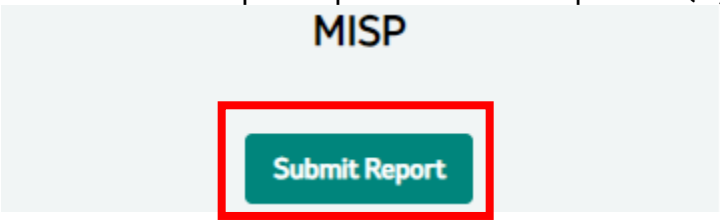
MSD Safety Reporting Portal
Guidance for MISP Investigators and Teams

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.

a) Investigator/Other's Name – *Enter the name of the Principal Investigator (PI) for the MISP*

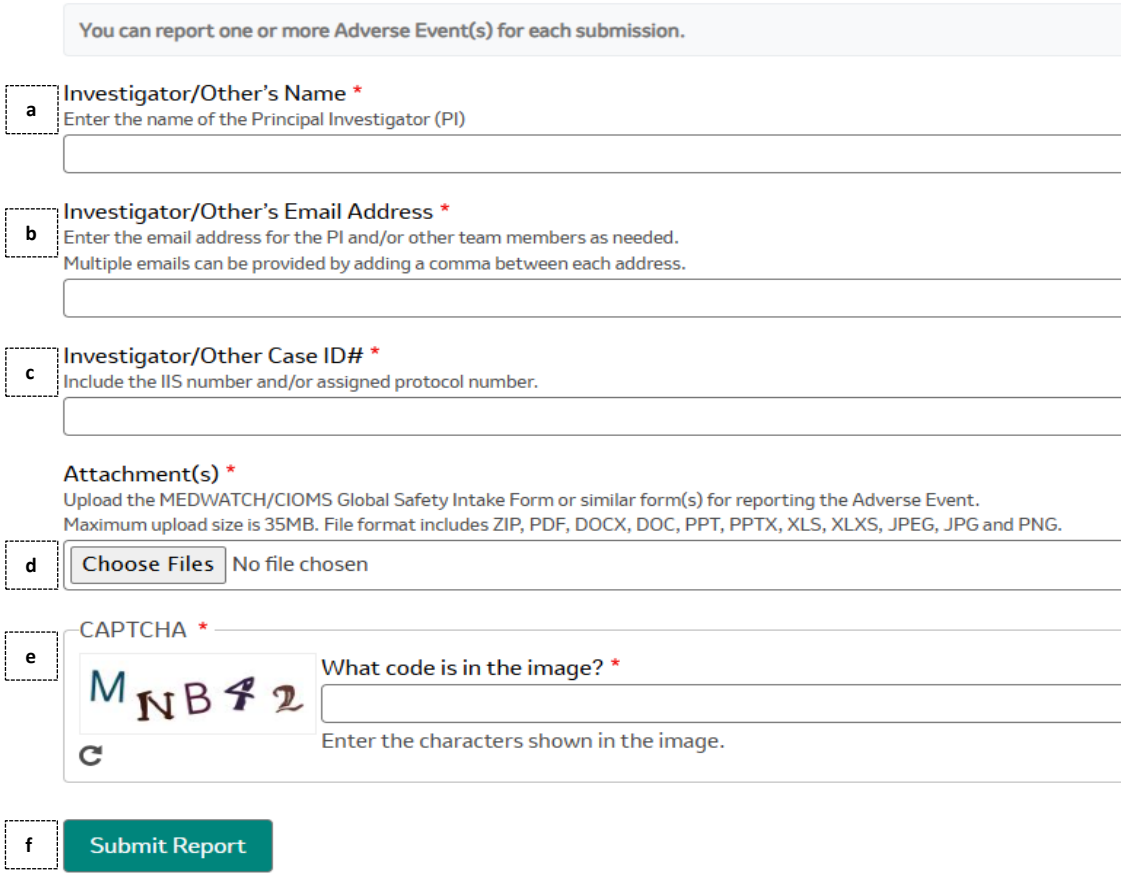
b) Investigator/Other's Email Address – *Enter the e-mail address for the PI and/or other team members as needed. Multiple emails can be provided by adding a comma between each address.*

c) Investigator/Other Case ID# - Include the MSD IIS number and/or MSD assigned protocol number

d) Attachment(s) – *Upload the MedWatch/CIOMS, Global Safety Intake Form or similar form(s) for reporting the Adverse Event.*

e) What code is in the image? – *Enter Captcha Code*

f) Select Submit Report



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)

Dear TestAER ,

We have processed your report with the following details:

Safety Reporting Portal Case Reference ID: 20230109-PVEP-0081

BP/Vendor's Case Reference ID#: 123

Date Reported (UTC): 09-Jan-2023 12:37

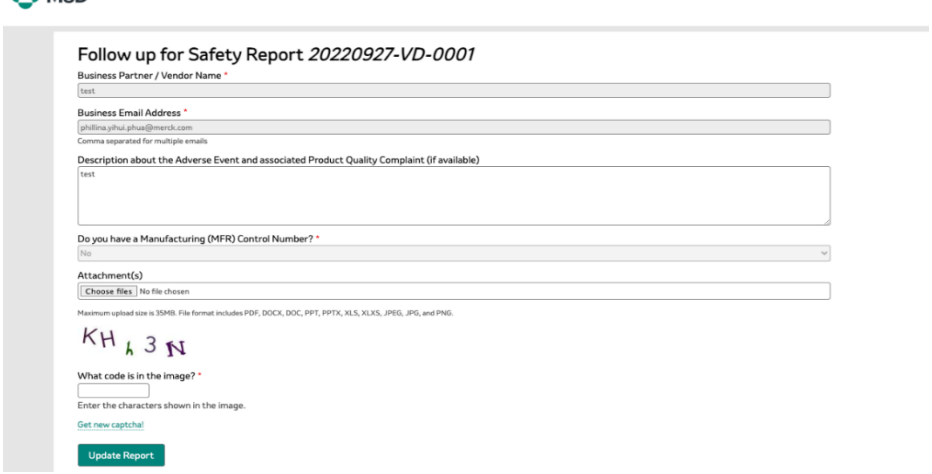
Your information is important to us. Thank you.

Best regards,

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

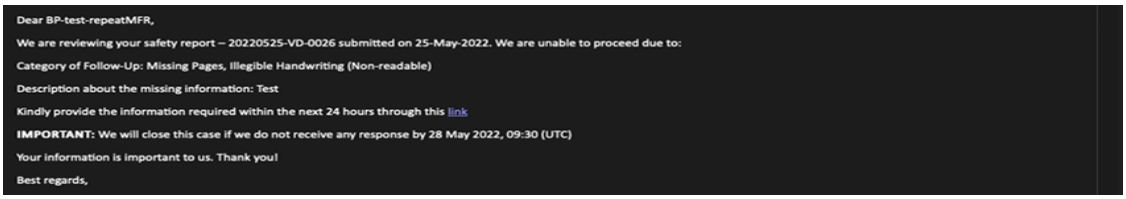
(*refer to image below*)

- ✓ **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)***



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)**


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

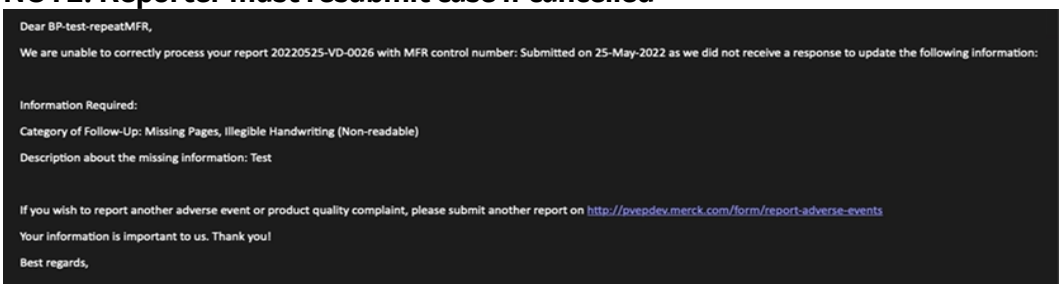
IMPORTANT: We will close this case if we do not receive any response by 28 May 2022, 09:30 (UTC)

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,