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			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	COSTA RICA		PRIVACY		45 Years	Male	Unk		Unk		

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

Other Serious Criteria: Medically Significant
he was bleeding (referring to blood in his stool) [Blood in stool]

Case Description: The initial case was missing the following minimum criteria: adverse event. Upon receipt of follow-up information on 19May2025, this case now contains all required information to be considered valid.

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

(Continued on Additional Information Page)

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Sutent (SUNITINIB MALATE) Capsule, hard

(Continued on Additional Information Page)

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 50 mg every (Continued on Additional Information Page)	#1) Unknown

17. INDICATION(S) FOR USE
#1) KIDNEY CANCER (Renal cancer)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 12-DEC-2024 / Unknown	#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.
202500025739

24c. DATE RECEIVED BY MANUFACTURER
19-MAY-2025

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

DATE OF THIS REPORT
20-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

Mfr. Control Number: 202500025739

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

A 45-year-old male patient received sunitinib malate (SUTENT), since 12Dec2024 at 50 mg cyclic (50 mg every day for 4 weeks and rest 2 weeks) for renal cancer. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: HAEMATOCHEZIA (medically significant), outcome "unknown", described as "he was bleeding (referring to blood in his stool)". It's currently on hold. As soon as the medication arrives, he will start taking it, because the dose was reduced. Right now, he is not taking it because he takes it for one month and then rests for 15 days. (As of today, 19May2025, he is in the rest period). The patient's wife appears to confuse the names of the medications, but it was confirmed that he has not yet started taking Inlyta. Instead, she was referring to the medication Sutent. Additionally, the wife mentioned: The doctor is going to prescribe another medication with a lower dose because he was bleeding (referring to blood in his stool), but she is not sure whether the new medication will be Inlyta. The action taken for sunitinib malate was unknown.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Sutent (SUNITINIB MALATE) Capsule, hard; Regimen #1	50 mg every day for 4 weeks and rest 2 weeks; Unknown	KIDNEY CANCER (Renal cancer)	12-DEC-2024 / Unknown; Unknown