

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY DOMINICAN REPUBLIC	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				Day	Month	Year	
		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				
Death (unknown cause) [Death]		TAGRISSO		Yes	No	Not Related	Not Related				
(Continued on Additional Information Page)											<input checked="" 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 type="checkbox"/> OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) TAGRISSO (OSIMERTINIB) Tablet		20. DID REACTION ABATE AFTER STOPPING DRUG?
15. DAILY DOSE(S) #1) 80 milligram, qd	16. ROUTE(S) OF ADMINISTRATION #1) Oral use	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
17. INDICATION(S) FOR USE #1) Lung cancer (Lung cancer)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
18. THERAPY DATES(from/to) #1) Unknown	19. THERAPY DURATION #1) Unknown	<input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> 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 to Ongoing Indication Lung cancer (Lung cancer)		

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER AstraZeneca Serban Ghiorgiu 1 Medimmune Way Gaithersburg, Maryland 20878 UNITED STATES Phone: +1 301-398-0000		26. REMARKS World Wide #: DO-ASTRAZENECA-202505CAM022591DO Study ID: PSP-23269 Case References: DO-AstraZeneca-CH-00878521A
	24b. MFR CONTROL NO. 202505CAM022591DO	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 27-MAY-2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT 28-MAY-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

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 (age not provided).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Tagrisso (osimertinib) 80 milligram qd, Oral use, on an unknown date for lung cancer.

It is unknown if any action was taken with Tagrisso (osimertinib).

The patient died (preferred term: Death) on an unspecified date.

The patient died on an unknown date. It is not known whether an autopsy was performed. The cause of death was death.

The event was considered serious (Death).

The reporter did not consider that there was a reasonable possibility of a causal relationship between Tagrisso and the following event (s): death (unknown cause).

The company physician did not consider that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): death (unknown cause).