



TasP

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



00288005

Ukaphila 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](mailto:pharmacovigilance@anrs.fr)  
Fax: +33 153 946 002

SAE No.

SAE Visit Date

20141119

Initial Notification Date

20141211

Notification time

1745

#### 1. Patient details

TasP ID

26696

Name

M.C.M.

Sex

☒ Male

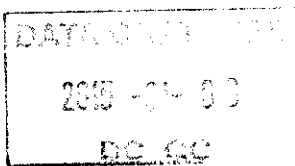
☐ Female

Date of birth

19920513

Enrolment date

20130722



#### 2. Measurements

Height

160 Cms

Last known: Weight

82.0

Kgs

Weight Date

20141119

CD4 count

387

CD4 Date

20141108

Viral Load

<50

Viral Load Date

20131212

#### 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 Name

Date investigator  
became aware

Date of onset of SAE

1. TB meningitis 20141210 20141119

2.

3.

4.

5.

#### 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.

This patient attended TasP clinic on 2014/11/14 complaining of a headache over ±10 days. He also displayed psychomotor slowing. He was referred to Hlabisa hospital as a query meningitis. On 2014/11/20 he did have lumbar puncture which showed a protein of 203 ~~indicated~~ typical of TB meningitis, but he was sent home as "normal". He was admitted on 26/11/14 with severe headache. LP not repeated. Not yet on TB treatment. CT brain booked for 2014/12/10.

## 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. TDF/FTC/EFV	1 tablet	PO	HIV	20130827		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None Reduce Interrupt Stop
2.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
3.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
4.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
5.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
6.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt 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

The patient has HIV and is at risk of opportunistic infections.

## 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 MELANIE HILL

Signature

Date form completed 2014 12 11