CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	GUATEMALA		PRIVACY		Unk	Female	Unk		Unk	

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
SYNCOPE ONE WEEK AFTER THE INFUSION [Syncope]	ENHERTU	Yes	No	Related	

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☒ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) ENHERTU (TRASTUZUMAB DERUXTECAN) Powder for solution for infusion
(Continued on Additional Information Page)

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15. DAILY DOSE(S)
#1) UNK

16. ROUTE(S) OF ADMINISTRATION
#1) IV drip

17. INDICATION(S) FOR USE
#1) HER2-positive metastatic breast cancer
(Continued on Additional Information Page)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)
#1) 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	Type of History / Notes	Description
Unknown to Ongoing	Indication	HER2 positive breast cancer (HER2 positive breast cancer)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
AstraZeneca
Serban Ghiorghiu
1 Medimmune Way
Gaithersburg, Maryland 20878 UNITED STATES
Phone: +1 301-398-0000

26. REMARKS
World Wide #: GT-ASTRAZENECA-202505CAM021461GT
Case References: GT-AstraZeneca-CH-00877752A

24b. MFR CONTROL NO.
202505CAM021461GT

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
23-MAY-2025

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE
☒ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous

DATE OF THIS REPORT
29-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 202505CAM021461GT

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 (age not provided).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Enhertu (trastuzumab deruxtecan) UNK, IV drip, on an unknown date for her2-positive metastatic breast cancer.

On an unknown date, the patient experienced syncope one week after the infusion (preferred term: Syncope).

The dose of Enhertu (trastuzumab deruxtecan) was reduced.

The patient recovered from the event(s) syncope one week after the infusion on an unspecified date.

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): syncope one week after the infusion.

Company Clinical Comment: Syncope is not listed in company core data sheet of trastuzumab deruxtecan. Underlying malignancy could be confounding. Due to limited information on circumstances leading to the event, start date and action taken of suspect drug, onset date and outcome of event, clinical course, treatment provided, concurrent conditions, concomitant medications, risk factors, relevant medical history, detailed etiological and diagnostic work up, the evaluation did not find evidence to suggest a causal relationship between the event and suspect drug.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) ENHERTU (TRASTUZUMAB DERUXTECAN) Powder for solution for infusion; Regimen #1	UNK; IV drip	HER2-positive metastatic breast cancer (HER2 positive breast cancer)	Unknown; Unknown