

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>PANAMA</b>	2. DATE OF BIRTH			2a. AGE <b>71</b> Years	3. SEX <b>Male</b>	3a. WEIGHT <b>Unk</b>	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	
		<b>PRIVACY</b>						<b>Unk</b>			

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

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

A 71-year-old male patient received axitinib (INLYTA). The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: DEATH (death), outcome "fatal", described as "He passed away about two years ago". A call was made to confirm whether the patient is continuing the Inlyta treatment.

(Continued on Additional Information Page)

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) <b>#1 ) Inlyta (AXITINIB) Film-coated tablet</b>		20. DID REACTION ABATE AFTER STOPPING DRUG?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) <b>#1 ) UNK</b>	16. ROUTE(S) OF ADMINISTRATION <b>#1 ) Unknown</b>	
17. INDICATION(S) FOR USE <b>#1 ) Unknown</b>		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) <b>#1 ) Unknown</b>	19. THERAPY DURATION <b>#1 ) Unknown</b>	

## 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 <b>Unknown</b>		

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER <b>Pfizer S.A. Laura Arce Mora Avenida Escazú, Torre Lexus, piso 7. Escazú San jose, COSTA RICA</b>		26. REMARKS
	24b. MFR CONTROL NO. <b>PV202500069709</b>	
24c. DATE RECEIVED BY MANUFACTURER <b>09-JUN-2025</b>	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 <b>10-JUN-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

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

10-Jun-2025 23:44

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

The patient's daughter responded. Reporter stated that the patient passed away approximately two years ago. Reporter only confirmed that her father was taking Inlyta. She did not wish to provide further information. The date and cause of death for the patient were unknown. It was not reported if an autopsy was performed.

No follow-up attempts are possible.