

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY PANAMA	2. DATE OF BIRTH			2a. AGE 78 Years	3. SEX Male	3a. WEIGHT Unk	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <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
		Day	Month	Year				Day	Month	Year	
			PRIVACY					Unk			

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)
passed away [Unknown cause of death]

Case Description: This is a spontaneous report received from a Consumer or other non HCP, Program ID: 164974.

A 78-year-old male patient received axitinib (INLYTA). The patient's relevant medical history was not reported. The patient took concomitant medications. The following information was reported: DEATH (death), outcome "fatal", described as "passed away".

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) Inlyta (AXITINIB) Film-coated tablet		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) #1) UNK	16. ROUTE(S) OF ADMINISTRATION #1) Unknown	
17. INDICATION(S) FOR USE #1) Unknown		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> 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		

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER Pfizer S.A. Laura Arce Mora Avenida Escazú, Torre Lexus, piso 7. Escazú San jose, COSTA RICA		26. REMARKS
	24b. MFR CONTROL NO. PV202500064834	
24c. DATE RECEIVED BY MANUFACTURER 28-MAY-2025	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous	
DATE OF THIS REPORT 29-MAY-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

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

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

The date and cause of death for the patient were unknown. It was not reported if an autopsy was performed.

Clinical Course: The patient was contacted to verify if they were still taking the medication Inlyta. The patient's niece answered and stated that the patient had already passed away. The patient's niece said: He had been taking for a while what you were sending, what Dr. PRIVACY gave him, but that was for a while, then you did not give us anymore, I mean, you used to send like a package (referring to the kit provided by the program). She did not remember the dose or frequency because they were pills given to him at the oncology center and during dialysis, the chemotherapy he was receiving.

No follow-up attempts are possible.