



Antiretroviral Treatment as Prevention - ANRS 12249
Ukuphila kwami, ukuphila kwethu (my health for our health)

Egadeni
Ukuphila kwami, ukuphila kwethu
Africa Centre TasP Trial

SAE-AC

Serious Adverse Event Reporting



00059971

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 10 30

i.e. Date of original Initial Notification Form

Complementary Notification Date

2013 11 29

1. Patient details

TasP ID

20433

Name

TV

Sex

Male

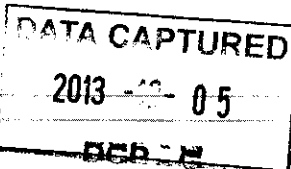
☒ Female

Date of birth

1971 11 02

Enrolment date

2013 04 08



2. Description of the reported SAE

Severe Microcytic hypochromic anaemia

Date of SAE onset

2013 10 01

3. Complementary information

Patient bled heavily per Vaginas starting on 1/10/2013. She thought she might have had a miscarriage but did not seek medical attention. Admitted to local hospital on 6/11/2013 for invx of anaemia. She was started on treatment for presumptive TB & discharged 11/11/2013

4. New diagnosis?

☒ Yes → Describe

Severe Anaemia

☐ No

Presumptive Pulmonary Tuberculosis

Date of new diagnosis

2013 11 08

5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

Yes

No

☒ N/A

→ Which treatment?

Date discontinued

11/11/2013

b) Did the event reappear after reintroduction of treatment?

Yes

☐ No

☒ N/A

→ Which treatment?

Date reintroduced

11/11/2013

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

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	T	OD	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
4.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed

DATA CAPTURED
2013 11 05
PDR

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? ☒ Yes ☐ No
This includes the patient's medical history

Describe

Presumptive Pulmonary Tuberculosis

8. SAE Outcome

Unknown to date ☐
☒ Ongoing ☐ → Another complementary SAE notification form must be submitted within 8 days from now.
 Improved ☐
 Worsened ☐
 Recovered ☐ → Date of recovery

Recovered without sequelae
 or
 Recovered with sequelae
 → Describe

Physician reporting SAE Complementary Notification

Name Collins Iwuji
 Signature [Signature]
 Date form completed 2013 11 29