



TasP

Antiretroviral Treatment as Prevention - ANRS 12249

Ukaphila kwami, ukaphila kwethu (my health for our health)



00059964

Shunqa
Ukaphila kwami, ukaphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

SAE-AC

ANRS 12249 Complementary SAE Notification

Completed forms must be sent to
ANRS within 8 days.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

SAE No.

Initial Notification Date

2013 03 19

i.e. Date of original Initial Notification Form

Complementary Notification Date

2013 08 06

1. Patient details

TasP ID

15691

Name

Z-M.

Sex

Male

☒ Female

Date of birth

1977 11 16

Enrolment date

2013 01 28

2. Description of the reported SAE

Weight loss, pelvic mass, microcytic anaemia

Date of SAE onset

2013 03 18

3. Complementary information

Admitted to hospital 23/7/2013 with abd pain/distension, vomiting and diarrhoea with an Hb of 5.1g/dL. USS scan abdomen showed enlarged para-aortic nodes. Transfused with blood & started on Anti-tuberculous chemotherapy for abdominal TB.

4. New diagnosis?

☒ Yes ☐ Describe

Abdominal TB.

No

Date of new diagnosis

2013 07 23.

5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

Yes

No

☒ N/A

Which treatment?

Date discontinued

b) Did the event reappear after reintroduction of treatment?

Yes

No

☒ N/A

Which treatment?

Date reintroduced

c) Has the complementary information mentioned above modified your judgement of causality regarding one or more treatments compared to your initial notification?

Yes ☐ Section 6

No ☒ Section 7

DATA CAPTURE

2013-08-13

DCP-F

6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

Generic Name	Dose	Frequency	New judgement of causality
1. ATRIPLA TDF/FTC/EFV	300/200/600mg	o.d.	<input checked="" type="radio"/> Unrelated Poss. related Cannot be assessed
2. FeSO ₄	200mg	t.d.	<input checked="" type="radio"/> Unrelated Poss. related Cannot be assessed
3.			Unrelated Poss. related Cannot be assessed
4.			Unrelated Poss. related Cannot be assessed

7. Other causes of SAE, if unrelated to drugs mentioned in Section 6 above

7a. According to the physician, is this SAE likely to be related to participation in the research?

Yes ☐ No ☒

7b. According to the physician, is this SAE related to any causes other than the research?
This includes the patient's medical history

☒ Yes
L Describe

No

Abdominal TB

8. SAE Outcome

Unknown to date

Ongoing

Improved

Worsened

Recovered

→ Another complementary SAE notification form must be submitted within 8 days from now.

Died 30/7/2013

→ Date of recovery

Recovered without sequelae

or

Recovered with sequelae

L Describe

Physician reporting SAE Complementary Notification

Name

COLLINS JWUSI

Signature

Xmp

Date form completed

20130806