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	COSTA RICA		PRIVACY		82 Years	Male	Unk	05	JUN	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
Intense diarrhea, very strong, my whole body was covered in poop [Diarrhoea]	TAGRISSO	Yes	Yes	Related	Related
Dizziness [Dizziness]	TAGRISSO	Yes	No	Related	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) TAGRISSO (OSIMERTINIB) Tablet

15. DAILY DOSE(S)
#1) Unknown

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

17. INDICATION(S) FOR USE
#1) LUNG CANCER (Lung neoplasm malignant)

18. THERAPY DATES(from/to)
#1) Ongoing

19. THERAPY DURATION
#1) Unknown

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 to Ongoing	Indication	Lung cancer (Lung 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-202506CAM004760CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00886726A

24b. MFR CONTROL NO.
202506CAM004760CR

24c. DATE RECEIVED BY MANUFACTURER
06-JUN-2025

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

DATE OF THIS REPORT
11-JUN-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 had been received from a consumer in Patient Support Program concerning a male elderly patient born in 1942 (age 82 years).

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.

On 05-Jun-2025, the patient experienced intense diarrhea, very strong, my whole body was covered in poop (preferred term: Diarrhoea) and dizziness (preferred term: Dizziness).

The dose of Tagrisso (osimertinib) was not changed.

At the time of reporting, the event dizziness and intense diarrhea, very strong, my whole body was covered in poop was ongoing.

The reporter assessed the events dizziness and intense diarrhea, very strong, my whole body was covered in poop was ongoing to be serious due to seriousness criteria of Medically Significant.

The reporter considered that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): dizziness and intense diarrhea, very strong, my whole body was covered in poop.
The company physician considered that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): dizziness and intense diarrhea, very strong, my whole body was covered in poop.

Company Clinical Comment: Dizziness is not listed in the company core data sheet of osimertinib. Due to limited information on the exact circumstances leading to the event, detailed relevant history, further details on reported event, previous neurological complications (if any), specific risk factors, baseline/ interim etiological and complete diagnostic work up, the evaluation did not find evidence to exclude a causal relationship between the event and suspect drug.