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	DOMINICAN REPUBLIC		PRIVACY		Unk	Male	Unk		Unk	

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

Other Serious Criteria: Congenital Anomaly

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Death [Death]	PALIVIZUMAB	Yes	No	Not Applicable	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) PALIVIZUMAB (PALIVIZUMAB) Injection

15. DAILY DOSE(S)
#1) 15 mg/kg

16. ROUTE(S) OF ADMINISTRATION
#1) Unknown

17. INDICATION(S) FOR USE
#1) (Not Coded)

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

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

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 #: DO-ASTRAZENECA-202507CAM008619DO
Study ID: PSP-23269
Case References: DO-AstraZeneca-CH-00909021A

24b. MFR CONTROL NO.
202507CAM008619DO

24c. DATE RECEIVED BY MANUFACTURER
11-JUL-2025

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

DATE OF THIS REPORT
15-JUL-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 has been received from a consumer in Patient Support Program. The report concerning a male patient born in 2025.

No medical history and concomitant products were reported.

On an unknown date, the patient started treatment with Palivizumab (palivizumab) qmonth 15 mg/kg.

It is unknown if any action was taken with Palivizumab (palivizumab).

The patient died (preferred term: Death) on an unspecified date.

The patient died on an unknown date. It is not known whether an autopsy was performed. The cause of death was unknown.

The reporter assessed the event death as serious due to seriousness crietria of Congenital Anomaly and Death.

The reporter did not assess causality for death.
The company physician considered that there was a reasonable possibility of a causal relationship between Palivizumab and the following event(s): death.

Company Clinical Comment: This is the case of male patient with reported fatal outcome (preferred term: Death) in association with palivizumab. Due to limited information on indication, start date, onset date, circumstances leading to death, detailed etiological and diagnostic work up prior to fatal outcome, the evaluation did not find evidence to exclude a reasonable possibility of a causal relationship between event and suspect drug.