SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

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

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

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

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- [x] PATIENT DIED
- [ ] INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- [ ] INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- [ ] LIFE THREATENING
- [ ] CONGENITAL ANOMALY
- [ ] OTHER

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) XIGDUO (DAPAGLIFLOZIN, METFORMIN) Tablet

15. DAILY DOSE(S) #1) Unknown	16. ROUTE(S) OF ADMINISTRATION #1) Oral use

20. DID REACTION ABATE AFTER STOPPING DRUG?
- [ ] YES [x] NO [ ] NA

17. INDICATION(S) FOR USE
#1) unknown (Product used for unknown indication)

18. THERAPY DATES(from/to) #1) Unknown	19. THERAPY DURATION #1) Unknown

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
- [ ] YES [ ] NO [x] 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	Indication	

(Continued on Additional Information Page)

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 #: CR-ASTRAZENECA-202508CAM018219CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00936677A

24b. MFR CONTROL NO.
202508CAM018219CR

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

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
22-AUG-2025

24d. REPORT SOURCE
- [x] STUDY
- [ ] LITERATURE
- [ ] HEALTH PROFESSIONAL
- [ ] OTHER:

DATE OF THIS REPORT
26-AUG-2025

25a. REPORT TYPE
- [x] INITIAL
- [ ] FOLLOWUP:

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 concerns a female patient born in 1933.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Xigduo (dapagliflozin, metformin) 5 milligram qd, Oral use, on an unknown date for unknown.

It is unknown if any action was taken with Xigduo (dapagliflozin, metformin).

 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 event was considered serious (Death).

The reporter did not consider that there was a reasonable possibility of a causal relationship between Xigduo and the following event (s): deceased patient.
The company physician did not consider that there was a reasonable possibility of a causal relationship between Xigduo and the following event(s): deceased patient.

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Indication	Drug use for unknown indication (Product used for unknown indication);

26-Aug-2025 17:01