CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

2025-AER-038851

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year	Years		Day	Month	Year	
Masked	GUATEMALA	Masked	Masked	Masked	82	Male		May	2025	

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

1) Tiredness as a weakness (Tiredness (10043890), Fatigue (10016256)) (/May/2025 -) - Recovering/Resolving
2) Tiredness as a weakness (Weakness (10047862), Asthenia (10003549)) (/May/2025 -) - Recovering/Resolving

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

II. SUSPECT DRUG(S)INFORMATION

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

1) Enzalutamide (Enzalutamide, Enzalutamide) (Suspect) (Verum) (40 Milligram, Capsule)(Unknown)

Cont..

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

15. DAILY DOSE(S)

1) 160.0 milligram(s) (160 milligram(s), 1 in 1 Day)

16. ROUTE(S) OF ADMINISTRATION

1) Oral

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

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) Prostate cancer [10060862 - Prostate cancer]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (22/May/2025 -)	

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.)

1) PROSTATE CANCER (10060862, Prostate cancer) (Continuing: Yes)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

Name : Astellas Pharma Global Development, Inc.
2375 Waterview Drive
Northbrook, IL, 60062-6111, UNITED STATES OF AMERICA

Study Information
Study Name: Enzalutamide Patient Support Progr (Cont..)
EudraCT Number:
Protocol No.: Enzalutamide_Astellas PSP
Center No.:
Subject Id :

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
☐ YES ☐ NO	2025-AER-038851
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
11/Jul/2025	☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
18/Jul/2025	☑ INITIAL ☐ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

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

Event Description :

This study case was received by Astellas business partner Adium on 11-Jul-2025 from an 82 Year(s) old Male patient in GUATEMALA and was received at Astellas from Adium on 14-Jul-2025, enrolled in post-marketing study: Enzalutamide Patient Support Program who was on Xtandi (enzalutamide), Capsule (160 milligram(s), 1 every 1 Day). Indication for use was Prostate cancer. The patient-initiated treatment on 22-May-2025.

Study No.: Enzalutamide_Astellas PSP; open label study.

The patient received enzalutamide for prostate cancer with following dosage regimen: 22-May-2025 - (Ongoing): oral route, 160 milligrams once daily.

Action taken with enzalutamide treatment in response to event was dose not changed.

On an unknown date in May-2025 patient experienced mild tiredness as weakness (Fatigue and Asthenia). The event was not treated. The outcome of event was recovering/resolving.

Underlying condition included prostate cancer.

Past medications were not reported.

Concomitant medications were not reported.

No relevant lab data was reported.

The patient assessed the following event with respect to enzalutamide:
- Tiredness as a weakness (Fatigue and Asthenia) (Seriousness: Non-serious; Causality: Related)

Consent to contact patient for follow-up information was denied.

No additional information was available.

Tracking of changes:
11-Jul-2025: Initial information was received.

Company Remarks (Sender's Comments) :

Event Information:
Tiredness and Weakness were assessed as Non Serious.

Non-Serious is based on events not meeting ICH seriousness criteria.

Tiredness as a weakness was coded as Tiredness and Weakness due to closest available MedDRA terms.

Product: Enzalutamide
Astellas assessed Tiredness and Weakness as Related based on temporal relationship. The confounders include elderly age of patient and underlying malignancy.

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

Product-Reaction Level

1) Drug	:	Enzalutamide (Enzalutamide)
Active Substance	:	Enzalutamide
Coding Class	:	Verum
Drug Characterization	:	Suspect
Form Strength	:	40 Milligram
Form of Admin	:	Capsule
Lot Number	:	Unknown
Daily Dose	:	160.0 milligram(s) (160 milligram(s), 1 in 1 Day)
Route of Admin	:	Oral
Indications	:	Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	From : 22/May/2025 To :Continuing
Action(s) Taken With Drug	:	Dose not changed

Causality

Continuation Sheet for CIOMS report

1) Tiredness as a weakness (Tiredness - 10043890, Fatigue - 10016256)

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

2) Tiredness as a weakness (Weakness - 10047862, Asthenia - 10003549)

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

Labeling :

1) Tiredness as a weakness	
CORE	Labeled
IB	Labeled
2) Tiredness as a weakness	
CORE	Labeled
IB	Labeled

24a. NAME AND ADDRESS OF MANUFACTURER (Continuation...)

Study # :Enzalutamide_Astellas PSP