SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

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

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
The doctor changed my treatment, it was no longer working for me [Drug ineffective]	ENHERTU	No	No	Related	Not Applicable

(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

15. DAILY DOSE(S)
#1) 5.4 milligram/kilogram, q3w

16. ROUTE(S) OF ADMINISTRATION
#1) Intravenous use

17. INDICATION(S) FOR USE
#1) Breast cancer (Breast cancer)

18. THERAPY DATES(from/to)
#1) 01-OCT-2024 / JUL-2025

19. THERAPY DURATION
#1) 274 days

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

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

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	Indication	Breast cancer (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 #: CR-ASTRAZENECA-202507CAM027491CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00922498A

24b. MFR CONTROL NO.
202507CAM027491CR

24c. DATE RECEIVED BY MANUFACTURER
31-JUL-2025

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

DATE OF THIS REPORT
04-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A solicited report has been received from a consumer in Patient Support Program. The report concerns a female patient born in 1959.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Enhertu (trastuzumab deruxtecan) 5.4 milligram/kilogram q3w, Intravenous use, on 01-OCT-2024 for breast cancer.

On an unknown date, the patient experienced the doctor changed my treatment, it was no longer working for me (preferred term: Drug ineffective).
The last dose of ENHERTU prior to onset was taken on 15-JUL-25.

The report described lack of effect for Enhertu. The reported term was "the doctor changed my treatment, it was no longer working for me" (preferred term: Drug ineffective).

Treatment with Enhertu (trastuzumab deruxtecan) was discontinued during JUL-2025.

The outcome of the event(s) of the doctor changed my treatment, it was no longer working for me was unknown.

The event was considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Enhertu and the following event(s): the doctor changed my treatment, it was no longer working for me.

This case was marked as suppressed due to Lack of Efficacy with no AE.