report a safety information/side effect. It also includes a "HOW TO REPORT?" section with a list of actions to take if a safety information/side effect is experienced.

2. At the time of the first connection select Sign Up



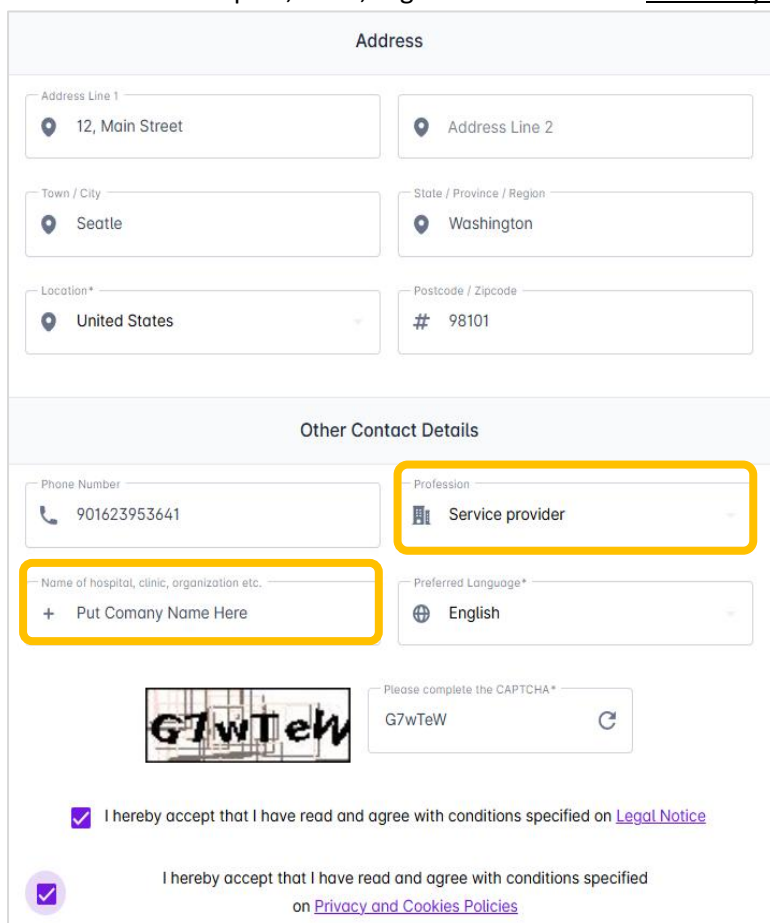
3. Complete all the fields with a special attention to the following:
Type of User: Select “Health Care Professional or Service Provider or Non PV Sanofi Employee”



Other contact Details:

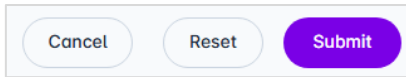
In “Profession” select “Service Provider”.

In Name of hospital, clinic, organization enter the name of your company.

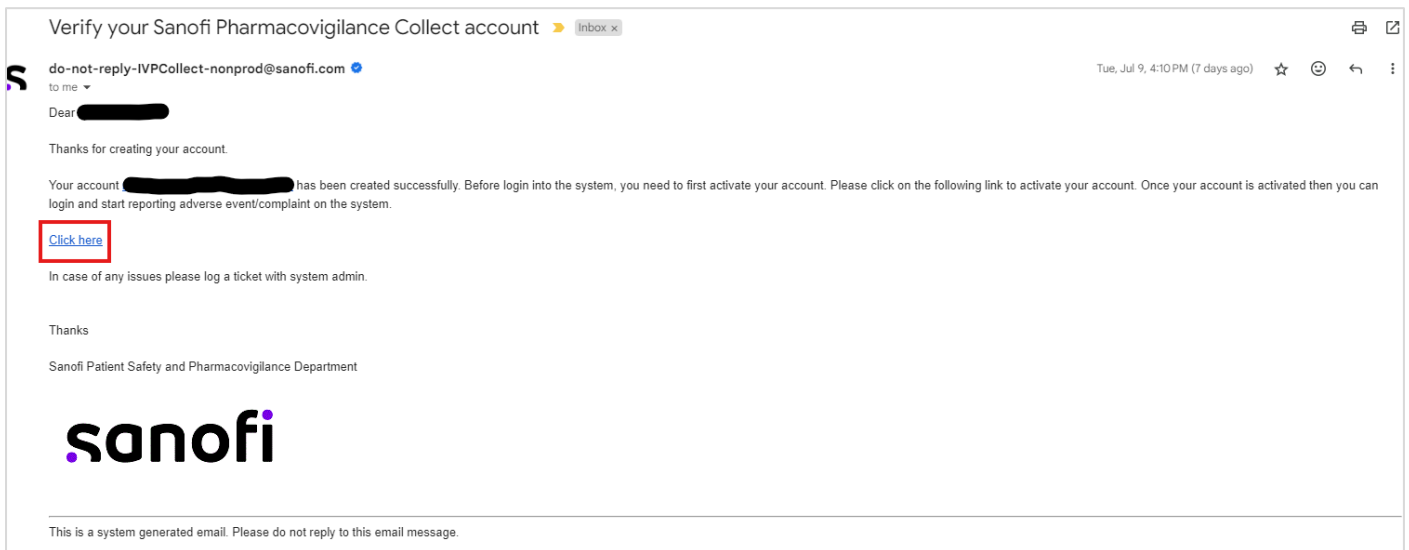


The image shows the full 'Sign Up' form. It is divided into two main sections: 'Address' and 'Other Contact Details'.
Address Section: Includes fields for 'Address Line 1' (12, Main Street), 'Address Line 2', 'Town / City' (Seattle), 'State / Province / Region' (Washington), 'Location*' (United States), and 'Postcode / Zipcode' (# 98101).
Other Contact Details Section: Includes 'Phone Number' (901623953641), 'Profession' (Service provider, highlighted with a yellow border), 'Name of hospital, clinic, organization etc.' (Put Comany Name Here, highlighted with a yellow border), and 'Preferred Language*' (English).
At the bottom, there is a CAPTCHA image (G7wTeW) and two checkboxes for terms and conditions: 'I hereby accept that I have read and agree with conditions specified on [Legal Notice](#)' and 'I hereby accept that I have read and agree with conditions specified on [Privacy and Cookies Policies](#)'.

4. Once all the fields are completed, click on Submit



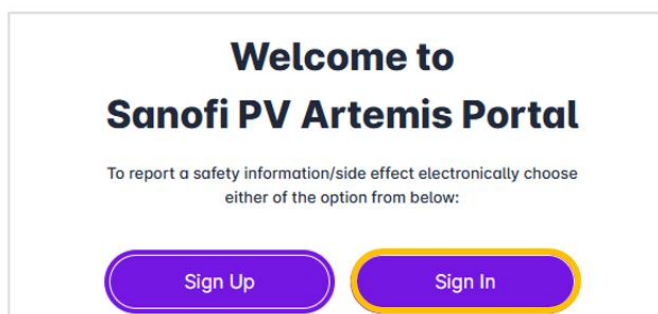
5. After submission, you will receive the email below which contains an activation link. Before you can sign in for the first time to report safety information, you will have to activate your account by clicking the “click here” link in the email.



Congratulations! You are now ready to report PV Data to Sanofi via the PV Portal!

How to report PV Data:

Sign In using your credentials.



Welcome to Sanofi PV Artemis Portal

To report a safety information/side effect electronically choose either of the option from below:

Sign Up
Sign In

[Forgot / Reset Password?](#)

Welcome to SANOFI PV Artemis Portal

Email address / Username

Password

Sign In

When you sign in, you have access to a dashboard where you can see and retrieve the reports you previously submitted via the PV Portal.

To submit new safety information, click the Report Initial Case button at the top right of the page:

Pharmacovigilance Collect Dashboard

🔍
+ Report Initial Case
☰

Case Number ↑	Primary Product ↑	Event ↑	Create Date ↑	Case Details	Case History
PVI-XI-2025-001029	DUPILUMAB	MYOCARDIAL I...	29-Oct-2025 15:13:13	📄	🕒
PVI-XI-2025-001028	DUPILUMAB	MYOCARDIAL I...	24-Oct-2025 17:13:49	📄	🕒
PVI-FO-2025-001001	TESTING PRODUCT FOR TR...	VOMITING	11-Sep-2025 09:38:18	📄	🕒
PVI-AL-2025-001063	DUPIXENT SINGLEDOSE PR...	HEADACHE	08-Sep-2025 18:06:13	📄	🕒

This will take you to a series of tabs where you can enter all the relevant details and data related to your safety report.

Be time conscious! You will receive a “Time Out” warning after 30 minutes of inactivity.

Session is about to expire!

Dear user, Your session is about to expire due to inactivity. Click on Continue button to keep your session active. In case you decide to click "Cancel" button, your current session will end and entered data will be lost.

Cancel
Continue

You can provide your password to continue with the report:

User Time Out!

Dear user, Your session has expired. Please click on the "Continue" button to resume your work.

Cancel

Continue

✔ Product ✔ Side Effect ✔ Patient ✔ Contact Details ✖ Summary

Product ⌵

DUPIXENT ⌵

[Change details](#)

Side Effect ⌵

Patient ⌵

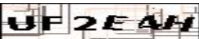
Contact Details ⌵

Please read and agree to the consent statement.

I authorize Sanofi and any of the relevant Sanofi Group Company affiliates to collect and analyze the information provided for the purpose of assessing side effects related to my use of a Sanofi product, and to disclose this information as required by law or regulation to health authorities in my country, and other countries around the world. All information concerning this report as well as any follow up queries for additional medical details will be in compliance with the Sanofi Patient Safety Reporting Privacy Notice.

I acknowledge that I have reviewed all my answers.

I acknowledge that I have read and agree to both the terms and conditions and the privacy policy as set forth in the [Legal Notice](#).

 Please complete the CAPTCHA*
UF2E4H [↻](#)

Submit Report

Thank you for your contribution to patient safety!