If reporting to <u>Country PV</u>, refer to Page 1 If reporting to <u>DPOC</u>, refer to Page 2

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

Select "Submit Report" option under Country (highlighted below)

PV		DPOC	MISP
Headquarters	Country		For MISP Investigators Only
Submit Report	Submit Report	Submit Report	Submit Report

Step 2: Report Adverse Events Screen – Complete Entry of Required Fields

(Refer to image below)

- a) <u>Business Partner/Vendor/Investigator/Other's Name</u> Enter the name of your company and/or your name
- b) <u>Business Partner/Vendor/Investigator/Other's Email Address</u> Enter your email address, multiple emails can be provided by adding a comma between each address
- *c)* <u>County of Incidence</u> *Select appropriate country*
- d) Description about the Adverse Event and associated Product Quality Complaint This field is not required if uploading an AE/PQC form
- e) <u>Business Partner/Vendor/Investigator/Other's Case ID#</u> *Optional* field to enter any case reference ID if available
- f) <u>Attachment(s)</u> Upload Attachment; Various formats accepted
- g) <u>What code is in the image?</u> Enter Captcha Code
- h) Select Submit Report

Merck Safety Reporting

You can report one or more Adverse Event/Product Quality Complaint(s) for each submission. Please ensure that your total attachments do not exceed 35mb.

	- Business Partner/Vendor/Investigator/Other's Name *
a 	<u>j</u> L]
	Business Partner/Vendor/Investigator/Other's Email Address *
b	
	- Comma separateo for multiple emails
	- Country of Incidence *
с 	Select a country
	Description about the Adverse Event / Product Quality Complaint
d	
	Purises Batter/Mender/Investigator/Other's Case ID#
	(cotional field for you to enter your company's internal case reference ID. if available)
	Attachmant/a)
 ¢	
т 	Choose Files No file chosen
	Maximum upload size is 35MB. File format includes ZIP, PDF, DOCX, DOC, PPT, PPTX, XLS, XLXS, JPEG, JPG, and PNG.
 а	CAPICHA
ь	J J FT Q What code is in the image?
	d. Forter the characters shown in the image
	C
	_
h	Submit Report

Step 1: Navigate to the MSD Safety Reporting Portal (Landing Page | Safety Reporting) Select "Submit Report" option under DPOC (highlighted below) PV DPOC MISP For MISP Investigators Only Headquarters Country Submit Report Submit Report Submit Report Submit Report Step 2: Report Adverse Events Screen – Complete Entry of Required Fields (Refer to image below) Business Partner/Vendor/Investigator/Other's Name – Enter the name of your company and/or your name a) b) <u>Business Partner/Vendor/Investigator/Other's Email Address</u> – Enter the email address for the PI and/or other team members. Multiple emails can be provided by adding a comma between each address. c) Consent for follow-up – Check Yes or No d) <u>County of Incidence</u> – Select appropriate country e) Description about the Adverse Event and associated Product Quality Complaint – Include Patient Identifier *i.e. age or gender, Date of Awareness, Batch #, and Batch expiry date* <u>Name of product</u> – *Enter the product name* f) g) Sample available for return - Check Yes or No h) Business Partner/Vendor/Investigator/Other's Case ID# – Optional field to enter your company's internal case reference ID, if available Attachment(s) – Upload MEDWATCH/CIOMS, Global Safety Intake form or similar form. Image i) requirement if reporting Product Quality Complaint. Various formats accepted. Acknowledgement of privacy statement – Review Our Company's Privacy Statement and Click Yes i) What code is in the image? - Enter Captcha Code k) 1) Select Submit Report Business Partner/Vendor/Investigator/Other's Name а Business Partner/Vendor/Investigator/Other's Email Address b Consent for follow-up С O Yes O No Country of Incidence d Select a country Description about the Adverse Event / Product Quality Complaint е Name of product f ---Sample available for return 4 g O Yes O No Business Partner/Vendor/Investigator/Other's Case ID# h Attachment(s)* of the MEDWATCH/CIOMS Global Safety Inteke Form or siz upload size includes ZIP, PDF, DOCX, DOC, PPT, PPTX, XLS, XLXS, JPEG, JPG ed photos of the product - with visible defect and batch d i Choose Files No file chosen The information provided concerning the reported event will be handled according to current worldwide regulatory requirement. Please read more about Our Company's privacy commitment at https://www.msdprivacy.co Acknowledgement of privacy statement i ☐Yes CAPTCHA * k What code is in the image? 2 XmGT Enter the characters shown in the image C Т bmit Report

Step 3: Transmit Report
✓ Report will transmit to the appropriate mailbox

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

File Message Help Acrobat Image: Signore Image: Signore				
Image: Signore Image: Signor				
No Block v All Cip More v Teams ☑ Confirm Produc ☑ Mindwell section ☑ NITIAL SOP E Dalata Paront Reroord Teams ☑ Confirm Produc ☑ Mindwell section ☑ NITIAL SOP E	Ilink R V Im. V Move Send to OneNote V Actions V	Asign Mark Categorize Follow Policy + Unread + Up + Select + Follow	Alon Reader Translate Zoor	n Reply with Report Scheduling Poll Message ~
	12 WOVE	lags is county	i ininersive i Language 2000	In the Protection the
20241107-DPOC-0002-1651 - New Safety Report				(2) Summarize
MSD_Safety.Reporting-Dev To © Kinner Murtagh, Brenda Retention Policy DPT - 3 Vears Delete (3 years)	Expires 11/7/2027		🕲 🕤 Reply 🐇 Re	ply All → Forward 11/7/2024 3:53 PM
test-pyep.docx 27 KB				
Dear DPOC,				
A new case has been reported in the Safety Reporting Portal.				
Portal Unique ID: 20241107-DPOC-0002-1651				
Date Reported to the Portal: 07-Nov-2024 20:52 (UTC)				
Country of Incidence: Australia				
Reporter: Test				
Reporter Email: <u>brenda.murtagh@merck.com</u>				
Consent for follow-up: Yes				
Name of product: TEST				
Sample available for return: No				
Number of Attachments: 1				
Business Partner/Vendor/Investigator/Other's Case ID#: TEST				
Case Description: TEST				
This is an automatically generated message - please do not respond to this email, as we won't receive your message.				
Best regards,				
Safety Reporting Portal				

Reporting an issue:

Step 1: Select "Report an Issue" in the top right hand corner or in the footer of the landing page (highlighted below) Welcome to MSD Safety Reporting

3	50.	Home Report an Issue
OR	Privacy Policy • Terms of Use • Forward-Looking Statement • Accessibility	
_	Copyright © 2023 Merck & Co., Inc., Rahway, NJ, USA and its affiliates. All rights reserved.	

<u>Step 2</u>: Complete Entry of Required Fields

Report an Issue

Please do not submit any adverse event cases through this form. This channel is intended for users to repo encountered while using this site. For other queries, please reach out to your respective PV contact.	rt only technical issues
Name *	
Email Address *	
Case Reference ID (optional)	
Message *	
Submit	

Step 3: Receive confirmation message

Report an Issue

Thank you for reaching out to us. We will investigate your issue and get back to you within 1 business day.

