CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

2025-088553(0)

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET		
		Day	Month	Year	Years		Day	Month	Year
Masked	PANAMA	Unknown	Unknown	Unknown	Unknown	Male	Unknown	Unknown	2025

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)

MedDRA Version : v.28.0

1) ADVERSE DRUG REACTION (Adverse drug reaction (10061623), Adverse drug reaction (10061623))
(//2025 -) - Recovered/Resolved

II. SUSPECT DRUG(S)INFORMATION

14. SUSPECT DRUG(S)(include generic name)

1) Opdivo (NIVOLUMAB) (Suspect) (Solution for injection)(Unknown)

Cont..

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

15. DAILY DOSE(S)

1) 17.14 milligram(s) (360 milligram(s), 1 in 3 Week)

16. ROUTE(S) OF ADMINISTRATION

1) Intravenous (not otherwise specified)

21. DID EVENT REAPPEAR AFTER REINTRODUCTION ☐ YES ☐ NO ☑ NA

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) product used for unknown indication [10070592 - Product used for unknown indication]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (01/Feb/2025 - Unknown)	Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

No concomitants used/reported

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

MedDRA Version : v.28.0

1) DISTAL ESOPHAGEAL CANCER (10030137, Oesophageal adenocarcinoma) (Continuing: Unknown)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

Name : BMS
UNITED STATES OF AMERICA
aepbusinessprocess@bms.com

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
☐ YES ☐ NO	2025-088553(0)
24c. DATE RECEIVED BY MANUFACTURER: 19/Jun/2025	24d. REPORT SOURCE: ☐ STUDY ☐ LITERATURE ☑ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 24/Jun/2025	25a. REPORT TYPE: ☑ INITIAL ☐ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) (Continuation...)

Event Description :

Information was received from a Pharmacist concerning a Male patient, who received Suspect product NIVOLUMAB (Solution for injection) via Intravenous (not otherwise specified)(360 milligram(s)1 every 3 Week, from 01-Feb-2025) for product used for unknown indication, lot number: Unknown;.

In 2025, the patient had adverse drug reaction (adverse drug reaction), which was considered non-serious. It is unknown if treatment was provided. The adverse drug reaction resolved.

The action taken with NIVOLUMAB medication was unknown.

Medical history and concurrent conditions included distal esophageal cancer.

Concomitant medications include chemotherapy.

The reporter considered event adverse drug reaction not related to NIVOLUMAB.

Consent to contact the pharmacist for follow-up information was denied, or it was indicated that no further information is available.

Tracking of Changes:
19-Jun-2025: Initial information was received.

14.SUSPECT DRUG(S) (Continuation...)

Product-Reaction Level

1) Drug	:	Opdivo
Active Substance	:	NIVOLUMAB
Drug Characterization	:	Suspect
Form of Admin	:	Solution for injection
Lot Number	:	Unknown
Daily Dose	:	17.14 milligram(s) (360 milligram(s), 1 in 3 Week)
Route of Admin	:	Intravenous (not otherwise specified)
Indications	:	product used for unknown indication [10070592 - Product used for unknown indication]
Therapy Dates	:	From : 01/Feb/2025 To :Unknown
Action(s) Taken With Drug	:	Unknown

Causality

1) ADVERSE DRUG REACTION (Adverse drug reaction - 10061623, Adverse drug reaction - 10061623)

Causality as per reporter	:	Not Related
Causality as per Mfr	:	Not Related
DeChallenge	:	Not applicable
ReChallenge	:	Not Applicable

Labeling :

1) ADVERSE DRUG REACTION
CORE Labeled

Primary Reporter:
Pharmacist
PANAMA