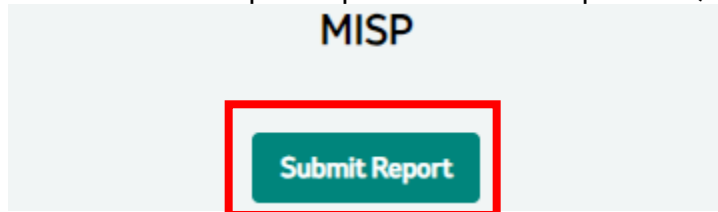


MSD Safety Reporting Portal

Guidance for MISP Investigators and Teams

Step 1: Navigate to the MSD Safety Reporting Portal ([Landing Page](#) | [Safety Reporting](#))

Select “Submit Report” option under Headquarters (*highlighted below*)



Step 2: Report Adverse Events Screen – Guidance to Complete Pre-Defined Required Fields

Please refer to the image below for each field.

- Investigator/Other’s Name – Enter the name of the Principal Investigator (PI) for the MISP
- Investigator/Other’s Email Address – Enter the e-mail address for the PI and/or other team members as needed. Multiple emails can be provided by adding a comma between each address.
- Investigator/Other Case ID# - Include the MSD IIS number and/or MSD assigned protocol number
- Attachment(s) – Upload the MedWatch/CIOMS, Global Safety Intake Form or similar form(s) for reporting the Adverse Event.
- What code is in the image? – Enter Captcha Code
- Select Submit Report

You can report one or more Adverse Event(s) for each submission.

a

Investigator/Other’s Name *
Enter the name of the Principal Investigator (PI)

b

Investigator/Other’s Email Address *
Enter the email address for the PI and/or other team members as needed.
Multiple emails can be provided by adding a comma between each address.

c

Investigator/Other Case ID# *
Include the IIS number and/or assigned protocol number.

Attachment(s) *
Upload the MEDWATCH/CIOMS Global Safety Intake Form or similar form(s) for reporting the Adverse Event.
Maximum upload size is 35MB. File format includes ZIP, PDF, DOCX, DOC, PPT, PPTX, XLS, XLXS, JPEG, JPG and PNG.

Choose Files

No file chosen

e

CAPTCHA *

What code is in the image? *

Enter the characters shown in the image.

f

Submit Report

MSD Safety Reporting Portal

Guidance for MISP Investigators and Teams

Step 3: Transmit Report

- ✓ Report will transmit to the appropriate mailbox

Step 4: Receive email acknowledging the case report was successfully transmitted

Thank you for reporting an Adverse Event to the MSD Safety Reporting Portal. We have received your safety report with the following details:

Safety Reporting Portal Case Reference ID: 20250127-MISP-0001-2952

Business Partner/Vendor/Investigator/Other's Case ID#: test

Date Reported to the Portal (UTC) : 27-Jan-2025 14:26

This is a portal generated acknowledgment email.

This is an automatically generated message - please do not respond to this email, as we won't receive your message. If you have any queries regarding this submission, please refer to the contact information stated in the agreement that is in place between our companies.

Step 5: Receive email acknowledging the case report was successfully processed

(this email will be sent when case has been accepted)



Step 6: If additional information is needed, an email is sent to the reporter

(refer to image below)

- ✓ Send additional information through the portal *(see screenshot below)*
- ✓ Once the follow-up information has been received and the case accepted, confirmation emails will be sent *(same as step 5 above)*

The MSD logo is shown above a screenshot of a web form titled "Follow up for Safety Report 20220927-VD-0001". The form contains several input fields: "Business Partner / Vendor Name" with the value "test", "Business Email Address" with the value "philina.yihui.phua@merck.com", and a "Description about the Adverse Event and associated Product Quality Complaint (if available)" with the value "test". There is a dropdown menu for "Do you have a Manufacturing (MFR) Control Number?" with the value "No". Below this is an "Attachment(s)" section with a "Choose files" button and the text "No file chosen". A note states "Maximum upload size is 35MB. File format includes PDF, DOCX, DOC, PPT, PPTX, XLS, XLSX, JPEG, JPG, and PNG." Below the attachments is a CAPTCHA image showing the letters "KH 3 N" and the text "What code is in the image?". There is a "Get new captcha" link and an "Update Report" button at the bottom.

Step 7: Reminders for additional information will be sent

- ✓ Reminders to send additional information to complete the case will be sent every 24 hours for 3 business days (3)

MSD Safety Reporting Portal

Guidance for MISP Investigators and Teams

Dear BP-test-repeatMFR,

We are reviewing your safety report – 20220525-VD-0026 submitted on 25-May-2022. We are unable to proceed due to:

Category of Follow-Up: Missing Pages, Illegible Handwriting (Non-readable)

Description about the missing information: Test

Kindly provide the information required within the next 24 hours through this [link](#)

IMPORTANT: We will close this case if we do not receive any response by 28 May 2022, 09:30 (UTC)

Your information is important to us. Thank you!

Best regards,

✓ If no action is taken by the reporter after 3 business days, the case will be cancelled

NOTE: Reporter must resubmit case if cancelled

Dear BP-test-repeatMFR,

We are unable to correctly process your report 20220525-VD-0026 with MFR control number: Submitted on 25-May-2022 as we did not receive a response to update the following information:

Information Required:

Category of Follow-Up: Missing Pages, Illegible Handwriting (Non-readable)

Description about the missing information: Test

If you wish to report another adverse event or product quality complaint, please submit another report on <http://pvepdev.merck.com/form/report-adverse-events>

Your information is important to us. Thank you!

Best regards,