

**TasP**Antiretroviral Treatment as Prevention - ANRS 12249
Ukuphila kwami, ukuphila kwethu (my health for our health)**Ukuphila kwami, ukuphila kwethu****Africa Centre TasP Trial****Serious Adverse Event Reporting****ANRS 12249 Initial SAE Notification****SAE-AI**Completed forms must be sent to
ANRS within 48 hrs.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

00317413

SAE No.

SAE Visit Date

20150803

Initial Notification Date

20150804

Notification time

1400

1. Patient details

TasP ID

44537

Name

E.K.M.

Sex

Male

☒ Female

Date of birth

19440802

Enrolment date

20140915

2. Measurements

Height

147 Cms

Last known: Weight

52.2

Kgs

Weight Date

20150219

CD4 count

196

CD4 Date

20150514

Viral Load

240

Viral Load Date

20150514

3. By which criteria is this adverse event considered to be "Serious"?

Tick all that apply

- ☐ Resulted in death → Date of death Probable cause
- ☐ Life threatening (i.e. at risk of death at time of event)
- ☒ Caused or prolonged hospitalisation (not elective hospitalisation for a pre-existing condition)
- ☐ Persistent or significant disability / incapacity
- ☐ Congenital abnormality / birth defect
- ☐ Grade 4 clinical and biological events
- ☐ Other serious, medically-important condition → Specify

4. Details of SAE

Enter each adverse event (e.g. symptom, sign, syndrome or diagnosis) on a separate line

Event NameDate investigator
became awareDate of onset of SAE

1. Breast Cancer 20150804 20150803

2.

3.

4.

5.

DATA CAPTURE

22-08-06

DCP-F

5. Description of SAE

Include details of body site, relevant laboratory tests, treatments received and relevant medical history.

Attach copies of any relevant hospital records, laboratory test results etc.

Participant on Atripla, CD4 count 196 and viral load suppressed. Relatives reported that she had been diagnosed with Breast cancer and was admitted to Hospital on 03/08/2015. More information to follow once she has been discharged.

6. Medications

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

Generic Name	Daily dose	Route of administration	Indication	Date started	Date stopped	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
1. Tenofovir	300mg	oral	HIV	20141006		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2. Emtricitabine	200mg	oral	HIV	20141006		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
3. Efavirenz	600mg	oral	HIV	20141006		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
4.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
5.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
6.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop

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 ☒ No ☐

Describe

Patients age and immune status are risk factors for cancer.

8. SAE Outcome

Died

Unknown to date

☒ Ongoing

Improved

Recovered



A complementary SAE notification must be submitted within 8 days

→ Date of recovery

Recovered without sequelae
or

Recovered with sequelae

→ Describe

Physician reporting SAE

Name GUGIELLO MUKULISI

Signature

Date form completed 20150804