

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY EL SALVADOR	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year	Unk	Female	Unk	Day	Month	Year	
		PRIVACY						01	MAY	2025	
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)											
Other Serious Criteria: Medically Significant											
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)		Product		Serious	Listed	Reporter Causality	Company Causality				
Neumonitis [Pneumonitis]		ENHERTU		Yes	Yes	Related					<input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> CONGENITAL ANOMALY <input checked="" type="checkbox"/> OTHER
(Continued on Additional Information Page)											

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) ENHERTU (TRASTUZUMAB DERUXTECAN) Powder for solution for infusion		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) #1) UNK	16. ROUTE(S) OF ADMINISTRATION #1) Intravenous use	
17. INDICATION(S) FOR USE #1) HER2+ metastatic breast cancer (Breast cancer metastatic)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) MAR-2024 / Unknown	19. THERAPY DURATION #1) Unknown	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)		
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)		
From/To Dates Unknown to Ongoing	Type of History / Notes Indication	Description Breast cancer metastatic (Breast cancer metastatic)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER AstraZeneca Serban Ghiorghe 1 Medimmune Way Gaithersburg, Maryland 20878 UNITED STATES Phone: +1 301-398-0000		26. REMARKS World Wide #: SV-ASTRAZENECA-202505CAM011090SV Case References: GT-AstraZeneca-CH-00869993A
	24b. MFR CONTROL NO. 202505CAM011090SV	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 13-MAY-2025	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous	NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT 16-MAY-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

16-May-2025 09:23

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A spontaneous report has been received from a physician. The report concerns a female patient born in 1949.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Enhertu (trastuzumab deruxtecan) UNK, Intravenous use, during MAR-2024 for her2+ metastatic breast cancer.

On 01-MAY-25, the patient experienced neumonitis (preferred term: Pneumonitis).

Treatment with Enhertu (trastuzumab deruxtecan) was temporarily Withdrawn.

At the time of reporting, the event neumonitis was improving.

The event was considered serious (Medically Significant).

The reporter considered that there was a reasonable possibility of a causal relationship between Enhertu and the following event(s): neumonitis.

Laboratory values are available.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	MAR-2024	Computerised tomogram pneumonitis		
2		HER2 gene amplification Positive		